Continuity of maternity care in a community setting: a randomised controlled trial using the Zelen design

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CERTIFICATE OF AUTHORSHIP / ORIGINALITY

I certify that the work in this thesis has not previously been submitted for a degree nor has it been submitted as part of requirements except as fully acknowledged within the text.

I also certify that the thesis is written by me. Any help that I have received in my research work and the preparation of the thesis itself has been acknowledged. In addition, I certify that all information sources and literature used are indicated in the thesis.

Signature of Candidate

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Of all life choices, none is more important to society, none has more far reaching consequences, none represents a more complete blending of social, biological and emotional forces than bringing another life into the world.

Shearman Report, 1989

Dedicated to James who gave me the space, freedom and love to complete this work and to the little people in my life: Michael, Sebastian, Sally and Cindy; who constantly remind me about what the real world is all about and make sure I stay in it!

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Peer reviwed publications and conference presentations from this research

A number of peer reviwed publications and conference presentations have arisen from this work. I have been the first, or only, author on these papers.

Peer reviewed publications

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Homer CS, Davis GK, Brodie PM, Sheehan A, Barclay LM, Wills J, Chapman MG. Collaboration in maternity care: a randomised controlled trial comparing community-based continuity of care with standard hospital care. *British Journal of Obstetrics and Gynaecology* 2001, 108, 1-7.

Homer CS, Davis GK, Brodie PM. What do women feel about community-based antenatal care? *Australian and NZ Journal of Public Health* 2000, 24 (5), 590-595.

Homer CS. Incorporating cultural diversity in randomised controlled trials in midwifery. *Midwifery: An International Journal*, 2000, 16 (4): 252-259.

Conference presentations

Homer CSE. Midwifery research in contemporary Australia: Ensuring a multicultural approach. Proceedings of the *Australian College of Midwives Inc. 11th Biennial National Conference*. Tasmania. September 1999, 214-223.

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Homer CSE. Ensuring cultural diversity in clinical trials: challenges in design and logistics*. The International Clinical Trials Symposium: Improving health care in the new millennium*. Sydney, September, 1999.

Homer CSE, Brodie PM. Innovations in maternity care: Researching a new model. *Fourth Nursing Practice Conference*. Adelaide, November 1998.

Homer CSE. Midwives and continuity of care: Balancing the experience. *New Models of Maternity Service Provision: Australian Midwifery Perspectives Conference.* Adelaide. November 1998.

Poster presentations

Homer CSE, Davis GK, Brodie PM. Women's perceptions of community-based antenatal care. Poster presentation at the *Perinatal Society of Australia and NZ 4th Annual Congress.* Brisbane, March 2000.

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Homer CS, Davis GK, Cooke M, Barclay LM. Women's experiences of continuity of midwifery care in Australia: A randomised controlled trial. Submitted to *Midwifery*, August 2000.

Abbreviations and glossary

ANC	Antenatal Clinic
AN-DRG	Australian Diagnosis-Related Groups
EDPS	Edinburgh Postnatal Depression Scale
GP	General Practitioner
IOL	Induction of labour
IUGR	Intrauterine growth retardation
NESB	Non-English speaking background
NMHRC	National Health and Medical Research Council (Australia)
NHS	National Health Service in the United Kingdom
NSW	New South Wales
OECD	Organisation of Economic Co-operation and Development
RAP	Risk Associated Pregnancy team
RCT	Randomised controlled trial
SAMBA	Study About Maternity carers Beliefs and Attitudes
SCN	Special care nursery
STOMP	St George Outreach Maternity Project
WHO	World Health Organization

Glossary of terms

Antenatal period	Period of time before birth occurs, ie, the pregnancy.
Apgar score	A numerical set of criteria for assessing the well being of the baby at one and five minutes after birth. The score ranges from 0 to 10 (10 being perfect).
Area Health Service	A unit of health system administration in NSW. Each service comprises a population of about one million people and is accountable to the NSW Health Department for the management of public hospitals and community health services in the area.

Augmentation	Accelerating the progress of labour using oxytocic drugs or by artificially rupturing the membranes.
Booking visit	The first antenatal visit to the hospital.
Caseload midwifery	Small groups of midwives (usually 2 or three) who provide all antenatal, intrapartum and postnatal care for a defined group of women.
Cardiotocograph	Electronic monitoring of the fetal heart rate. This procedure may be undertaken in the antenatal period and during labour. During labour, the procedure is commonly known as electronic fetal monitoring (EFM).
Continuity of midwifery care	A consistent philosophy or organisational structure around which care is provided. This may be achieved through a model of team midwifery where a small number of midwives care for a group of women through the antenatal, intrapartum and postpartum periods.
Continuity of midwifery carer	Care provided by a midwife whom the woman has met previously and feels that she knows.
Core midwives	Midwives within a maternity unit who are not 'team midwives'. Core midwives are usually based in one area (antenatal, labour and birth or postnatal) and do not follow the same group of women from one stage to another.
Elective caesarean section	A caesarean section performed before the onset of labour.
Emergency caesarean section	A caesarean section performed after the onset of labour.
Electronic fetal monitoring	Monitoring the fetal heart rate using an electronic monitor which is either external (strapped to the women's abdomen) or internal (using an electrode attached to the baby's head).
Epidural	Injection of an anaesthetic agent outside the dura mater which covers the spinal canal causing loss of sensation to the lower part of the body.
Episiotomy	An incision of the perineum and vagina to enlarge the vulval orifice.

Gestational age	The duration of pregnancy in completed weeks from the first day of the last normal menstrual period.
Induction of labour	The artificial initiation of labour either by the use of drugs or by rupturing the membranes.
Intrapartum period	Period of time when labour and childbirth occurs.
Medicare	The Australian system of universal health insurance with revenue raised through a compulsory levy and taxes. Medicare provides access to public hospital services for all Australians through a negotiated payment to state governments. Medicare also supports access to general practitioners and specialist services including pathology, x-ray and ultrasound.
Multiparous woman	A woman who has already given birth. A woman having her second or subsequent baby.
Neonatal death	The death of a live born infant within 28 days of birth.
Nulliparous woman	A woman in her first pregnancy
Parity	The total number of live births before the pregnancy or birth under consideration.
Perinatal death	A still birth or neonatal death.
Perinatal mortality rate	The number of perinatal deaths per 1,000 total births in a year.
Postnatal or postpartum period	Period of time after childbirth, usually up to 42 days.
Premature infant	An infant born before 37 completed weeks gestation.
Premature labour	The spontaneous onset of labour before 37 completed weeks of gestation.
Primiparous woman	Woman in her first pregnancy or who has just given birth to her first baby.
Prolonged rupture of membranes	The spontaneous rupture of membranes for at least 24 hours before the onset of regular contractions with cervical dilatation.
South East Health	The Area Health Service in which this research was conducted.

Special care nursery	Level 2 neonatal unit which can give oxygen therapy, commence mechanical ventilation and has paediatric house staff with a paediatrician on call. Any infants requiring sustained mechanical ventilation are transferred to a Level 3 neonatal intensive care unit.
Stillbirth	The complete expulsion or extraction from its mother of a product of conception of at least 20 weeks gestation or 400g birth weight who did not, at any time after birth, breathe or show any evidence of life such as a heartbeat.
Team midwifery	System of midwifery care where small teams of midwives (usually 6-10 midwives per team) provide care throughout the childbearing experience, including antenatal and intrapartum care, for a defined group of women.
Third degree tear	A perineal laceration or tear, passing through the anal sphincter and involving the anal canal.
Vacuum extraction	A form of instrumental delivery in which the baby is delivered vaginally with the aid of a shallow rubber cup fixed to the baby's head using suction.

Abstract

This research investigated a new community-based model of continuity of care provided collaboratively by a small team of midwives and obstetricians (St George Outreach Maternity Project or STOMP). The study considered whether STOMP improved maternal and neonatal clinical outcomes, resulted in a better experience for women and could be implemented within the current resources of a public teaching hospital in Sydney, Australia.

A randomised controlled trial using a Zelen design was used to compare the STOMP model with standard care. One thousand and eighty-nine women were randomly allocated to either the STOMP model or standard hospital-based care. The Zelen design was used to increase the participation of women from non-English speaking backgrounds and to reduce disappointment bias in women allocated to the control group.

The results suggest that the model of community-based continuity of care is associated with a lower caesarean section rate, more positive experiences for women and costs less than standard care. There were no differences in the number of medical complications experienced in either group, but more women in the control group were admitted to hospital during the antenatal period. There were four perinatal deaths in each group.

Women in the STOMP group reported a higher quality of antenatal care compared with the control group. Women in the STOMP group also reported that the community-based service was accessible and convenient with reduced waiting times for appointments. Women in the STOMP group were more likely to have received adequate information about labour, birth and the postnatal period and felt more 'in control' during labour compared with the control group. Women from both groups reported problems with postnatal care, particularly when provided in the hospital.

The study also examined the impact of the STOMP model on women from Chinese and Arabic-speaking backgrounds. The STOMP model appeared to reduce the rate of elective and emergency caesarean section in Chinese-speaking women compared with English-speaking women. Small numbers precluded statistical analysis on these data so the results must be interpreted with caution. Women from Chinese-speaking

backgrounds reported receiving insufficient information. The STOMP model improved the provision of information, however Chinese-speaking women still reported inferior experiences. There were also differences in the method of infant feeding.

The results indicate that the model provides effective, cost efficient and satisfying maternity care. New models of maternity care can be implemented within current resources when organisations have a strong commitment to change.

Chapter 1 Introduction

Maternity services in the Australian public sector are mostly hospital-centred and provided by a range of health professionals. For example, in most hospitals, women see a number of different health care providers (midwives, obstetricians, general practitioners) through their pregnancy and are attended by different caregivers again in labour and during the postnatal period. There is little continuity of care or support across the antenatal, intrapartum or postpartum periods. This situation is not ideal and changes have been recommended by numerous Australian national and state government reviews into maternity services over the past decade (Senate Community Affairs References Committee 1999); (NHMRC 1996); (Department of Health Western Australia 1990; NSW Health Department 1989; Shearman 1989; Victorian Department of Health 1990). Many of the recommended changes have focused on the need to provide continuity of care and increased choice for women.

'Continuity of care' and 'continuity of carer' are frequently used terms but often poorly defined (Lee 1997). In this dissertation, continuity of <u>carer</u> refers to care by a midwife whom the woman has met previously and feels that she 'knows'. In contrast, continuity of care refers to a consistent philosophy or organisational structure around the care provided. For example, a team of six midwives may provide continuity of care, although the woman may not 'know' or have a continuing relationship with each individual midwife. This latter exemplar is often known as 'team midwifery'. Continuity of care is an important focus of the research presented in this dissertation.

The research was conducted in the context of both consumer and professional concern around the current system of maternity care. This concern was, in part, related to the realisation that health systems had failed to implement widespread changes in the provision of maternity care after the state and national reviews (Senate Community Affairs References Committee 1999); (NHMRC 1996); (Commonwealth Department of Health 1993).

A new model of maternity care, the St George Outreach Maternity Project (STOMP) was designed and implemented to improve clinical outcomes and the experience of pregnancy and childbirth for women at no additional cost to the organisation. STOMP was an innovative model of maternity care, which involved continuity of midwifery care

in a community-based setting. The model of care was provided in collaboration with obstetricians and obstetric registrars and was evaluated through a randomised controlled trial. The study is the subject of the research presented in this dissertation.

The STOMP study adds to the growing body of international literature on models of continuity of midwifery care. The differences between this research and the seven studies previously published in this field (as identified by (Waldenström & Turnbull 1998) are presented in Appendix 1 (page 232). Despite seven trials in the past 30 years, uncertainty still exists as to the safety and efficacy of midwifery models of care (Waldenström & Turnbull 1998). The STOMP study contributes to the ongoing debate.

This chapter presents an overview of the factors that influenced the development of the STOMP model and its method of evaluation. The aims, objectives and study questions are also outlined. The final section of the chapter describes the structure of the dissertation.

1.1 Factors influencing the development of the STOMP model

A number of factors influenced the development and evaluation of the STOMP model. These include recommendations from local, state, national and international policy documents, research evidence and the commitment to improved services that was present at St George Hospital where the study was conducted. Other important determinants that guided the development of the STOMP model included financial considerations, the consultation process within the organisation and the experience of maternity units in the UK, where team midwifery schemes have been discontinued. Evaluation was influenced by the characteristics of the population, the need to address issues of disappointment or measurement bias and the importance of a rigorous appraisal. These factors are discussed in the next section.

1.1.1 Policy statements advocating change

A number of state and national government reports in Australia have recommended major changes to the provision of maternity services. Recommendations include providing opportunities for continuity of care, increasing collaboration between midwives, obstetricians and general practitioners (GP) and moving antenatal care to community settings (Maternity Services Advisory Committee 1999; NHMRC 1996; NSW

Health Department 1989; NSW Health Department 1996; Senate Community Affairs References Committee 1999; Victorian Department of Health 1990).

Two of these Australian reports were most instrumental in the development of the STOMP model. In New South Wales (NSW), the landmark review of maternity services known as the *Shearman Report* (NSW Health Department 1989) emphasised certain principles in its recommendations. These included: equitable access to quality care; recognition of the needs of women from non-English speaking backgrounds (NESB); maximising each woman's participation in decision-making during pregnancy, childbirth and the postpartum period; and, promoting cooperation and collaboration among doctors, midwives and other health professionals. The report recommended that options should be explored to expand and to redefine the role of hospital-employed or salaried midwives, and suggested that these midwives could be located in community health centres to provide care during pregnancy and childbirth for low risk women. There were also a number of strategies to meet the needs of women from NESB. These included: increased funding for interpreter services; development of new models of care, including midwives' clinics and shared care with bilingual GPs; and the establishment of ethnic obstetric liaison midwives to provide continuity of care and education.

Widespread change in the provision of maternity services and the development of new models of care did not occur in NSW public maternity services as a result of the *Shearman Report* (NSW Health Department 1989). This dearth of change was one of the driving forces behind the development of STOMP. The *Shearman Report* provided a valuable framework of recommendations on which to guide the design of the model.

The National Health and Medical Research Council (NHMRC) released *Options for Effective Care in Childbirth* in 1996 (NHMRC 1996). This report also guided the development of the STOMP model and the evaluation. Recommendations in this report included facilitating continuity of care and carer in the antenatal period and encouraging the development of small teams of midwives and general practitioner obstetricians. The report stated "we suggest [a model of joint practice run by midwives and obstetricians providing continuity of care] deserves more attention and appropriate evaluation by both professional and health planners" (p. 26).

Continuity of care and community-based care were important components in both these reports and in others conducted in Australia at a similar time (Victorian Department of Health 1990); (Department of Health Western Australia 1990). The *Australian National Non-English Speaking Background Women's Health Strategy* (Alcorso & Schofield 1991) also made recommendations, which assisted the development of STOMP. For example, the strategy suggested that outreach midwifery schemes offering continuity of care to women from NESB should be introduced in Australian public hospital systems to ensure that care is provided within local communities.

Two reviews of maternity care in the United Kingdom (UK) were also influential in the development of the STOMP model. The Winterton report (House of Commons 1992) highlighted the need for women to have choice, continuity and control in the birth of their babies. *Changing Childbirth*, also known as the Cumberledge report (Department of Health Expert Maternity Group 1993), was the English government's response to the Winterton report. *Changing Childbirth* focused on the provision of maternity services and set specific targets and indicators for the providers of maternity care. The recommendations from the report were based on three fundamental principles of care, which were most relevant in the development of STOMP (p. 18):

> The woman must be the focus of maternity care. She should be able to feel that she is in control of what is happening to her and be able to make decisions about her care, based on her needs, having discussed matters fully with the professionals involved;
>
> Maternity services must be readily and easily accessible. They should be sensitive to the needs of the local community and based primarily in the community; and
>
> Women should be involved in the monitoring and planning of maternity services to ensure they are responsive to the needs of a changing society. In addition, care should be effective and resources used efficiently.

Despite all these reports and recommendations over a decade, by 1996, it seemed that few public hospital maternity services in Australia had managed to achieve widespread change necessary to introduce the components of continuity of care and community-based care into the provision of maternity care. The STOMP model was an endeavour to achieve change within a public sector metropolitan hospital in Sydney.

1.1.2 Research suggesting change

Previous research into models of care that provide continuity of midwifery care suggested that there were positive benefits for women and health systems. Continuity of midwifery care has been shown to reduce interventions in labour, particularly

augmentation of labour, analgesic use and electronic fetal monitoring (Flint et al. 1989; Kenny et al. 1994; Rowley et al. 1995; Waldenström & Nilsson 1997). A small Canadian trial in 200 women demonstrated a significant reduction in caesarean section rate (Harvey et al. 1996) and one of the Australian trials reported a trend towards a reduced elective caesarean section rate in high risk women (Rowley et al 1995). A retrospective cohort study in California has also shown that supportive nurse-midwifery care in labour was associated with a reduced caesarean section rate (Butler et al. 1993).

Continuity of midwifery care has been shown to improve women's experiences with care during pregnancy and childbirth (Waldenström & Nilsson 1993); MacVicar et al 1993; (Flint et al 1989; Kenny et al 1994; MacVicar et al. 1993). In particular, women who have received continuity of care report greater preparedness for birth and early parenting (Flint et al 1989; McCourt et al. 1998), increased satisfaction with psychological aspects of care (Waldenström & Nilsson 1993) and higher participation in decision making (Turnbull et al 1996) than women who received standard care.

Continuity of midwifery care was also associated with reduced costs to the health system in both Australian studies (Rowley et al 1995); (Kenny et al 1994), although there were deficiencies in both cost analyses, demonstrating the need for more research. The issue of cost is further addressed in Chapter 8 where the cost analysis for this study is presented.

Results from these studies were compelling and influential in the development and design of the STOMP model. The specific means by which the literature informed the design of the model are presented in Chapter 2.

1.1.3 Local commitment to change

Another important factor in the development of the STOMP model was the extent of the hospital's commitment to change. The maternity unit at St George Hospital had been committed to improving their service over a number of years. This was evident from a series of innovations that had already occurred in the maternity unit. For example, a birth centre was established in 1990 as a result of the *Shearman Report* (NSW Health Department 1989). The birth centre was one of only three in Sydney at the time. Despite initial difficulties, with opposition from obstetricians and midwives, the birth centre remains a well established option for women and excellent clinical outcomes have been reported (Homer et al. 2000).

The establishment of a midwives' clinic in 1995 was another example of the maternity unit's commitment to an improved service. The midwives' clinic enables women of low obstetric or medical risk to have continuity of midwife carer throughout the antenatal period. This clinic was established partly as a result of the *Shearman Report* (NSW Health Department 1989) but also in response to a customer survey conducted in 1994 (Everitt et al. 1995).

This customer survey, known as the *Maternity Services Customer Satisfaction Project* (Everitt et al 1995), was another important factor in the development of STOMP. The survey used a combination of qualitative and quantitative methods to establish customer satisfaction levels and identify problem areas in the service provided by the hospital. A sample of women from English and NESB who were current, recent or potential users of the service were included in the survey. Problems identified included: the lack of continuity of care and carer in the antenatal and postnatal periods; insufficient respect for individual opinions and beliefs; and conflicting advice regarding breastfeeding. Difficulties accessing antenatal care at the hospital (because of a lack of car parking facilities) were also reported. Women from NESB reported difficulties in obtaining culturally appropriate care and accessing adequate information. The survey made 26 recommendations, including the establishment of new models of care that provide continuity of care and carer and the consideration of community-based antenatal clinics. The STOMP model was developed to specifically target these two recommendations.

1.1.4 The consultation process

The process of implementing the new model of care began during the latter half of 1996 with a series of formal and informal discussions between midwives, obstetricians and managers in the maternity unit. The purpose of these early discussions was to discuss the principles of continuity of care and community-based care and to canvas opinions about the proposed shift to a model of team midwifery. The researcher and others wrote a paper describing the issues around continuity of care and the change to the organisation that would result from the introduction of midwifery teams. This paper was distributed to all midwives, managers and obstetricians. Numerous inservice sessions and frequent informal interactions were conducted with staff members. External consultation also took place. This included discussions with experts in models of

midwifery care in Australia (Rowley et al 1995); (Kenny et al 1994) and in the United Kingdom through a study tour sponsored by NHMRC (Brodie 1996a). A working party, which included midwives, obstetricians, managers and researchers, was established to initially develop the model, and subsequently to guide the implementation and evaluation.

During the consultation and development phase, it was decided that two STOMP teams would be established. Each team would consist of six midwives and provide antenatal, intrapartum and postnatal care for 300 women per year. Establishing two teams of midwives was unusual in Australia. Both previous projects had been based on only one team of midwives (Kenny et al 1994; Rowley et al 1995) which meant that access to the model was limited to less than 300 women annually. Other research in the UK and Sweden also involved only one team of midwives (Flint et al 1989; Turnbull et al 1996; Waldenström et al. 1997). Further discussion of the factors that influenced the size of the teams and the caseload (that is, the number of women who would be cared for by each team) is provided in Chapter 2 where the design of the STOMP model is discussed.

During the consultation phase it was also decided that the focus would be on providing continuity of <u>carer</u> (with two or three midwives) during the antenatal period and continuity of <u>care</u> (one of the six team midwives) during labour and birth. Factors that influenced this decision are discussed in Chapter 2.

1.1.5 Financial considerations

The maternity unit did not have any additional funds to establish new models of care. Therefore, the STOMP model was designed with the understanding that no additional funding would be available for the implementation. The model was aimed at women without private health insurance who were attending a public hospital for maternity care. Charges were not levied on the women receiving care. The STOMP model was implemented by reorganising the current maternity service's existing resources and staff. Internal restructuring provided the midwifery staff for the two STOMP teams by shifting 12 midwives from their existing wards or units, for example, antenatal, labour and delivery and postnatal wards, to create the teams. A detailed description of this process is in Appendix 2.

In many ways, the lack of additional funding was an advantage, rather than a disadvantage. Implementation within an existing budget meant the model was embedded in the organisational structure from the outset. We anticipated that full integration would make the new model less vulnerable to discontinuation in times of budgetary constraint.

Integration of innovation in maternity care has been uncommon in Australia. Pilot programs have usually been established with the assistance of additional funding either from federal or state government bodies (Hambly 1997; Kenny et al 1994; Thiele & Thorogood 1997). This can mean that programs are vulnerable to discontinuation when the support ends. It also can mean that the programs are not seen or managed as a part of the existing or 'mainstream' service.

1.1.6 Experience in the UK

The 1993 report from the UK, *Mapping Team Midwifery* (Wraight et al. 1993) was another important determinant in the development of STOMP. *Mapping Team Midwifery* was a review of team midwifery schemes that had been implemented as a result of *Changing Childbirth* recommendations (Department of Health Expert Maternity Group 1993). Of concern was the finding that more than one quarter of schemes established in 1990 were discontinued by 1991. Discontinuation occurred because of inadequate staffing levels, problems with deployment onto the teams, lack of commitment from midwives and obstetricians, lack of consultation, discontent among midwives, failure to increase continuity of care and personality clashes within teams.

These factors were important in the development of the STOMP model. Chapter 2 discusses the specific influences that guided the design of the model including issues that arose from the experience in the UK.

1.2 Issues considered in the design of the evaluation

While local, state, national and international factors were important factors in the design of the STOMP model, the design of the evaluation was also carefully considered. The characteristics of the population were considered, as was the need to address disappointment bias, which had been identified in similar randomised controlled trials as a limitation (Kenny et al 1994; Rowley et al 1995).

Chapter 1: Introduction

1.2.1 Choice of study design

It was decided during the early stages of the development of the STOMP model, that the evaluation should be by randomised controlled trial. At that time, there was uncertainty about the safety and sustainability of a model of team midwifery. In 1996, the NHMRC stated that there was "an urgent need for other trials [of team midwifery] within an Australian context" (p. 24). Once a randomised controlled trial was chosen, the detailed design of the trial was carefully considered.

Previous randomised controlled trials of midwifery models of care in Australia had used a conventional design, where women are identified, consent is sought and randomisation occurs (Kenny et al 1994; Rowley et al 1995). Both these trials reported that measurement or disappointment bias may have played a part in their results. Disappointment bias occurs in an unblinded study when participants become enthusiastic about the intervention during the consent stage but are subsequently randomly allocated to the control group. Control group participants receive standard care, however some may subsequently feel discontented with this allocation. Any dissatisfaction reported later in 'satisfaction' questionnaires may therefore be related to the participants' discontentment with the allocation process rather than actual dissatisfaction with their care.

In response to the potential effect of disappointment bias, a randomised consent design (Zelen 1979) was chosen for the STOMP study. In the randomised consent design, participants are randomly allocated prior to seeking consent. Those participants allocated to the intervention group are then approached and offered the intervention, which they can decline or accept. Some researchers are critical of the randomised consent design and this debate is further explored in Chapter 3, which describes the Zelen design in greater detail.

The randomised consent design is also known as pre-randomisation design (Snowden et al. 1998). For the remainder of this dissertation it will be known as the 'Zelen' design.

1.2.2 Characteristics of the population

The multicultural population served by the hospital was an important consideration in the development of the STOMP model and the evaluation. Australia ranks as one of the most multicultural societies in the world (Rissel 1997), due to the active support given

by the Australian Government to immigration through most of the 20th century (Australian Bureau of Statistics 1997). The overseas-born population in Australia has increased from 2.8 million in 1976 to 4.2 million in 1996. People from the United Kingdom and Ireland still make up the majority of migrants, however the Vietnam war and the outbreak of war in Lebanon resulted in an increase in migrants to Australia from Asia and the Middle East in the past decade (Australian Bureau of Statistics 1997).

In 1997, 23 per cent of women who gave birth in Australia were themselves born in another country. The Asian population has grown the most in recent years, with the proportion of mothers who were born in Asia increasing from 5.5 per cent in 1991 to 7.7 per cent in 1997. Mothers born in countries where English was not the first language, were also more likely to reside in the more populous states, NSW and Victoria (Day et al. 1999a).

The St George Hospital is situated in the south-eastern area of Sydney, NSW, in an Area Health Service known as South East Health. South East Health has a culturally and linguistically diverse population. Thirty five percent of the resident population was born overseas with major cultural groups being from Greece, China, Italy, Egypt, Hungary and Lebanon (NSW Health Department 1999). In the 1996 *Census of Population and Housing* (Australian Bureau of Statistics 1996), only 58 per cent of the population in the local district served by the St George Hospital spoke English at home, with the most common other languages being Greek (7.7%), Chinese (7.5%), Arabic (5%) and Macedonian (4%). In 1997, 27 per cent of women who gave birth in South East Health were themselves born in non-English speaking countries, with the largest representation being from China or Hong Kong and Lebanon (Nivison-Smith 1998).

It was important that the STOMP study recruit a sample of women that reflected the cultural and linguistic diversity of the population. A review of 12 similar studies over the past 30 years suggests that few other trials investigating models of midwifery care have recruited a sample representing a diversity of cultures and language (Appendix 3, page 239). Some studies have only recruited English-speaking women (see for example (Giles et al. 1992). This is most likely because of the logistical difficulties in arranging interpreters and the cost associated with translation of documents. While these reasons are valid, it can mean that the sample recruited is not representative of the population on which the intervention may be applied and the results will be biased.

Women from NESB tend to be under-represented in research (Brown & Lumley 1994; Cartwight 1986). Phoenix (Phoenix 1990) also reported a distinct lack of multicultural and multiethnic representation in many studies in maternity care. However, ensuring representation is not always easy. Researchers using surveys in the United Kingdom reported difficulty in accessing certain groups of women, particularly those from Asian communities (Summers et al. 1997). Summers et al (1997) commented that "these are only one of several subgroups in the population who may get a relatively poor deal from maternity services and are less likely to respond to blanket survey methodologies" (p. 50). In Australian research, response rates in non-English speaking women have also been reported to be low (Brown & Lumley 1994). People from minority cultural groups do not participate in health related research for a range of reasons, including a lack of understanding about the relevance of the study, distrust of the research process (Lipson & Meleis 1989), language barriers and fears about confidentiality (DeSantis 1990). Some cultural mores only allow the participation of women with their husband's permission (Berg 1999).

Certain techniques have been suggested to improve participation among culturally diverse groups. These include: obtaining community support; using age, gender and culturally matched research assistants for recruitment; translating documents; and, acknowledging and being appreciative of the participant's involvement (DeSantis 1990; Milburn et al. 1992). Other strategies suggested are: a systematic approach to sampling and recruitment; flexible and sensitive protocols; and, paying significant attention to the selection, training and ongoing support of bilingual interviewers who collect data (Small et al. 1999).

Berg's (1999) study of Filipino American women recruited 165 women utilising some of these techniques. While it appeared that these were useful strategies in encouraging participation, the eventual participants were highly educated and attracted to the study because it was conducted through a major university. Consequently, while the sample included a group of women previously poorly represented in research, the women themselves were unrepresentative of the wider Filipino population.

Much multicultural research seems to take a singular approach to the group under investigation (Berg 1999; Rice 1994; Yelland et al. 1998) where specific cultural or language groups are studied. This approach is important to gain insight and information

regarding the needs of the particular group being studied. However, it is important to include people from a range of cultural groups in research that will ultimately determine the outcomes of service provision for a culturally diverse population. If the STOMP model of care was proven to be of benefit to women and the health system, it was possible that others would use it as a model of providing maternity care. A sample that was representative of the cultural and linguistic diversity of the population was therefore essential. Cultural diversity influenced the choice of study design.

In summary, it was felt that the Zelen design (Zelen 1979) would help ensure a diverse and representative sample was recruited as selection bias would be reduced. The use of the Zelen design to achieve this aim is further discussed in Chapter 3. The cultural diversity also influenced the selection of strategies used in the recruitment and the consenting process. These strategies are described in Chapter 4, which describes the methods used in the study.

1.2.3 Measuring the financial impact

As the new model was implemented within current resources an analysis of costs was an essential component of the evaluation. This would ensure that the model was cost efficient and ultimately, sustainable, that is, would be able to continue in the long term. The cost analysis complimented the randomised controlled trial.

Economic analyses of new models of maternity or midwifery care are uncommon (Twaddle & Young 1998) although essential if new models of care are to be widely implemented. Managers and health administrators working with the current climate of budgetary restraint need to be sure that any new model of care they implement will not cost more than their existing service. The two Australian studies into team midwifery that used economic analyses were limited in their capacity to precisely detail the costs associated with the new model. Rowley et al (Rowley et al 1995) used Australian national cost weights for diagnostic-related groups. This system failed to account for ambulatory care, for example, antenatal clinics and postnatal domiciliary care. Kenny et al (Kenny et al 1994) only costed interventions that were significantly different between the intervention and control groups so the overall cost of care was not provided. Sensitivity analyses were not presented in either study.

The cost analysis comparing STOMP care with standard care from the perspective of health system is presented in Chapter 8. Sensitivity analyses are presented which demonstrate the cost implications of changing assumptions.

1.2.4 Measuring satisfaction

The study wanted to assess women's 'satisfaction' with the new model as it is an important measure of the effect of health care. However, difficulties exist in defining and measuring satisfaction in a meaningful way. It is possible that satisfaction with maternity care directly relates to the outcome of the pregnancy. For example, the birth of a healthy baby might mean that the woman expresses 'satisfaction' with her care regardless of whether or not her overall experience was positive (Jacoby & Cartwight 1990). These women may care less about what happened to them during the pregnancy and birth due to their relief and pleasure at the outcome (Brown et al. 1999). It also appears that general questions about 'satisfaction' extract high reported levels of satisfaction with care (Stimson & Webb 1975; World Health Organisation 1978) and may mask important differences in specific aspects of the experience (Locker & Dunt 1978). Green et al (Green et al. 1998a) suggest that general or global questions may mask particular areas of dissatisfaction in the expression of relief, gratitude, happiness in a healthy baby. Using an overall measure of satisfaction as an indicator of maternity service provision is inadequate as it is insensitive to the specific factors that make up satisfaction (Hundley et al. 1997). The use of more focussed, episode-specific questions (Fitzpatrick 1991a; Fitzpatrick 1991b) and open-ended questions (Dougall et al. 2000; Thomas et al. 1996) may improve the measurement of this multifaceted phenomena.

Other researchers have been critical of the measurement of 'satisfaction' as it is believed that the vast majority of patients are loath to be critical of any aspect of their hospital stay (Westbrook 1993). Researchers from geriatric medicine (Owens & Bachelor 1996), gastroenterology (Dougall et al 2000) and mental health (Williams et al. 1998) have questioned the measurement of satisfaction as a useful exercise as high satisfaction ratings do not necessarily mean that patients had good experiences. It has been suggested that experiences of satisfaction might reflect attitudes such as "they are doing the best they can" (Williams et al 1998). Williams et al (1998) suggested that in satisfaction surveys, we must know what people mean when they say they are

'satisfied' with any particular aspect of a service. It would appear that in many cases, when patients are asked whether they are satisfied with their care they tend to say "yes" (Westbrook 1993). Owens and Bachelor's research (1996) in elderly people found that while the majority voiced satisfaction, on further analysis they were found to be dissatisfied with their care, but their loyalty to the nursing staff precluded honesty in initial answers.

In the STOMP study, the' experiences of women were the focus of the questionnaires rather than satisfaction per se. Phrases such as "are you satisfied" were avoided. Instead, a range of specific issues that relate to the specific nature of the experience for the woman were addressed. For example, in the antenatal period, questions about access, waiting times and different aspects that contribute to quality of care were used to elicit specific responses about the women's experience rather than whether or not they were 'satisfied' with their care.

1.3 Aims and research questions

The STOMP model differed to previously reported models of maternity care. Antenatal care was provided from community-based settings and with a focus on continuity of carer in the antenatal period. Salaried hospital midwives and a staff specialist obstetrician provided antenatal care in the community. The context in which the new model was implemented was also unusual. The study hospital was situated in an area of high cultural and linguistic diversity, that is, a large proportion of childbearing women were born in non-English speaking countries. Great effort was taken to enable women from diverse cultural groups to participate in the study, as it was acknowledged that any change in service would affect all the women in the community served by the hospital. The STOMP model was implemented within the existing budget of the hospital's maternity unit, which is again unusual in an Australia context. No additional funding was received to establish the new model of care.

The research aimed to implement a new model of maternity care within an Australian metropolitan teaching hospital and compare the safety, acceptability, cost effectiveness and women's experience of the new model of maternity care with standard care. The new model of care was implemented as a means to achieve change in the provision of public maternity care within existing resources.

The research addressed the following questions:

1. Does the STOMP model result in comparable maternal and neonatal outcomes compared with standard care? (Chapter 5)

2. Are community-based antenatal services, established as an outreach of a teaching hospital, associated with a better experience for women? (Chapter 6)

3. Did the STOMP model improve women's experiences during labour, birth and the postnatal period? (Chapter 7)

4. From the perspective of the health system, did the STOMP model cost more or less to provide than the standard model? (Chapter 8)

5. Did the STOMP model meet the needs of women from non-English speaking backgrounds? (Chapter 9)

6. Can a Zelen design be used to recruit a culturally and linguistically representative sample of women and strengthen the findings from research into maternity care? (Chapters 4 and 9)

1.4 Organisation of the dissertation

The dissertation is organised around the main research questions outlined in this chapter. The findings in relation to each question are presented as separate chapters. These incorporate a detailed description of the process of analysis used and the particular outcome measures used.

Chapter 2 describes the standard care models available at St George Hospital and describes how these and evidence in the field assisted the design of the STOMP model.

Chapter 3 discusses the use of the Zelen design in the research. The two types of Zelen designs are described. Some of the recent controversy surrounding the use of the design and its advantages and disadvantages are discussed.

Chapter 4 describes the methods used in the study, including the population, sample size calculations, method of randomisation and consent, outcome measures and process of data collection. An overview of the analysis is presented. A detailed description of each analysis is found in the chapters (5-9) that present the results. Chapter 4 also provides a description of the study sample.

Chapters 5 to 9 present the findings of the research. Chapter 5 is concerned with maternal and neonatal outcomes. The effect of the model on caesarean section rate is discussed in detail in this chapter as it was the primary measure on which power and sample size was calculated. Chapter 6 presents the evidence around women's reported dissatisfaction with antenatal care and the various strategies that have been suggested to improve the experience. As the provision of antenatal care from midwives and obstetricians in a community setting in Australia is unusual, the antenatal experiences of the women are presented separately from the postnatal experiences. Chapter 7 primarily addresses with the impact that continuity has on the experiences of women during childbirth. Experiences with the STOMP model of during labour, birth and the postnatal period compared with standard care are also presented in this chapter. Chapter 8 presents a cost analysis, which examines the mean cost of providing STOMP care compared with standard care. The final chapter in this series, Chapter 9, is concerned with the implications of cultural and linguistic diversity in Australian society particularly in relation to maternity care. The results presented in Chapter 9 are a secondary analysis, comparing the experiences of women from English, Chinese and Arabic-speaking women and examining whether the STOMP model influenced these experiences. Chapter 10 returns to the study questions and addresses each in turn as a synthesis of the results from each of the previous chapters. The final chapter also discusses the implications of this study for Australian maternity care.

1.5 Summary

This chapter has overviewed some of the factors that influenced the development of the STOMP model and the method of evaluation. State, national and international policy directions and recommendations, previous research, a local commitment to improvement in maternity services and financial considerations were all considered in the development of the STOMP model. The design of the evaluation was influenced by the need to reduce disappointment bias and recruit a representative sample of women from NESB.

The next chapter describes the standard care options that were available at St George Hospital. The evidence, which informed the design of the STOMP model, is discussed and a description of the STOMP model is presented.

Chapter 2 The design of the STOMP model

2.1 Introduction

This chapter outlines the standard care options provided at St George Hospital during the study. The chapter then describes the features of the STOMP model and outlines the theory and evidence that supported the development and implementation of the STOMP model. Some of the research was not available when the model was initially designed, however it is presented here to demonstrate the controversies and uncertainties that persist.

2.2 Standard care options

The various standard options for care were discussed with each woman at her booking visit. Depending on the woman's risk status and expectations of maternity care, she made a choice between the various options. This did not always occur so easily. For example, by the woman's booking visit, the birth centre was usually oversubscribed and she was placed on a waiting list. Antenatal clinics were often rushed which meant that for some women, particularly those from NESB, all the options were not fully explained.

Standard care options at St George Hospital were characterised by a lack of continuity of care and carer, with two main exceptions, the birth centre and the midwives' clinic. The next section briefly describes each of the standard care options and highlights some of the problems that have been reported.

2.2.1 Hospital-based antenatal clinic

The antenatal clinic was situated on the hospital campus and conducted four half-day sessions per week. Women attending the antenatal clinic were seen by available midwives and doctors. Women who were designated 'high risk', had regular consultations with medical staff and usually did not receive any antenatal care from midwives.

There was an attempt to provide continuity of care for women but this was informal and in many ways, ad hoc. Some obstetricians arranged their clinic so certain women, for example, high risk women, saw them at each visit. Women from Arabic, Cantonese/Mandarin speaking backgrounds had some measure of continuity of

midwifery care as two bilingual midwives (ethnic obstetric liaison midwives) worked in the antenatal clinic on designated days and provided care to low risk women.

Criticisms of hospital antenatal clinic services include prolonged waiting times, lack of continuity of caregiver, conflicting advice and rushed staff (Senate Community Affairs References Committee 1999); (Laslett et al. 1997); Williamson & Thomson 1996; Victorian Department of Health 1990; (NSW Health Department 1989; Victorian Department of Health 1990; Williamson & Thomson 1996). The St George Hospital's *Maternity Services Customer Satisfaction Project* also identified problems with the lack of continuity in the antenatal clinic and the long waiting times. Accessing the clinic was also identified as a problem as finding a car park around the hospital campus was difficult (Everitt et al 1995). The STOMP model was designed to address some of these criticisms, especially, continuity of care, waiting times and accessibility.

2.2.2 Shared care with general practitioners

Women could choose to have antenatal care with their general practitioner (GP). In GP shared care, women attended the antenatal clinic at the hospital for their booking visit, and then, if necessary at 30 weeks gestation, 36 weeks and 41 weeks. All other antenatal visits were with the GP.

Shared care with GPs in Australia is not without its critics. A survey conducted in Victoria in 1994, indicated a very low level of satisfaction with GP shared care. Only 33 per cent of women receiving shared care rated their experience as 'very good' compared with 46 per cent of women attending a public antenatal clinic, 72 per cent attending a private obstetrician and 80 per cent receiving team midwifery care in a birth centre (Laslett et al 1997). A more recent survey in Victoria reported problems with GP shared care including fragmentation of care, increase in number of antenatal visits and costs to women, duplicate investigations, variability in the quality of care and a lack of coordination of care (Brown et al 1999). There are also limited opportunities for midwives to provide care with GPs in community-based settings. This issue is discussed later in this chapter.

2.2.3 Midwives' clinic

The midwives' clinic was established in 1995 to provide antenatal care for women with low risk pregnancies. The clinic was conducted for two hours one evening per week and

staffed by five midwives. Women who required regular review by medical officers were unable to attend the midwives clinic. Obtaining interpreter services in the evening was often difficult. This meant that few non-English speaking women attended the clinic.

The midwives' clinic aimed to provide continuity of carer in the antenatal period. Women were allocated to see one midwife throughout their pregnancies. When this was not possible, because either the midwife was on leave or fully booked, a second midwife provided care. The midwives in the clinic did not provide intrapartum or postnatal care, therefore, while women could have continuity of carer antenatally, there was no opportunity for them to receive continuity of care or carer during labour or the postnatal period. The midwives' clinic was restricted by its brevity, duration and risk status. This meant it could only cater for a small proportion of women at low obstetric risk who were able to attend the evening session and did not develop any complications during pregnancy.

STOMP aimed to move the midwives' clinic model forward by catering for women who developed risks in the antenatal period.

2.2.4 Care during labour and birth

Most women receiving standard care attended the hospital's delivery suite for labour and birth. A small proportion of women at St George Hospital (12%) attended the birth centre. The birth centre is described later in this chapter (on page 20).

The delivery suite contained six delivery rooms with a core staff of certified and student midwives. The midwives who staffed the delivery suite did not routinely attend the antenatal or midwives clinic to provide antenatal care nor did they provide postnatal care. In the delivery suite, women received care from the midwives on duty. Midwives worked conventional eight to ten hour shifts and women who laboured through one or more shift changes received care from a number of midwives.

Factors which have been reported to cause women to express discontent with care during labour and birth include: a lack of continuity of care; a lack of control and involvement in decision making; insufficient information; and, a perception that caregivers are unhelpful (Green et al. 1990). These factors were considered in the designing the STOMP model for intrapartum care and it was hoped that providing continuity of care would ameliorate these experiences.

2.2.5 Postnatal care

Women receiving standard care had their postnatal care provided primarily in the 24 bed postnatal ward. Women were usually transferred to this ward within four hours of the birth. Again, women received postpartum care from the rostered midwives, most of whom did not routinely work in the antenatal clinic, midwives clinic or delivery suite, although many midwives rotated through these areas at three to six month intervals. Women were able to go home early (within 48 hours) and received midwifery visits at home for up to five days. Midwifery visits at home is known as domiciliary midwifery.

Postnatal care is an area that receives much criticism in the literature. Fragmentation of care and conflicting advice have been found to be aspects of postnatal care that are not supportive to women (Audit Commission 1998; Ball 1994; Ball 1989; Cooke & Stacey 2000). Continuity of care and carer has been suggested as a strategy to improve this aspect of care. Postnatal care is however, probably the most difficult aspect to provide in a continuity of care model. A description of how the STOMP model addressed the issue of providing postnatal care is provided later in this chapter.

2.2.6 Birth centre care

The birth centre was purpose-built and opened in 1990. It was situated 50 metres from the delivery suite and contained two birthing rooms each with a double bed and a spa bath. Women who wished to receive care in the birth centre were accepted if they were deemed to be at low obstetric risk. Midwives in the birth centre provided antenatal, intrapartum and postpartum care unless medical or obstetric complications necessitated review by an obstetrician and subsequent transfer to the antenatal clinic or the delivery suite. Women were transferred to the delivery suite in order to receive electronic fetal monitoring, intravenous infusions or epidural analgesia.

Birth centres are more common in Australia and the United States of America (USA) than in the UK. In Australia, the numbers of birth centres have increased significantly over the past 20 years (Waldenström & Lawson 1997). Despite this expansion, only four per cent of all births in NSW in 1998 took place in a birth centre (NSW Health 2000). Birth centres are restricted by their admission criteria (usually low risk) and by their philosophy of low intervention. Women who develop obstetric risks during pregnancy are transferred to standard care, thus losing the opportunity to have continuity of care or even midwifery care. In addition, not all women want, or can have,

a birth that is free of intervention. Induction of labour, an epidural anaesthetic or electronic fetal monitoring may be indicated for some women. Some women may also choose to have an epidural anaesthetic. Birth centres exclude these women.

2.2.7 Care for women with risk-associated pregnancy

In June 1997, six months after the commencement of the STOMP study, the risk-associated pregnancy (RAP) team was established at St George Hospital. The RAP team is a multidisciplinary model providing continuity of care through the antenatal, intrapartum and postpartum periods for women with specific risks, particularly hypertension. The RAP team is made up of four midwives, an obstetrician and a physician. Women are eligible for the RAP team if they are booked at St George Hospital and have a diagnosis of hypertension in pregnancy and have made at least two visits to the day assessment unit (DAU); or, require admission to the antenatal ward for more than one week. A small number of women were transferred from STOMP to RAP during the study, although they were retained in the analysis. A process was developed for determining which women should be transferred to RAP and which women should remain on STOMP with support and guidance from the RAP team. The transfer process involved an individualised approach with communication and collaboration between the teams along with the consideration of each woman's needs and wishes.

2.3 Designing the STOMP model

The STOMP model of maternity care was designed to incorporate choice, continuity and quality of care for women in a setting that was easily accessible and convenient to them. Continuity of midwifery care, community-based antenatal care and collaboration, were key elements of the STOMP model. The STOMP model intended to provide an improved service using existing staff at no extra cost to the organisation. The next section presents the information that guided the choices that were made in the design phase of STOMP.

2.3.1 Important factors in 'satisfying' maternity care

Three main factors have been identified in numerous government reports and independent research as important contributors to 'satisfactory' or positive experiences of maternity care for women (Brown & Lumley 1994; Green et al 1998a; House of

Commons 1992; NHMRC 1996; NSW Health Department 1989; Victorian Department of Health 1990). These are: the need for continuity of care; the desire for choice of care and place of delivery; and, the right of women to maintain control over their bodies at all stages of the childbearing process.

Australian government reports have recommended an increased provision of continuity of <u>care</u> throughout the childbirth experience (NHMRC 1996), (NSW Health Department 1989; Victorian Department of Health 1990) whereas the UK reports (Department of Health Expert Maternity Group 1993; House of Commons 1992) have placed more emphasis on continuity of <u>carer</u> in labour. In this dissertation, continuity of <u>care</u> is defined as a consistent philosophy or organisational structure around which care is provided and continuity of <u>carer</u> refers to care by a midwife whom the woman has met previously and feels that she 'knows'.

Continuity of care and carer and other factors, which contribute to positive experiences for women during the antenatal, labour and birth and postnatal periods are below.

In the antenatal period

A number of factors have been reported to contribute to satisfying antenatal care. These are predominately related to the organisation of care and the nature and quality of the care provided. For example, in relation to the organisation of care, Zadoroznyi (Zadoroznyi 1996) reported that satisfaction with antenatal care was related to having sufficient time with midwives, short waiting times and flexible appointments. In relation to the nature of care, important determinates of satisfaction include: friendliness and support; consistency of care; good communication; having care givers who listen; and, allowing women to participate in decision making (Brown & Lumley 1994; Green et al 1998a; Hirst et al. 1998; McCourt et al 1998; Morgan et al. 1998; MORI (Market and Opinion Research International) 1993; Proctor 1998; Wilcock et al. 1997). The most valued characteristics of caregivers responsible for antenatal care are the ability to provide information and advice, show an interest in women's concerns and questions, be responsive and have enough time for discussion (McCourt & Percival 1999).

Hirst et al (Hirst et al 1998) suggest that what women really want from antenatal care is reassurance rather than routine health checks as these can cause unnecessary anxiety. Provision of reassurance and support (both emotional and practical) is therefore an important component of antenatal care. In the frequently cited Sikorski et al

(Sikorski et al. 1996) study, women who received a reduced schedule of antenatal visits were less happy with their care and rated lower on psychological measures than women who received the standard number of visits. A secondary analysis of the original trial found that women who were satisfied with the reduced schedule were more likely to have a clinician who listened and encouraged them to ask questions (Clement et al. 1999). These actions may have provided women with the support and reassurance they sought.

The effectiveness of support during pregnancy has been reviewed by the *Cochrane Collaboration* (Hodnett 2000a). Social support by a health professional, either at home, during antenatal visits or by telephone, was not found to have an impact on birth weight and incidence of preterm labour. However, a number of individual trials reported improvements in psychological outcomes. Middlemiss et al (Middlemiss et al. 1989) reported reduced antenatal anxiety, Oakey et al (Oakley et al. 1990) found reduced worry about the baby and Blondel et al (Blondel et al. 1990) noted increased satisfaction with antenatal care. Oakley et al (Oakley et al. 1996) reassessed women seven years after the initial trial and found that there were still important differences between the groups. Women who had received social support reported fewer health problems in their children, fewer concerns about their social well being and a greater sense of personal well being compared with those who had received standard care. Support during pregnancy is consistent with the expectations around continuity of care, that is, care will be woman-centered, individualised and informative.

In summary, women seem to value care that is responsive to their needs, provided in a convenient and flexible manner and provides reassurance and support as well as physical care and monitoring.

During labour and birth

In a similar manner to antenatal care, the factors that determine satisfying care during labour and birth are multifaceted. Positive experiences are determined by: the nature and quality of information provided to women (Fleissig 1993; Waldenström & Nilsson 1993); a sense of control over the care provided (Hundley et al 1997); (Green et al 1990), and, the existence of a trusting relationship with midwives (Tinkler & Quinney 1998). Brown and Lumley (Brown & Lumley 1994; Brown & Lumley 1998) also identified that 'having an active say in decisions made during labor and birth' was an important

predictor of satisfaction. Green et al (Green et al 1990; Green et al 1998a) found that 'feeling in control during labour' was associated with feelings of fulfillment and postnatal emotional well being. Having caregivers during labour who are perceived as being helpful has been associated with a higher rating of care during labour and birth (Brown & Lumley 1998). Obstetric intervention has been shown to predict a negative childbirth experience (Brown & Lumley 1994); (Seguin et al. 1989); (Jacoby 1987).

Quantitative surveys in the UK have provided evidence to support the importance of continuity of carer during labour. A survey of 2 300 women in UK reported that over 80 per cent of women felt that continuity of carer throughout labour was important (Audit Commission 1998). An earlier survey of 1 800 women found that 65 per cent of women gave some importance to knowing the midwife in labour (Melia et al. 1991).

Qualitative research suggests that continuity of carer in labour is important and valued by women (Coyle 1998; Farquhar et al. 1994; McCourt et al 1998; Morrison et al. 1999; Walsh 1999). Many of these studies were small with samples that are potentially unrepresentative of a wider population. For example, the samples consisted of women who chose to give birth at home (Morrison et al 1999) or in a birth centre (Coyle 1998). Lee's (Lee 1994) research found that women who had previously met their labour midwife were significantly more satisfied than those who had not. Women in Lee's study (Lee 1994) however ranked a midwife who 'inspires confidence and trust' and one who gives 'safe and competent care' above a 'known midwife' in terms of valued elements of care.

The results of these mainly qualitative studies, which support providing continuity of carer in labour, are in contrast to the results from a review conducted by Green et al (Green et al. 1998b). This structured review of the evidence from quantitative studies concluded that, while women prefer a smaller number of caregivers, having continuity of midwife carer during labour was 'the icing on the cake'. It seemed more important to women to have a midwife who was competent and caring than one whom she had met before. Green et al (Green et al 1998b) argue that there is no justification in making continuity of carer in labour the main determinate of a service. Other research suggests that knowing a named caregiver throughout pregnancy and childbirth is not a top priority for all women (Fellowes et al. 1999). Fellowes et al (Fellowes et al 1999) reported that it was more important for women to have good quality care from all health professionals

than to have continuity of carer in labour. Continuity of midwife carer in labour was found not to be a clear predictor of women's satisfaction with care in other research by Morgan et al (Morgan et al 1998) and Shields et al (Shields et al. 1999). Waldenström (Waldenström 1998) also reported that there were no differences in satisfaction with intrapartum care or the birth itself when comparing women who were delivered by a known or unknown midwife in a birth centre. Waldenström (Waldenström 1998) suggests that continuity of carer may be less important in a birth centre because of the consistent philosophy, attitudes of the caregivers and the calm environment. These studies (Morgan et al 1998; Waldenström 1998) should be interpreted with caution as they were all sub-group analyses from larger projects.

While uncertainty exists as to whether the provision of continuity of carer in labour is worth the cost and logistical effort, continuity of care is easier to organise and provides a form of continuous support to women in labour. Advantageous effects have been demonstrated when health care workers or lay people provide continuous support during labour. The Cochrane review of *Caregiver support for women during childbirth* reported positive benefits including a reduction in analgesia, less instrumental births and caesarean sections and a decreased need for augmentation of labour (Hodnett 2000b). There were also more positive psychological effects associated with continuous support during labour, including feeling of being 'in control' and finding labour to be less painful than expected. In two of the studies included in the review (Hofmeyr et al. 1991; Langer et al. 1998), there was also an increased likelihood of breastfeeding at four to six weeks postpartum.

In summary, during labour and birth, women seem to value consistency and continuity, a trusting relationship with clinicians, adequate information and an ability to be 'in control' of the care and the events that occur during labour and birth.

In the postnatal period

While a wide range of research into aspects of the antenatal and intrapartum experience has been conducted, there appears to be considerably less research into the factors that contribute to satisfying care in the postnatal period. Postnatal care has been reported to influence women's sense of self confidence and self esteem in the early postnatal period (Ball 1989) and may have an important role in the prevention of postnatal distress or depression (McCourt & Percival 1999). Fragmentation of care and

conflicting advice are aspects of postnatal care that are often not supportive to women (Audit Commission 1998; Ball 1994; Ball 1989; Cooke & Stacey 2000). Lack of rest, busy, rushed staff, inadequate time to ask questions, inappropriate or non-individualised advice with too much information provided in a short period are other inadequacies of postnatal care (Audit Commission 1998; Cooke & Stacey 2000; McCourt & Page 1996). Women were also more satisfied with their postnatal care when they felt they 'had a say' in when they went home (Audit Commission 1998). Inadequate and inconsistent advice about breastfeeding has been reported as being unhelpful, confusing and may lead to early cessation of breastfeeding (Audit Commission 1998); (Stamp & Crowther 1994).

In Australia, as in many other countries, the length of hospital stay after birth has reduced with little evidence to say that this is beneficial for women and babies (Cooke & Barclay 1999). The *Shearman Report* in NSW (NSW Health Department 1989) identified five to seven days as the <u>optimal</u> period of postnatal care. In NSW, the average length of stay following the birth of an infant in a public hospital was four days in 1997 (Day et al 1999a). Domiciliary midwifery care, where midwives provide postnatal care in women's homes, was introduced in NSW largely as a result of the *Shearman Report* (NSW Health Department 1989) and has been rated highly in a number of studies. The main reasons for the high levels of satisfaction seem to be related to continuity of carer and consistency of advice and support (Cooke & Stacey 2000; Kenny et al. 1993; Waldenström 1987).

In summary, the factors that women value in the provision of postnatal care seem to focus on consistency of information and individualised care. Continuity of care and carer may be one strategy to ensure that these factors are provided.

2.3.2 The organisation of care and carers

It is clear from the evidence, that continuity of care and carer are important aspects of a maternity service that meets the needs of women. The dilemma is how best to operationalise the philosophy of continuity of care and carer in an Australian public health system. This next section describes three models that provide continuity of care and carer in varying degrees.

One of the ways that continuity of carer has been provided is in a caseload model. In this model, small groups of two or three midwives provide antenatal, intrapartum and

postnatal care to a group of women. The South East London Midwifery Group Practice is an example of a caseload model (Leap 1996). In this model, a group practice of five midwives provides continuity of carer from a community-based setting. Each midwife is the primary midwife for 35 women a year and is also the second midwife for another 35 women a year. Each midwife is involved in the antenatal, intrapartum and postnatal care for these 70 women. The midwives are on-call 24 hours a day for approximately three blocks of three months of the year (three months on-call followed by one month on holiday). The One-to-One model is another example of caseload midwifery (McCourt & Page 1996). One-to-One midwives have a personal caseload of 40 women per year and are organised into partnerships and group practices. This means that each midwife is on-call for 80 women a year (her 40 women and her partner's 40 women). A group practice of six midwives in a caseload model can provide care for 230 to 240 women a year.

Another way to provide continuity of care and care is in a team midwifery model. In this model, six midwives provide antenatal, intrapartum and postnatal care for a defined number of women. Care during labour and birth is provided by one of the six midwives. This model was used in the two Australian models of midwifery care (Rowley et al 1995) in Australia, although Rowley et al (1995) did not include postnatal care. Team midwifery usually means that women have less continuity of carer in the antenatal period with a higher probability of a continuity of carer, or a 'known' midwife, during labour. In the Australian models (Rowley et al 1995), each midwife attempted to meet all the women on the team during the antenatal period. The net result being that women saw six or seven different midwives in the antenatal period and experienced little continuity of carer. The attempt to meet all the women also placed extraordinary demands on the midwives, many of whom would come into the hospital on their days off duty to meet women so that they would feel they 'knew' them in labour. It is unclear whether having met a midwife once (sometimes briefly) constitutes being 'known'. The six midwives shared being on-call for the women on the team. A team midwifery model (with six midwives) can cater for at least 300 women a year.

Another option is to use a team midwifery model, with a modification to increase the probability of continuity of carer in the antenatal period. As women value friendliness, consistency and support in the antenatal period (McCourt et al 1998; Morgan et al 1998; Wilcock et al 1997) they may find increased continuity of carer in the antenatal

period beneficial. This option means that women have a lower probability of having continuity of carer during labour, as they receive care from one of the six midwives. Continuity or consistency of care would be an important focus in this model. It is likely that a team of six midwives could cater for at least 300 women per year. This model has not been formally evaluated and it is not clear whether women would prefer this to standard care, or to a more conventional team midwifery model.

After much discussion and debate it was decided that the emphasis in the STOMP model would be on continuity of carer in the antenatal period and continuity of care during labour. A number of pragmatic issues also influenced this eventual choice, including the needs of the midwives and the hospital, the industrial constraints and the size of the teams. These are outlined below.

Pragmatic decisions in the organisation of carers

There was a need to design a model that was not an overwhelming change for the midwives, was acceptable and appealing to women and sustainable for the organisation. STOMP therefore, focussed on providing continuity of carer in the antenatal period and continuity of care during labour.

In deciding how best to provide continuity of care and carer in the STOMP model, we were conscious of the need to respond to what women wanted, but aware that the model also had to be sustainable in terms of midwife exhaustion or 'burn out'. Continuity of carer makes it possible for midwives to develop meaningful relationships with women and this has been found to be a major source of satisfaction for midwives (Farmer & Chipperfield 1996; Sandall 1997). A reduction in burn out has also been attributed to: flexibility and autonomy; being based in the community; being able to negotiate with one other; and, collaboration with other professionals (Leap 1996). Clearly these factors were important to consider in the design of the STOMP model.

Another factor to consider in designing the model was the prior experience of the midwives who would provide the care. In many hospitals in Australia, particularly in urban settings, midwives work in allocated areas (for example, antenatal clinic or delivery suite), and become experts in their sphere of practice. At St George Hospital, most midwives rotated through all areas (that is, antenatal, labour and delivery and postnatal) on a three to six monthly basis. This ensured that midwives maintained skills in all the areas. This approach focuses on the needs of the institution rather than the

needs of individual women. Women do not receive continuity of care or carer, but midwives retain their full spectrum of clinical skills and therefore can be more flexibly utilised by the organisation. Continuity of care and carer requires a shift in organisation and practice that is quite different from the experience of most midwives in Australia. Providing continuity of care and carer requires a dramatic shift in the way organisations' function and the manner in which midwives provide care (Page et al. 2000) as the midwife's allegiance is to the woman rather than the hospital (Brodie 1996b). Most midwives at St George Hospital had not experienced this shift in emphasis before, nor had most worked in a system where they needed to be on-call to provide care to women in labour. It was decided that a caseload model would be too great a shift for the organisation and the clinicians and so a modified team midwifery model was implemented.

Industrial relations issues also impacted on the design of model. In NSW, midwives are employed under the NSW Nurses' Award, which operates on a system of time sheets completed on a fortnightly basis. Salaries are calculated according to the shifts worked with higher rates attracted by after-hours and weekend work. There was no provision to enable midwives to be contracted to provide a certain service, for example, continuity of care for 50 women per year, in return for a fixed, annualised salary. Therefore, any new system needed to be within the confines of the NSW Nurses' Award and be agreed upon by both midwives and management. A caseload model would have been difficult to implement within the confines of the NSW Nurses' Award.

The size of the teams (the number of midwives per team) and the caseload (how many women each team would care for) was guided by previous research and financial considerations. Financial sustainability was an important component of the design of the STOMP model as the model was implemented within the current budget of the maternity unit and no additional funds were available. In the earlier models of team midwifery in Australia, teams of between six and eight midwives provided care for between 200 and 400 women per year (Kenny et al 1994; Rowley et al 1995). *Mapping Team Midwifery* in the UK reported that, on average, hospital-based teams contained eight to eighteen midwives and community-based teams, between three and six midwives (Wraight et al 1993). Stock and Wraight, in a subsequent publication (Stock & Wraight 1993), acknowledge that while smaller teams are often logically more difficult to organise, they translate to an improvement in continuity of care. During the design

phase of STOMP, it was decided that a team of six midwives would need to cater for 300 women a year in order to be financially sustainable.

In summary, as continuity of care and carer is associated with satisfying maternity care for women, it is necessary to reorganise care to ensure continuity can occur. Three models, which are to provide continuity of care and carer, have been described. The pragmatic issues that influenced the design of the STOMP model have also been discussed. There were other factors considered in the design of the STOMP model. These included basing care in the community, the importance of incorporating women with medical and obstetric complications and the place of birth. These are discussed in more detail in the next section.

2.3.3 Locating antenatal care in the community

The STOMP model responded to the state and federal government reports that recommended antenatal care be based in the community (NHMRC 1996; NSW Health Department 1989; Victorian Department of Health 1990). Women in Brisbane have reported choosing community-based care because of availability with appointment times and decreased travel and waiting time (Del Mar et al. 1991; Ramsay 1996). Previous models of continuity of midwifery care in Australia have provided antenatal care from hospital-based clinics (Kenny et al 1994; Rowley et al 1995). Community-based antenatal care in Australia is generally only available to women who attended private medical practitioners, either specialist obstetricians or GPs. Midwives have a limited, if any, role in these models.

Community-based antenatal services provided by GPs and midwives have been evaluated in the UK and found to be feasible, satisfactory for the majority of women (Fleissig et al. 1996; Williams et al. 1989) and offer greater flexibility and choice (Perkins & Unell 1997). The 'One-to-One' midwifery project is an example of a model of continuity of carer in a community setting. 'One-to-One' midwifery (McCourt & Page 1996) was established as a demonstration project in the UK as a result of *Changing Childbirth* (Department of Health Expert Maternity Group 1993). The project provided care for all women regardless of risk group, in both hospital and community settings. The results indicated that women had a strong preference for community-based antenatal care.

Community-based maternity services, other than those provided in the private sector, are uncommon in the general Australian public health system. A review of the literature failed to uncover any reports of a 'mainstream' community-based antenatal program in Australia. A number of small pilot projects have provided community-based antenatal care by midwives (Hambly 1997; Ramsay 1996; Thiele & Thorogood 1997). These projects were small and available to a limited number of predominantly 'low risk' women. A small number of special community-based antenatal services that have catered for specific disadvantaged groups, for example, adolescent (Brodie 1994) or indigenous women (Bartlett et al. 1998) have been reported. These services are unavailable to most women because they only cater for minority groups.

In Australia, the move to community-based care has been interpreted by public health systems as a cost saving measure. By virtue of the manner in which health services are funded in Australia (Leeder 1999), costs of providing care can be shifted from the state-funded public hospitals to the federally-funded GP in the community. It does not always follow that women receive better care, or indeed more cost-effective care. Problems including: fragmentation of services and provider; an increase in number of antenatal visits and costs to women; duplication in investigations; variability in the quality of care; and, a lack of coordination of care have been reported in recent research from Melbourne (Brown et al 1999).

Difficulties have been experienced in Australia when midwives have attempted to work in small teams in the community (Jones 1999). One of the reasons for this is the system of health care funding in Australia. State governments fund public hospitals and their associated services while the federal government funds GPs through the Medicare system (Leeder 1999). Therefore, there are currently no mechanisms to allow midwives to be contracted to provide antenatal care in GP practices. General practitioners are thus reluctant to employ midwives as they are unable to attract a Medicare rebate for midwifery care. It is unlikely that this current funding system is going to change, at least in the next decade (Senate Community Affairs References Committee 2000).

The design of the STOMP model had to fit into the existing health structures and funding arrangements in order to be sustainable from a financial perspective.

2.3.4 Catering for women with obstetric or medical complications in the antenatal period

Another factor that influenced the design of the STOMP model was the need to cater for women who developed obstetric or medical complications in the antenatal period. Transfer from community-based care to consultant-based care, because of pregnancy-related complications, have been associated with the potential for disappointment in women (Creasy 1997). Some of the models of continuity of midwifery care transferred up to one third of women who developed obstetric risks in the antenatal period to standard care (MacVicar et al 1993; Turnbull et al 1996; Waldenström et al 1997). Transfer usually meant women did not receive continuity of midwifery care. The few community-based antenatal projects that have been reported in Australia only catered for low risk women (Hambly 1997); (Thiele & Thorogood 1997); (Ramsay 1996). Women with medical or obstetric risks were excluded from these models or were transferred back to hospital-based care when risks were identified.

During the design phase of the STOMP model, it was hypothesised that many women with medical or obstetric risks could be managed appropriately in a community-based setting with collaborative midwifery and obstetric care. We felt that women should not be divided into low and high-risk categories because all women would benefit from continuity and consistency of care. In addition, women with complications need medical expertise and intervention where necessary and their safety should not be compromised. Therefore, the STOMP model was conducted in collaboration with an obstetrician and obstetric registrars. The means in which this occurred is described in more detail later in this chapter (see page 34).

2.3.5 Place of birth

During the design phase of the STOMP model, it was decided that intrapartum care would be provided in the delivery suite rather than the birth centre or at home. Homebirth is not a common option in Australia. There has been only one publicly funded homebirth service reported in Australia. This was a small pilot project in Western Australia (Thiele & Thorogood 1997). In 1998, only 0.2 per cent of women in NSW chose a homebirth (NSW Health 2000). While a publicly funded homebirth service is a potential option in the long term, at this stage it would have been unwise to attempt such a radical change in the provision of maternity care.

Birth centres are reasonably well known in Australian maternity care, and in some hospitals, commonplace. The philosophy behind birth centre care is to provide care to low risk women in a less clinical environment with as little intervention as possible in the normal progress of pregnancy and labour. Favourable outcomes have been reported in retrospective reviews of birth centres in Australia (Homer et al 2000); (Ryan 1999); (Biro & Lumley 1991; Martins et al. 1987) and in a randomised controlled trial conducted in Sweden (Waldenström et al 1997; Waldenström & Nilsson 1993). In a population-based survey of new mothers in Victoria in 1993, women who attended birth centres were significantly more likely to: report having an active say in decisions during labour; have their wishes taken into account; and, have known midwives before labour. These are all factors that have been strongly associated with satisfaction with childbirth (Brown & Lumley 1998). Birth centres have a non-interventionist philosophy and are available for women who are expected to have a normal labour and birth. When women develop complications during pregnancy or labour, they are transferred to standard care.

The birth centre at St George Hospital can only cater for 350-400 women per year as it only has two birthing rooms and a staff of five to six midwives. The two teams in the STOMP model would cater for 600 additional women per year. Clearly the resources of the birth centre were inadequate to meet the STOMP model requirements which meant STOMP care was provided in the delivery suite.

It was also recognised that not all women recruited to STOMP would choose a non-interventionist style of care. We wanted STOMP to be a model of care available to most women, regardless of risk or expectations around birth. We also knew, from retrospective research in the unit, that our delivery suite had similar obstetric outcomes to the birth centre in a matched cohort of women (Homer et al 2000). This acknowledgement reaffirmed the decision to provide labour care in the delivery suite. The two Australian trials (Kenny et al 1994; Rowley et al 1995) had also provided care in the delivery suite.

In summary, this section has described some of the main concepts that influenced the design of the STOMP model. These included continuity of carer and carer, financial and industrial considerations, location of antenatal care, place of birth and the needs of women with complications. The next section describes the specific characteristics of the STOMP model and the means by which it was made operational.

2.4 Characteristics of the STOMP model

Each of STOMP teams consisted of seven full time equivalent (FTE) midwives, which gave a working roster of six midwives per team. The additional midwife was required to cover the annual leave entitlements within the team. Adequate uptake of annual leave entitlements was seen as an essential component of the STOMP model to ensure that the midwives did not become exhausted and 'burnt out'. Under the current NSW Nurses Award, midwives who work rotating rosters are entitled to six to seven weeks annual leave. This meant that there was almost always one of the seven midwives on annual leave.

The caseload of each STOMP team was guided by the Australian research by Kenny et al (Kenny et al 1994) and Rowley et al (1995) and informed through our consultation process with others who had expertise in this area. Flint's book *Midwifery: Teams and Caseloads* (Flint 1993) was also used, however her recommended personal caseload of 36 women per year was thought to be too low to be financially sustainable in our setting. Each STOMP team was implemented with a caseload of 300 women per year or 50 women per midwife per year.

The next section will describe how the STOMP model operated in the antenatal period, during labour and birth and postnatally.

2.4.1 The organisation of antenatal care

The six midwives in each STOMP team were arranged into two groups of three to provide antenatal care. This was seen as a means to increase the possibility of a closer, trusting relationship developing between the midwife and the woman, as she only would meet two or three midwives rather than the six that constituted the entire team. All women were aware of the aim of the model, which was that during labour, one of the six STOMP midwives would provide care. It was explained that the intrapartum carer might be one of the two or three midwives that the woman had met, but equally, it might be one of the other midwives in the team. A 'meet the midwives' evening was arranged bimonthly and all women, their partners and significant others were invited to attend. If continuity of carer in labour was important to a woman she was able to attend these sessions and meet all the midwives in an informal setting.

Antenatal care was provided in the community with hospital-salaried midwives and obstetricians. It was hypothesised that this would provide greater convenience and access for women. Two different sites were chosen. One clinic was in an early childhood centre and the other in a family planning centre. The STOMP clinics became known by their respective localities: Rockdale and Hurstville. The sites were selected as they were easily accessible to women (adequate public transport and car parking options), had appropriate facilities (two rooms for consultation) and were geographically central to the greatest number of the childbearing women in the district. The staff at both the early childhood centre and the family planning centre were very supportive of the project and welcomed the move of antenatal services into community centres.

The STOMP clinics were conducted collaboratively. Two midwives and an obstetrician or obstetric registrar attended each session. This meant that the STOMP model could cater for women with risks. Collaboration also allowed women who requested obstetric care (for reassurance or support) to receive this in a community-based setting. Provision of obstetric antenatal care in conjunction with midwifery care from a community-based setting is unusual in an Australian context. Obstetric staffing was slightly different between the two sites. The staff specialist obstetrician attended the Rockdale clinic but did not routinely see all the women who attended. The midwives requested consultations when necessary. Some of these consultations were scheduled in advance for particular women, and others were on an ad hoc basis. One of two obstetric registrars attended each of the clinics at Hurstville STOMP, with ultimate responsibility provided by the Professor of Obstetrics at the hospital. The decision to staff the Hurstville STOMP clinic with registrars was based on a number of factors, including the need for the hospital to provide adequate training opportunities for medical staff and the clinical demands placed on the department at the time. Obstetric staff reviewed each woman's antenatal record at the first visit to the clinic. Women were only assessed when it was deemed necessary from the record review or as requested by the midwife or the woman. At other times, the obstetric staff contributed to teaching and support of the midwives and attended to other paperwork. Women were also able to have GP shared care. This occurred in the form of alternating visits, that is, every second visit was with the GP. These women all remained in the STOMP group for the analysis.

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All women carried an antenatal card, which was a smaller duplicate of the version kept by the hospital. At the time of the study, records held by the women were in the evaluation phase (Homer et al. 1999) and not available across the maternity unit. The STOMP teams did not provide antenatal or parenting education classes. Women were offered the regular classes that were provided (at a small cost) by the hospital.

2.4.2 The organisation of care during labour and birth in STOMP

One of the midwives from each STOMP team was always 'on call' for women in labour or to answer questions. Women were able to access the STOMP midwife by telephoning the hospital's switchboard and requesting that the respective STOMP midwife be paged. The midwife would then call the woman and discuss her particular situation and plan of care. On occasions, women arrived in the delivery suite unannounced. These women were admitted and cared for by the midwives on duty while the on-call STOMP midwife was contacted.

STOMP midwives worked 12 hour 'on call' shifts and most did not come into the hospital unless required to provide labour care for a STOMP woman. The decision to work 12 hour on call shifts was prompted by a number of factors. Proctor's (Proctor 1998) research showed that women valued continuity <u>during</u> labour and did not want to experience a change of staff when labour was established. Rowley's (1998) work has also suggested that having only one caregiver in labour is advantageous. The consultation process at St George Hospital also influenced the decision. Midwives who had only ever worked conventional eight-hour shifts were concerned that a 24 hour on call period would be too great a change in the initial phase. Once a STOMP midwife's 12 hour shift was complete, she handed over primary responsibility of the woman to the next STOMP midwife. The first midwife was able to remain with the woman if appropriate, for example, if she was expected to birth soon, but the oncoming midwife assumed responsibility. This principle was in place to ensure that an over-tired midwife did not jeopardise the care of the woman. Ideally, women would receive continuity of carer in labour but this did not always occur. As discussed earlier, this compromise was influenced by previous research and was guided by our internal and external consultation process.

In the delivery suite, STOMP midwives received support from the 'core' midwives (that is, midwives who normally worked in the delivery suite and were not in either STOMP

team). This support was important for practical reasons, for example, it enabled STOMP midwives to have meal breaks. More importantly, core midwives provided STOMP midwives with advice, guidance and assistance with solving problems. In the event of two women from the same STOMP team being in labour simultaneously, the midwives made a decision based on need and staffing levels. Either the one STOMP midwife provided care for both women with the assistance of the core midwives, or a second STOMP midwife was called. Team work and mutual support was important in making these decisions.

STOMP midwives continued to provide midwifery care in the Operating Theatre for women who had an elective or an emergency caesarean section. This was usually in the role of preparing the woman and her partner for surgery, and receiving and accompanying the baby and the woman's partner back to the delivery suite or if necessary, the special care nursery (SCN). Midwives at St George Hospital did not 'scrub' or assist in the theatre in any other manner.

2.4.3 The organisation of postnatal care

Issues surrounding the provision of postnatal care and support were influential in the development of the STOMP model. It was decided that postnatal care would be provided in the hospital and in women's homes, continuing the cycle back into the community. After the birth, women were transferred to the postnatal ward. Women could either choose to remain in hospital for postnatal care, or, be discharged early (4 to 48 hours) and visited at home by the STOMP midwives.

Ensuring continuity of care and carer in the postnatal period was difficult. A compromise was reached where women were cared for by a STOMP midwife on a morning shift and at other times the core midwives provided care. Every morning shift, a STOMP midwife from each team was rostered for duty on the postnatal ward. This meant that there were two STOMP midwives and two or possibly three core midwives to provide postnatal care for the 24 women on the ward and the STOMP women at home. STOMP midwives worked eight hour shifts when providing postnatal care. The STOMP midwives predominantly cared for the STOMP women in the ward but also cared for other non-STOMP women if necessary, for example, when there were few STOMP women requiring postnatal care in hospital. STOMP midwives also provided care at home for STOMP women who chose to leave hospital early.

A typical day for a STOMP midwife could include providing care for three STOMP women on the ward and three or four at home. The midwife would come on duty at 7.30am review the women on the ward and plan their care for the day. She would discuss the day's workload with the manager of the postnatal ward, the other STOMP team's midwife, and the core midwives. Discussion would include the number of women in hospital and at home, the needs of the ward while the STOMP midwives were in the community and the use of vehicles. At some stage through the morning the STOMP midwife would visit women at home. While she was out of the ward, the other STOMP midwife or the core midwives and the manager would provide care for the women on the ward. Outside the morning shifts, the core midwives on the postnatal ward cared for STOMP women. The STOMP midwife, in conjunction with the woman, planned the care to be provided on the other shifts. This process ensured consistent information, care and support was provided for the woman. STOMP midwives usually rostered themselves to the postnatal ward for two to four consecutive days to increase continuity of carer.

2.4.4 The STOMP midwives

STOMP midwives were recruited from the existing staff of midwives within the Division of Women's and Children's Health at St George Hospital. As most midwives in the unit routinely rotated through all areas of care, finding midwives with adequate skills in all areas may have been less difficult than in other hospitals where midwives did not move from area to area on a regular basis.

In November 1996, an 'Expression of Interest' for the first team, known as the Rockdale team, was distributed to areas in the maternity unit. This was the culmination of the first series of formal and informal sessions, where the STOMP model and the role of the midwives was described and discussed (see page 6). Six midwives responded to this advertisement and all were subsequently appointed. These midwives came from different areas within the maternity unit, although most had worked within the hospital for some time. The second team, known as the Hurstville team, was recruited in May 1997. The majority of these midwives had come to St George Hospital recently with the expressed interest of ultimately joining a team providing continuity of midwifery care.

Both teams were made up of midwives with a range of experience and skills. They were not necessarily the most experienced or senior midwives in the unit. Some were newly

graduated and others had 10 years of experience. Table 2.2 in Appendix 2 (page 235) describes the length of midwifery experience for the 12 midwives originally recruited to STOMP. Midwives entering the STOMP teams were required to complete a 'Skills Inventory' which consisted of a self-assessment process aimed at identifying skills that needed 'updating'. This tool was adapted with permission from research in the Midwifery Development Unit in Scotland (McGinley et al. 1995). Identifying areas of skill deficit gave midwives an opportunity to address these areas prior to commencing on the team and/or during the early days of STOMP. Clinical leadership, teaching and professional support was provided by a midwifery consultant who was attached to the teams for the first year and by the staff specialist obstetrician. STOMP midwives were also well supported by managers, clinical leaders in midwifery and obstetrics and by the midwives in the wider maternity unit.

2.4.5 Policies and procedures

STOMP teams followed the St George Hospital's standard policies and procedures for all aspects of maternity care. This principle was adopted for a number of reasons. Firstly, the research was designed to test the safety, efficiency and cost of the new model of care. It was not designed to alter midwifery practice but change the structure and place in which midwifery care was provided. In essence, if procedures were specifically altered, the research findings would have been compromised. It would be impossible to say if the results were due to the effect of the new model or the different procedures. Secondly, the new model was being introduced as a component of the mainstream system, rather than an 'add-on' service. This meant it was important that the service was seen as a whole and the policies as seamless between the community setting and the hospital. Thirdly, a commitment to evidence-based practice was, and continues to be, the philosophy of the maternity unit at St George Hospital. All policies and procedures were grounded in research evidence and therefore were independent of the midwife providing care.

The change in structure aimed to develop the capacity of STOMP midwives to provide individualised care by improving the relationship with the women. It was hoped that this 'relationship' would mean that policies and procedures were applied more appropriately.

2.4.6 Leadership and support within the maternity unit

Implementing a new model of care requires fundamental changes at all levels within the organisation as well as a transformed culture (Page et al. 1995). In implementing STOMP, we asked midwives, obstetricians and managers to move out of their 'comfort zone' of familiar routines and roles to a new way of providing care that centred on what the women needed rather than what the organisation could provide. The introduction of the STOMP model resulted in considerable disruption to all staff within the maternity unit and resulted in widespread changes to the way people worked and related to one another. This process was facilitated by the commitment and leadership demonstrated by staff within the unit.

STOMP midwives, particularly in the first year, received direct support from a midwife consultant, with additional support from the manager of the delivery suite and the postnatal wards. Fortnightly meetings were held with each team to discuss issues that had arisen, to provide opportunities for solving problems and to ensure consistency of care was maintained. Individual and one to one support was also available to the midwives. The meetings provided midwives with time to reflect on their practice and processes for making decisions. Regular social events were also important to assist the midwives to develop cohesive working relationships with one another. Core midwives also required additional support through the transition process. Strategies such as regular ward meetings and newsletters about the research were used. Minutes of STOMP meetings were also circulated and informal communication networks were used to minimise the sense of disruption and alienation that may have occurred. All midwives in the unit attended one of a series of 'team building' days that were provided. These days were designed to help midwives, in their small teams, understand more about the ways in which teams work and develop strategies to help address issues of effective communication and support.

Regular talks were given by members of the working party which guided the development of the model in a variety of staff forums to ensure that all midwifery and medical staff were aware of the project and its current status. The research newsletter, which reported on all the research projects being conducted within the maternity unit and was written by the researcher, also provided a source of information for staff. Research support and guidance was also provided through regular meetings.

These processes were extremely important for the successful implementation of the new model of care. The STOMP model required widespread reorganisation of human resources within the maternity unit. Effective communication, shared solving of problems, flexibility and trust were essential components of the organisational processes. The commitment and support provided from managers and senior staff within the maternity unit meant that the model was successfully implemented, evaluated and continues to be an option for women.

2.5 Summary

The STOMP model of care was developed to give women increased choice, control, continuity and ease of access to care. Government policy documents, both in Australia and the UK, were used as starting points but previous and ongoing research and experience has also influenced the development of the STOMP model. Compromises were required, as this was a new model of care both for the organisation and the staff. The change needed to be one that was acceptable, sustainable and manageable within the public health system.

STOMP care differs from standard care by its capacity to provide continuity of care and carer, even when women develop complications during pregnancy and labour. Chief differences between STOMP and the standard models of care are presented in Table 2.1 (on the next page).

Chapters 1 and 2 have described the development and design of the model. The next chapter begins to discuss how the model was evaluated. It describes the Zelen design, the advantages and disadvantages of the design and some of the controversy surrounding its use. Reasons for use of the Zelen design are also discussed

Table 2.1: Differences between the STOMP model and standard care at St George Hospital.

	STOMP	Standard
Antenatal care provided in community-based settings	Yes	No
Obstetric care is available in community-based settings	Yes	No
Same midwives provide antenatal, intrapartum and postpartum care	Yes	No (only birth centre)
Care is collaborative involving midwives and obstetricians	Yes	Yes
Transfer to standard care in event of medical complications	Rarely	Not applicable
Postpartum domiciliary midwifery visits	Yes	Yes
Postpartum domiciliary midwifery visit from a midwife met in the antenatal period	Yes	No

Chapter 3 **The Zelen design**

3.1 Introduction

The STOMP study used a Zelen design. Chapter 3 describes the difference between a conventional design and a Zelen design in randomised controlled trials. The two versions of the Zelen design are illustrated and examples of the use of the design in clinical research are discussed. The advantages and disadvantages of the design are highlighted and the strategies that were used to overcome some of the difficulties posed by the design in the STOMP study are addressed.

3.2 Conventional design

The Zelen design (Zelen 1979) provides an alternative sequence in the randomisation-consent process, with randomisation preceding consent. In conventional designs, prospective participants are identified, approached and asked to provide consent and are randomly allocated to (usually) one of two options (Figure 3.1).

Figure 3.1: The progression of participants in a conventional randomisation design.
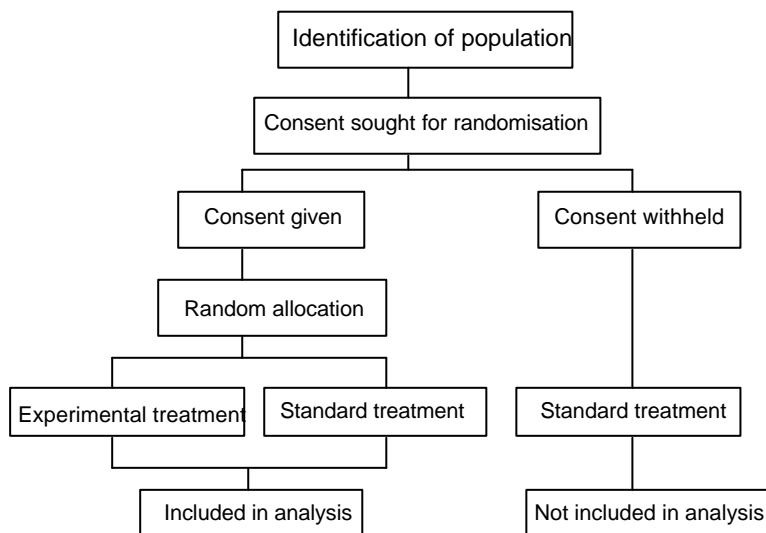
In a conventional design, detailed knowledge of the alternative interventions is given to the prospective participant. The participant gives consent and is allocated to one of the groups. Detailed knowledge of the study may influence the responses of participants in trials that measure outcomes reflecting feelings and opinions (Dennis 1997). For example, negative responses may reflect a control participant's disappointment or dissatisfaction with their allocation to an experimental or control group, whereas positive responses may correspond to a treated participant's apparent loyalty to the intervention.

Chapter 1 described how a conventional design in research into models of midwifery care may have contributed to the dissatisfaction that control group women reported in their surveys (Kenny et al 1994; Rowley et al 1995). Women in these studies may have been dissatisfied solely because they were disappointed that they were not allocated to the new model of care and their satisfaction surveys may not have been 'true' reflections of their experiences with standard care.

The effect of the consent-randomisation progression on outcomes has also been reported in other research where the unblinded nature of the trial leaves participants, who are not randomly allocated to their treatment of choice, feeling 'disappointed and demoralised' (Bradley 1993). For example, trials in The Netherlands testing the therapeutic effectiveness of heroin provision have reported that participants allocated to the control group have been disappointed and this has affected the trial results. Disappointment has also led to large scale withdrawals from the study and has adversely affecting the trials' validity (Uchtenhagen 1994 cited in (Hartnoll et al. 1980; Schellings et al. 1999).

These examples demonstrate that the use of a conventional design can mean some trials produce misleading results. Other factors also influence the results, particularly the extent to which they can be generalised to a larger population. The next section will discuss selection bias, which can mean an unrepresentative sample is recruited.

3.2.1 Factors that influence recruiting a representative sample

The system of recruitment-consent-randomisation followed in conventional designs appears to be objective. In reality, objectivity may not always occur and selection bias may result. Personal experience suggests that clinicians (midwives, nurses and doctors) sometimes make personal or professional judgements about which women the researcher can access for recruitment and consent. An inability to speak English,

perceived low intelligence and social or emotional problems may be used as spurious reasons to keep potential participants away from researchers. Clinicians might also have their own opinions on the merits of the research. This may mean that they are reluctant for 'their' patients to be included and deny women the capacity to decide on participation for themselves.

Busy, understaffed outpatient or antenatal clinics may also contribute to selection bias as the potential sample is reduced. Clinicians may lack the time to refer women to researchers. The sense of anxiety that is often felt in these busy areas means the pressure to move people through the system, without further delay, is high. These processes are usually subtle and clinicians and researchers may be unaware they are occurring. Nonetheless, they may mean women are removed from the sample.

Personal experience suggests that researchers can also make idiosyncratic judgements about which women are approached, contributing to selection bias. Certain types of people, for example, English speaking women who are articulate, friendly or affable may be perceived by the researcher as being more likely to participate and therefore are more likely to be approached. Frequent refusal is an unpleasant experience. Researchers recruiting may therefore be more inclined to approach those are likely to participate.

Socio-economic status also influences recruitment and participation. Zelen (1979) suggests that researchers more often approach people from high and low socio-economic groups than people from the middle ranges of socio-economic status. Zelen (1979) suggested that people of high socio-economic status are more likely to be approached because their clinicians believe they will understand the research and give consent. In contrast, people of low socio-economic status are often approached as it is felt that they will leave the decision up to the doctor. This phenomenon will affect the characteristics of the eventual sample.

The type of trial also seems to influence the type of participants who are recruited. People who consent to large prevention trials seem to be better educated, from a higher socio-economic strata, married, employed and greater users of preventative care and other medical services (Hunninghake 1987; Hunninghake et al. 1987). On the other hand, more privileged and better educated individuals are discouraged from participating in some treatment trials (Thong & Harth 1991). This means a person's

characteristics influence their likelihood of being recruited. The generalisability of results from such trials may therefore be questionable unless recruiting protocols are rigorous.

The factors identified in this previous section may bias results in a randomised controlled trial. The Zelen design may be able to reduce some of the biases related to use of the conventional progression of consent-randomisation. The Zelen design is discussed in the next section.

3.3 The Zelen design

In a Zelen design, participants are identified and random allocation takes place before consent is sought for the intervention. There are two versions of the Zelen design: 'single consent' and 'double consent' (Zelen 1979; Zelen 1990). In the single consent version, participants allocated to the control arm are not asked for consent – they receive standard treatment without mention of the trial. Participants allocated to the experimental arm are asked whether they consent to the new treatment. If they decline they receive the standard treatment. All randomly allocated participants are included in the analysis, whether they consented or not (Figure 3.2).

Figure 3.2: The progression of participants using a single consent Zelen design.
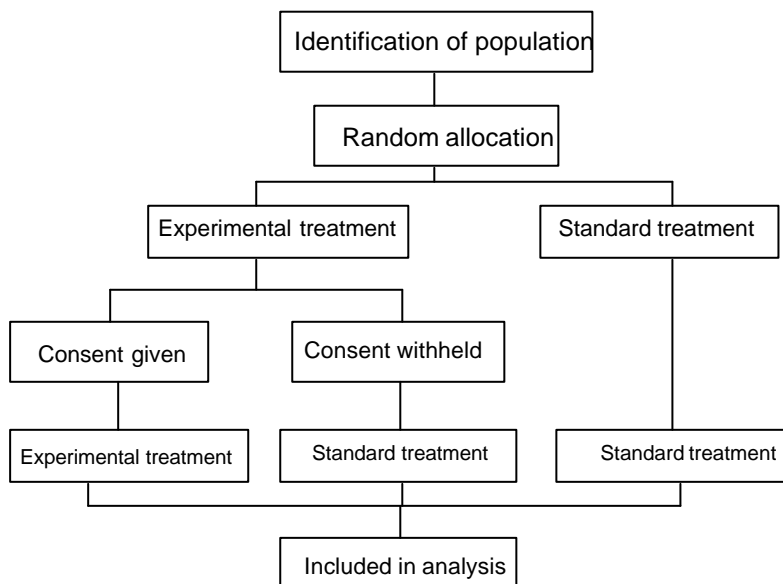
The double consent version differs as participants allocated to the control arm are asked for their consent to the standard treatment and those who decline may receive the experimental (or some other) treatment. Participants allocated to the experimental arm are asked whether they consent to the new treatment. If they decline they receive the standard treatment as in the single consent version (Figure 3.3).

Figure 3.3: The progression of participants using a double consent Zelen design.
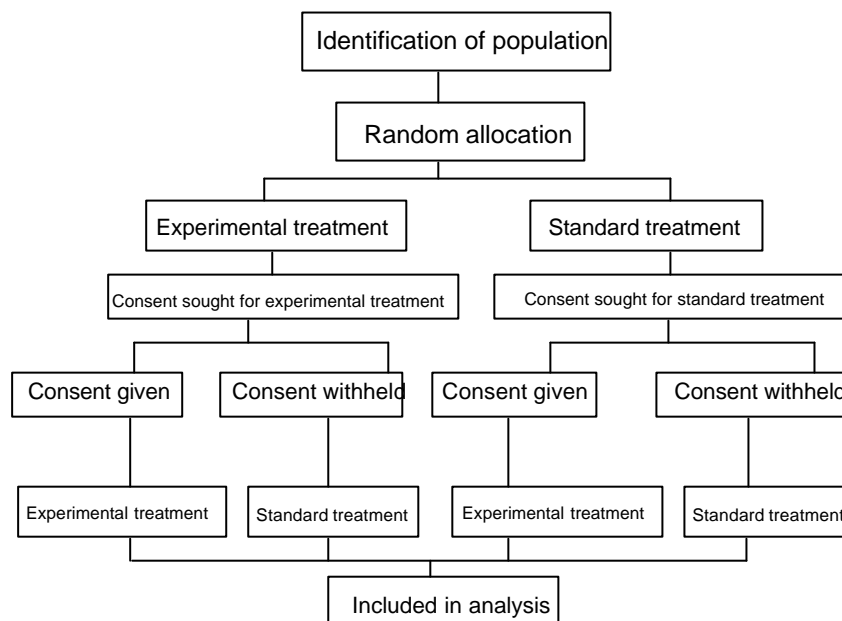
The single consent version is suitable when the experimental treatment is only available within the confines of the trial and is being compared to standard care. The double consent version is suitable when the experimental treatment is available outside the trial, or when two 'standard' treatments are compared.

Both versions are 'unblinded' as the clinician and researchers know who is to be approached for consent. An assessment of outcome can however be made blind to allocation.

3.4 Use of a Zelen design

The Zelen design appears to have been used infrequently since it was first proposed more than 20 years ago. Only a few trials are reported in the literature. Most have been in the field of cancer (Fisher et al. 1985; Moertel et al. 1984), with a few examples from

neonatalology (Bartlett et al. 1985; O'Rourke et al. 1989) and osteoarthritis (Chang et al. 1990).

Two trials of continuity of midwifery care have also used the Zelen design (Flint et al 1989; MacVicar et al 1993). Flint et al (Flint et al 1989) randomly allocated women after their first visit to either standard hospital care or being offered a new model of care. It is unclear why the Zelen design was chosen but this was presumably to reduce disappointment bias. It is possible however that a selection bias still occurred in this study, as women were randomly allocated after they had attended for their first visit and women who were 'subjectively' viewed as being unlikely to participate or consent might have not been included in the random allocation process. In the other trial of continuity of midwifery care, MacVicar et al (MacVicar et al 1993) used the Zelen design to reduce disappointment bias. Women were selected for the sample only after a consultant obstetrician had seen them. It is not clear whether it was this obstetrician who made the final decision about which women to randomly allocate, but again it is possible that selection bias played a role in the selection of the sample.

Two trials of continuous support during labour have used the Zelen design (Cogan & Spinnato 1988; Hemminki et al. 1990) to reduce the control group's sense of disappointment and knowledge of, and desire for, the intervention. The design has also been used in two small studies of extracorporeal membrane oxygenation in newborns babies (Bartlett et al 1985; O'Rourke et al 1989). It was thought to be unethical in these studies to discuss a potentially life saving treatment with parents and then withhold because the subsequent allocation was to the control group.

A more recent trial used the Zelen design to test the physical, social and psychological effect of contact with a stroke family care worker (Dennis et al. 1997). Participants were randomly allocated prior to consent. Those allocated to the intervention group were approached and asked to consent to follow up. Dennis (Dennis 1997) justified use of the Zelen design, writing "detailed knowledge of the trial and its exact purposes are likely to bias or influence results. Thus, responses may reflect a control subject's disappointment or dissatisfaction with not receiving a potentially beneficial treatment or a treated patient's appreciation or loyalty to those providing the treatment" (p. 1077).

The Zelen design is clearly advantageous in some research, as it seems to reduce the sense of disappointment that participants allocated to the control group express. Other advantages are also outlined in the following section.

3.5 Advantages of a Zelen design

Zelen designs have been found to be advantageous in trials that have compared operations for breast cancer where conventional designs are unpopular with participants and clinicians (Zelen 1990). In surgical research, the design has been suggested as a means to overcome the difficulty recruiting participants who have a definite preference for one procedure over another (Stirrat et al. 1992). Proponents of heroin provision trials in The Netherlands have indicated that the Zelen design would be the best choice for their research as it would result in less disappointment bias, fewer dropouts and would lead to more reliable results being obtained (Schellings et al 1999). Schellings et al (1999) suggest that the design has wider applicability, particularly when the experimental intervention is highly attractive to potential participants and when the control group receive standard treatment.

In a conventional design, participants have a 50 per cent chance (in a one-to-one ratio) of being able to receive the intervention. In a Zelen design, when participants who have been randomly allocated to the intervention group are approached for consent, they know that they can receive the new treatment. Zelen (1979) suggests that his design is advantageous for the participant, as they know which treatment will be given before providing consent. The consent process is simplified and there is a greater likelihood of the participants having a better understanding of the intervention to which they are consenting. Researchers may be more certain that the participant is giving informed consent to the intervention. Knowing the intervention to which participants are randomly allocated to receive may also ease both information giving and decision making processes for the clinician and participant and may not compromise the patient-physician relationship.

The Zelen design may also improve rates of accrual in trials in which recruitment is difficult, as the design is weighted to include those who might otherwise have refused (Snowden et al 1998). In conventional trials, all <u>consenting</u> participants are included in an intention to treat analysis, whereas, in a Zelen design, all <u>randomly allocated</u> participants are included. The post-randomisation loss in conventional designs when

participants withdraw because they are allocated to the arm that they least desire, is another aspect that may be reduced with the Zelen design (Zelen 1992).

There may be an apparent loss of efficiency due to the expected refusal of a proportion of participants (for example, if 90 per cent of participants accept treatment, 81 participants would be needed in a conventional design as compared to 100 in a Zelen design). Zelen (1979) argues that "this loss in efficiency may be illusory" (p.1244). Usually, only a proportion of eligible patients in an institution are approached and asked to participate in a trial. Using a Zelen design, more patients can be entered into the trial as face-to-face approaches and selection bias does not influence recruitment. The Zelen design may mean efficiency is improved over a conventional design.

3.6 Criticisms of the Zelen design

The main criticisms of the Zelen design include its potential loss of statistical power, ethical concerns with the consent-randomisation process and the collection of clinical data.

3.6.1 Loss of statistical power

Some researchers reject the Zelen design claiming that, in general, a number of randomly allocated participants will refuse the intervention resulting in incompatibility of the groups (Anbar 1983; Ellenberg 1984; Matts & McHugh 1987). A loss of statistical power may also occur if a large proportion of participants randomly allocated to the intervention group decline to participate. It has been estimated that if the overall refusal rate is greater than 15 per cent, twice the number of patients will have to be recruited (Ellenberg 1984). If the intervention is attractive or desirable, it is likely that this dilution effect will be minimal, as only a small proportion of participants will decline. For example, low refusal rates were seen in the trials of continuous support in labour and continuity of midwifery care (Cogan & Spinnato 1988; Flint et al 1989; Hemminki et al 1990; MacVicar et al 1993).

3.6.2 The process of obtaining informed consent

The main reason for the rejection of the Zelen design appears to be because consent is not given for randomisation (Ellenberg 1992; Marquis & Huston 1994). In most research using a Zelen design consent is obtained post-randomisation.

Chapter 3: The Zelen design

Informed consent has promoted much controversy in recent years, particularly in the *BMJ* in response to the trial conducted by Dennis et al (Dennis et al 1997) which was described in section 3.4 (page 47). McLean (McLean 1997) cautioned against Zelen designs because of the risk of embarking down the 'slippery slope' away from one of the fundamental ethical principles, that being, respect for persons. McLean (1997) agreed while that no harm had come to the participants in the Dennis et al trial (Dennis et al 1997), their agreement had been based on partial rather than full information and she felt that it was a dangerous to believe that this was adequate. McLean (McLean 1997) also indicated that if certain types of research could not fulfill unequivocal scientific standards, it is doubtful whether they should be done in the first place. Taking this argument and applying it to trials of new models of maternity care, it would mean that trials to test satisfaction should be abandoned because the results achieved in a conventional trial will never be clear. Dennis (Dennis 1997) questions whether it is ethical to randomly allocate patients into trials, which because of a methodological weakness cannot provide an answer to the main question (p.1077).

In contrast, it has been suggested that fully informed consent for randomisation can be 'needlessly cruel' for potential trial participants (Tobias & Souhami 1993). Tobias and Souhami (1993) who describe themselves as being committed to the value of clinical trials, believe that the process of obtaining consent is traumatic for patients at a time when sensitivity is paramount. They feel that the process can damage the patient's trust in their relationship with their doctor and patients end up being more confused and uncertain about the best decision. This can lead to low recruitment and high dropout rates among participants who have given consent and are subsequently randomly allocated to the control group.

It is likely that participants are better informed when consent is sought as in a Zelen design. Participants are 100 per cent certain of the treatment they will receive in a Zelen design rather being 50 per cent certain in a conventional design.

3.6.3 Collection of clinical data

The collection of clinical data from participants who decline to take part in the trial has also been reported as a concern with use of the Zelen design (Snowden et al 1998).

Clinical data are widely collected in health care institutions for review and quality control purposes. Data are also routinely forwarded to health departments and disease

registries to enable state and national reporting of health outcomes. For example, the annual report *NSW Mothers and Babies* (NSW Health Department 1998a; NSW Health Department 1998b) is based on data forwarded (without consent of the women involved) by midwives to the NSW Health Department. Data from these state reports is used to compile the national report, *Australia's Mothers and Babies* (Day et al. 1999b; Day et al 1999a). All these reports are widely utilised to assess maternity services and health outcomes and planning new services, however, none of the 250 000 Australian women were asked for their consent for the collection and distribution of this information. One might suggest that these women were actually involved in an ongoing trial, that is, a trial of the effectiveness of Australian maternity service provision.

The Australian Council on Health Standards (Australian Council on Health Standards 1997) also relies on data forwarded by institutions in order to develop and revise standards for gynaecological and obstetric care. These data are forwarded without the consent of the women involved. Collection of data and personal information is not confined to maternity care. The NSW Pap Smear registry receives information on all women who have a papanicolaou smear sample sent to a pathology laboratory. Women can choose to have their name removed from the registry, but only after it has been entered. Mandatory notification to the health department of certain infectious diseases is also performed without specific consent. For example, in Australia, new cases of human immunodeficiency virus and acquired immunodeficiency syndrome are reported to a national centre and a report containing non-identifying details including age, gender and mode of transmission is released quarterly.

Many hospitals worldwide collect data on medical history and clinical outcomes on what is known as an obstetric database. Women are not asked permission for this collection. These data are mostly used for quality control purposes and peer-review audits within maternity units. Maternity units that do not collect this information would be seen as having quality assurance practices below acceptable standards.

3.7 A Zelen design instead of a conventional design

The process of choosing of the most appropriate design has been addressed in research that was conducted in the UK as a part of the Extra Corporeal Membrane Oxygenation (ECMO) trial in severely ill neonates in the mid-1990's (UK Collaborative Trial Group 1996). This trial recruited mature newborns with acute and potentially

irreversible respiratory failure and randomly allocated them to either ECMO, a form of respiratory support that had little unbiased evidence as to its efficacy, or to conventional management utilising ventilator support. Parents were asked to consent to this trial when they were very distressed and anxious and were given little time to make their decision. Results of the trial indicated that infants who received ECMO were more likely to survive than those who received conventional management.

A series of qualitative interviews with 37 parents of surviving infants some time later revealed startling confusion over the randomisation and consent process (Snowden et al. 1997). Many parents did not understand the nature of the trial, the process of random allocation or the need for this method of allocation.

The researchers had initially proposed a Zelen design, however this was rejected after discussions with consumer group representatives. It was felt that the potential non-disclosure in a Zelen design was unethical and that those who were not informed would feel upset or angry that they were unwitting participants in a clinical trial. It is possible that the use of a Zelen design would have reduced the confusion relating to the process around randomisation for these parents. Zelen (1979) suggested that presenting potential participants with only one option reduces the, often difficult, decision-making process and the anxiety associated with the process of random allocation. Allmark (Allmark 1999), a medical ethicist has suggested that the process of obtaining informed consent in the ECMO trial had the potential to cause harm, particularly by disappointing those who ended up in the control group. Others have argued that consent for a neonatal trial is not only difficult to obtain, it is unlikely to be fully informed because of the parents' distress and the immediacy of the decision (Mason 1997). An editorial in *The Lancet* suggested that the Zelen design may be appropriate in these neonatal trials (Anonymous 1995). The opposing view is that parents have the right to decide how much information they receive and should therefore be able to make their own decision about participation (Meren 1995).

Conscious of this ongoing debate about the potential usefulness of the Zelen design in the ECMO trial, Snowden et al (Snowden et al 1998) conducted an additional qualitative study with the parents of 25 infants from the original trial. This study asked parents how they would have reacted to a Zelen design. The parents were evenly divided in accepting or rejecting the design, however those who rejected the design were more

likely to be from the control group. It was apparent that Zelen randomisation would not necessarily minimize the stress for those who were allocated to the intervention group as the participants felt that they would still have to make an 'impossible' decision. Some parents saw Zelen randomisation as a kinder approach, whereas others felt that the gathering of information as a coping strategy and access to information as a right (Snowden et al 1998). It is possible that the results of this qualitative study might have been different if the parents were unaware of the results of the ECMO trial or if the results were reversed. It is possible that responses of the parents were mediated by the fact that ECMO infants were more likely to survive and that all parents interviewed were those of surviving infants.

3.8 The Zelen design in the STOMP study

The Zelen design was chosen for the STOMP study primarily to overcome the bias that exists when participants are disappointed with their allocated research group in the conventional consent-randomisation progression (Torgerson & Roland 1998). In the STOMP trial, disappointment bias was reduced, as women who were allocated to the control group were not already enthusiastic or committed to the new model of care. The design also ensured recruitment of a diverse range of participants as all women who were identified as being eligible to participate were enrolled. Random allocation to STOMP was also a means to equitably distribute access. Each STOMP team could only cater for 300 women per year, which meant that not all women would be able to have this model of care while only two teams were in place.

The 'single consent' version of the Zelen design was used in the STOMP study, although consent was sought from both groups. The intervention group was offered the STOMP model and the control group were asked to participate in a survey. Selection bias was reduced as women were identified as being eligible and randomly allocated before the researchers or clinicians had met them. This meant that conscious and subconscious judgements about who should be approached based on appearance, convenience, language spoken, socio-economic background, level of education and researcher-driven reasons were largely removed. During the recruitment phase of the STOMP study, a dedicated research midwife attended each antenatal clinic to discuss the study with women who had been randomly allocated to a group, answer questions

and to conduct the process of obtaining informed consent from women who agreed to participate.

Serious consideration was given to the impact that the choice of design would have on participants, clinicians, researchers, the ethics committee and potential publishers of the study. We were confident that we would have a high acceptance rate from women as had occurred in earlier trials using this design. Refusal rates of eight (MacVicar et al 1993) and nine (Flint et al 1989) per cent have been previously reported. The ethical considerations and the intention to 'above all, do no harm' were paramount in the decision. In retrospect, we do not see that there was another way of ensuring that selection and disappointment bias did not arise and do not believe that, in using the Zelen design, the care of women receiving standard care in the study was adversely affected.

Clinical data were collected on all women as this was normal practice at the hospital. Clinical data are routinely collected on all women who attend the hospital for care during pregnancy, labour and birth and the postnatal period. This information is used in the maternity unit's standard quality review process and as a means to report, as required by the NSW Health Department, to the Australian Council for Health Standards. Any change in models of care or type of intervention are closely monitored through this data collection process. All identifying information is removed. In the STOMP study, the identifying information was only available to the researchers and women's names were not stored with their data.

The study was submitted to the Institutional Ethics Committee in the South Eastern Area Health Service in December 1996 and was approved with only one minor alteration (each page of the consent form had to be on hospital letterhead paper). There were no concerns voiced by the committee at that time or any other period during the conduct of the trial. In December 1997, Australia's NHMRC awarded the research group a large three year grant under a scheme known as the *Centres of Clinical Excellence in Hospital-based Research*. The 'flagship' of this grant application was the STOMP trial and, again, there was no question about the ethics or merits of such a trial.

In December 1999, my colleagues and I submitted the first paper from the STOMP study to the *British Medical Journal.* The paper was titled "Collaboration in maternity care: a randomised controlled trial comparing community-based continuity of care with

standard hospital care" and reported the clinical outcomes (Chapter 5 in this thesis). Despite very favourable reports from the blind review process, particularly in relation to the use of the randomised consent design with one reviewer writing "I support the author's choice of this [Zelen] methodology", the paper was rejected. The main reason cited by the Editorial Committee was the choice of design with their letter stating "some members of the committee were doubtful about how ethical a Zelen design was". No methodological problems were raised that would affect the validity or reliability of the findings. Clearly, the debate on the Zelen design continues.

3.9 Summary

This chapter has discussed the reasons for the use of the Zelen design in the STOMP study and the advantages and disadvantages of the design. The Zelen design was chosen as it provided the best means to reduce selection and disappointment bias. The ethical issues, including informed consent, were given due consideration during the planning and conduct of the study.

There is considerable controversy over the Zelen design within the medical literature. Controversy, nonetheless, is healthy and necessary. Dilemmas of this nature remain open for interpretation and continued debate is required between researchers who select and use such designs as Zelen's and those who review and critique such studies.

The next chapter describes the methods that were used in the STOMP study, including the setting, sample size calculation, outcome measures and data collection strategies. The methods used to recruit a linguistically diverse and representative sample are also discussed.

Chapter 4 Methods

4.1 Introduction

This chapter describes: the setting for the study; the enrolment; randomisation and consent procedures; the outcome measures and, methods of data collection. A general overview of the analysis is presented. More detailed and specific descriptions of the analyses are supplied in each of the subsequent chapters (5-9) which present the results of the study.

4.2 Study population

4.2.1 The setting

St George Hospital is a NSW public hospital situated in metropolitan Sydney and located within South East Health. The hospital has approximately 500 beds and provides a wide range of services including women's and children's health, accident and emergency, cancer care and intensive care. St George Hospital is a teaching hospital of the University of NSW and the University of Technology, Sydney.

The Division of Women's and Children's Health at St George Hospital provides an integrated obstetric and midwifery service. The standard care options offered by the Division have been outlined in Chapter 2 (section 2.2). In addition, a day assessment unit is used to monitor women with high-risk pregnancies as outpatients. 'Preparation for Parenthood' classes are also available at a small cost. The Division is responsible for the education and training of student midwives, medical students, resident medical officers and obstetric registrars.

A total of 2 642 infants were born at the hospital in 1996. Of these, 2 314 (88%) were in the delivery suite and 328 (12%) in the birth centre. The average length of stay was 3.6 days with a bed occupancy of 87 per cent (NSW Health Department 1998b).

A culturally diverse area

South East Health extends from Sydney Harbour in the north, through Botany Bay and Port Hacking to the Royal National Park in the south (approximately 45 kilometers from the city centre). It has a resident population of 755 661 that represents 11 per cent of

the population of NSW. Commuters to the city, universities, beaches and industrial sites expand the population of South East Health to more than 1 000 000 people per day.

Women born in China or Hong Kong (4.8%) and Lebanon (3.1%) made up the largest groups of non-English speaking women who gave birth in South East Health during 1996 (Nivison-Smith 1998). These proportions were higher in the St George District. Arabic and Cantonese/Mandarin were identified as the main language groups of women using maternity services at St George Hospital (Everitt et al 1995).

Definition of cultural groups

Race, ethnicity and culture are terms that are the source of ongoing debate in professional and lay literature. Culture is difficult to measure and describe as there are many intervening variables, including language, religion and diet (Anonymous 1996). Some studies have used self-identity (Hickey et al. 1991) or questions about country of birth (NSW Health Department 1998a) to establish cultural identity. Epidemiological studies have usually used crude categories, for example, 'white'; 'African-Caribbean' and Asian' groups (Douglas 1998). Acculturation of migrant communities has meant culture varies depending upon the process through which immigrants and their children acquire the values, behaviours and attitudes of their new country (Rissel 1997).

In the STOMP study, 'language spoken at home' was chosen to categorise women. Cantonese and Mandarin speaking women were categorised as Chinese-speaking. Chinese-speaking countries of birth included China, Hong Kong and Taiwan. Arabic-speaking countries included Lebanon, Iran and Afghanistan. There were women who did not belong to any of these categories. These were classified as 'other' language speakers. The most frequent languages identified in the 'other' category were Macedonian and Vietnamese.

4.2.2 Catchment areas for STOMP

An examination of the residential postcodes of women who delivered at the hospital in 1996 showed that there were two main catchment areas: Rockdale and Hurstville. One STOMP team was assigned to each catchment area.

4.2.3 The participants

The study participants were non-insured women drawn from the population of women who lived in the catchment areas and 'booked into' St George Hospital for the birth of their babies.

4.2.4 Eligibility criteria

Women were considered eligible for the trial if they were less than 24 weeks gestation at their first visit, lived in one of the catchment areas and planned to have their baby in the delivery suite at the hospital. Exclusion criteria included the presence of significant maternal disease at booking (for example, renal disease with impaired renal function, essential hypertension or insulin dependent diabetes), two previous caesarean sections or a previous classical caesarean section. Women who developed medical complications after randomisation <u>were not</u> transferred from the STOMP group to standard care.

4.3 Design

The 'single consent' version of the Zelen design was used in the STOMP study. Consent was sought from both groups.

4.4 Power and sample size projection

The study sought to examine a number of outcomes related to physical, psychosocial and emotional aspects of care. A detailed description of the outcome measures is presented later in this chapter (page 70).

The sample size calculation used a number of primary variables that are important in the measurement of maternal health. These variables are commonly used in state and national reports of the outcomes of maternity care in Australia (Day et al 1999a; NSW Health 2000). The change that may be clinically beneficial and the sample size required to demonstrate such a change, with 80% power and 95% confidence, are presented in Table 4.1.

Table 4.1: The sample size required to detect significant differences in selected clinical variables.

Clinical variable	Estimated rate for control group	Difference to detect	Required sample size
Episiotomy rate	20%	Decrease to 10%	438
Epidural rate	26%	Decrease to 16%	558
Augmentation of labour rate	30%	Decrease to 20%	626
Normal vaginal delivery rate	65%	Increase to 75%	792
Caesarean section rate	10%	Decrease to 5%	948

The sample size was calculated with 80% power and 95% confidence. The variables are those conventionally used in the assessment of maternity care.

A sample of 948 women was required to detect a 50 per cent reduction in the caesarean section rate. The sample size calculation used caesarean section rate as the primary outcome measure. Caesarean section rate is an important clinical outcome that is easy to measure. It also has significant physical and emotional implications for women and for the costs of providing maternity care. Chapter 5 provides a more detailed discussion of the implications of caesarean sections for women and for the health system.

The estimation of the caesarean section rate was based on previous research in the maternity unit which demonstrated an emergency caesarean section rate of four per cent in low risk women attending the birth centre (Homer et al 2000). We accepted that women would be less 'low risk' than this cohort and that elective caesarean sections would be included and therefore increased the caesarean section rate to 10 per cent. In hindsight, it is acknowledged that the estimated caesarean section rates were too low.

Additional women were recruited to the study to account for an anticipated 10 per cent attrition rate (first trimester miscarriage and transferring hospitals). As the delay between random allocation and consent was four to five weeks, this attrition is potentially higher than in other studies.

The sample size was confirmed on pragmatic grounds. The conduct of a study of this size and nature impacted on the whole maternity unit and we realized that the energy and enthusiasm necessary might be difficult to sustain in the long term. Two years was

seen as a reasonable time in which to conduct the study. It was determined (from data on the number of births in the catchment areas) that it would be possible to recruit 1000 women within this time.

The study had insufficient power to evaluate the effects of the new model of care on perinatal mortality. However, data could be aggregated in a subsequent meta-analysis to further understand the effects associated with continuity of care in a public sector maternity service.

4.5 Random allocation to STOMP or control group

Random allocation occurred prior to the woman's first hospital visit. A referral letter was sent from the woman's GP to the hospital in order to 'book in' at St George Hospital. This referral letter included information such as the woman's age, parity (the number of children the woman has had before), estimated date of confinement, past obstetric history and medical conditions. The referral letter was used to determine eligibility for inclusion in the study.

A clerk put aside the referral letters of women who lived in the two catchment areas. Two research midwives reviewed all the letters to determine eligibility and to register women in the study. A pre-prepared list was used to randomly allocate women between the STOMP and the control groups with equal probability. Two separate lists were used in order to stratify by parity. One list was for nulliparous women (those having their first baby) and one was for multiparous women (those having their second or subsequent baby).

A remote randomisation system was used to ensure concealment of allocation. The research midwife telephoned an administrative assistant, who was not associated with the study in any way, to register each woman. Allocation was not revealed until her details were recorded on the list. This removed the chance of bias in the order in which women were registered and allocated. Figure 4.1 illustrates the selection and allocation process.

Lists were stored in a locked cupboard and accessed only by the administrative assistants. The research midwives did not have access to these lists until the randomisation phase was complete. Randomisation took place between January 1997 and April 1998.

4.5.1 Group assignment

Eligible women were randomly allocated with equal chance to either the intervention group, that is, offered the opportunity to receive the STOMP model or the control group. The control group received standard care. Women randomly allocated to the control group were asked to participate in a 'satisfaction' survey.

4.5.2. Following allocation

Following allocation, all women were sent a letter, detailing the time and date of their first antenatal clinic appointment, known as the booking visit. Booking visits were usually four to five weeks following the letter, unless the woman was older than 35 years when she was seen earlier. The clerk who made the appointments for the booking visit kept a record of women who were in the STOMP study and notified the research midwives of women who changed, or did not attend, their booking visit. The clerk was also able to notify the researcher of women who miscarried or transferred to another hospital. This list of 'research' women was unavailable to the clinicians in the hospital.

Women allocated to the STOMP group were sent a letter and a pamphlet outlining the STOMP team prior to their booking visit. The letter and pamphlet were available in Chinese and Arabic.

Figure 4.1: Progression of women from receipt of referral letters to time of seeking consent at the booking visit.

```
                    ┌─────────────────────────────────────┐
                    │ Referral letters received by booking clerk │
                    └─────────────────────────────────────┘
         ┌──────────────────────────┐        ┌──────────────────────────┐
         │ Women who lived in catchment │      │ Women who lived out of catchment │
         │          areas            │        │          areas            │
         └──────────────────────────┘        └──────────────────────────┘
         ┌──────────────────────────┐
         │ Referral letters reviewed by research │
         │ midwives to determine eligibility │
         └──────────────────────────┘                     │
         ┌──────────────────────────┐        ┌──────────────────────────┐
         │ Telephoned administrative assistant │      │   Not included in study   │
         └──────────────────────────┘        └──────────────────────────┘
         ┌──────────────────────────┐
         │ Each eligible woman registered using │
         │   initials and date of birth │
         └──────────────────────────┘
              ┌──────────────────┐
              │ Random allocation │
              └──────────────────┘
         ┌────────┐          ┌────────┐
         │ STOMP  │          │ Control │
         └────────┘          └────────┘
     ┌────────────────┐   ┌────────────────┐
     │ Consent sought for │ │ Consent sought for │
     │   STOMP care    │   │      survey     │
     └────────────────┘   └────────────────┘
```

4.6 Recruitment

Research midwives attended every antenatal clinic through the recruitment phase of the study (February 1997 to May 1998) to seek consent from women in the study. The consultation with the research midwife took place before the woman had seen any midwives or doctors in the clinic. Consent forms were translated into Arabic and Chinese. The English version of the consent forms is found in Appendix 4 (page 240).

The Zelen design (Zelen 1979) meant that the new model was only explained and offered to women who were randomly allocated to the STOMP group. The new model was not compulsory and women were freely able to reject it and receive standard care. Eight-eight per cent of women (n=483) accepted the offer of STOMP care.

Women randomly allocated to the control group were offered the current standard care and were asked to participate in a study that was examining women's satisfaction with the care at the hospital. Standard care meant they could choose between the routine antenatal clinic, midwives clinic, birth centre or shared care with their GP. Ninety-four

per cent of women (n=507) agreed to participate in the survey. Two women from the control group erroneously received STOMP care. This was an unintentional protocol violation that occurred when the women were incorrectly offered the STOMP model in the final days of recruitment. These women were retained in the control group for the analysis.

Women from NESB were seen with a health care interpreter in attendance. Health care interpreters are widely used in Australia and are trained and accredited by the Australian National Association of Accredited Translators and Interpreters. Seventy-three per cent (n=134) of women from Chinese speaking, 39 per cent (n=68) from Arabic speaking and 14 per cent (n=30) from other NESBs required an interpreter.

The ethnic obstetric liaison midwives assisted by providing explanations about the study with Arabic and Chinese speaking women regardless of whether they required an interpreter or not. The Ethnic Obstetric Liaison Program was established in Sydney between 1990 and 1992 following a recommendation from the *Shearman Report* (NSW Health Department 1989). Two midwives (an Arabic and an Chinese speaker) filled the role at St George Hospital. Health care interpreters were utilised for women from other language groups. Involvement of the ethnic obstetric liaison midwives was done with caution, so that women did not feel pressured to participate in the study and the relationship between the midwife and woman was not disturbed.

4.6.1 Issues in recruitment and consent

Research midwives who recruited participants were very conscious of the dilemmas in the process of seeking informed consent. There was a methodological imperative to ensure as many women as possible consented to participate. This is because all clinical outcomes would be analysed on an intention to treat basis. This is, the analysis of the effect of the intervention was carried out regardless of the type of care ultimately received. The intention to treat analysis is described in more detail later in this chapter (page 81). The research midwives were also mindful of the importance of respecting a woman's choice and allowing her to make a non-pressured decision.

Some women may have consented because they believed this was what the hospital (or the research midwives) wanted them to do. It has been reported that potential participants feel pressured to participate in studies if they are in powerless, dependant positions, or if they feel they must please those who are responsible for their treatment

or care (Wilson 1989). We were conscious of this issue and created strategies to reduce this concern. For example, letters were sent to women allocated to the STOMP group prior to their booking visits, explaining the research and the new model. This gave women an opportunity to read about the STOMP model prior to being asked to participate. Information sheets and consent forms were available in the two most common languages (Arabic and Chinese). Women from NESBs were seen with a health care interpreter in attendance. Research midwives did not wear a hospital uniform. This was a strategy to reinforce that they were not part of the 'care' team. Throughout the consenting process, it was made explicit to the women that: the research midwives would not be caring for them; they should feel free to decline to participate; and, in doing so, future care would not be jeopardised. Once the research midwife had explained the study, women were given time alone to read the consent form, to discuss the study with their partner or significant others, before making their decision.

During the first six months of recruitment it became apparent that some women, particularly those from NESBs, were unaware of the role and function of a midwife in the Australian health care system. Women from mainland China were particularly concerned that midwives were 'untrained'. This meant that some Chinese-speaking women were reluctant to attend the STOMP clinic, as they were reluctant to receive care from people who they perceived as inexpert and unprofessional. We undertook a project with the local multicultural unit to help overcome this concern. An article titled "What is a midwife in Australia?" was written for the Better Health Column project, which is an educational initiative of the NSW Multicultural Health Communication Service. The article was translated into 18 community languages and distributed widely throughout the NSW Health Department and community facilities (NSW Health Department 1998c). After this exercise, it appeared that Chinese-speaking women were more accepting of midwifery care in the community.

4.6.1 Issues in obtaining consent

During the design and planning phase of the STOMP study, it was decided that women allocated to the control group would <u>not</u> be advised of the new model of care, nor that they had been allocated not to receive this model. When the research midwife approached the control women, they were informed that their names had been

randomly selected from a list of all women who lived in their area and that they were invited to participate in a study about their experience at the hospital.

On three occasions, women allocated to the control group requested the new model of care that they had learned about outside the hospital. One of these women, in the last weeks of recruitment, brought a newspaper clipping describing STOMP. Another woman's husband had heard of the new clinic, as it was situated close to their home, and was very keen for his wife to attend. The final woman was a 16 year old who wanted to go to the new clinic because her own mother had just received care through STOMP. These three cases challenged the research team and caused some anxiety. We had to decide whether each individual should be able to choose her model of care or whether the conduct of the study was the paramount consideration. In these three instances we attempted to ensure the women received the best available option without jeopardising the research. The women were informed of the random allocation process and the implications of altering this. Ultimately, all three chose to attend the midwives clinic where they would receive antenatal continuity of carer.

4.7 Sample

Between January 1997 and April 1998, 1 282 women were randomly allocated to two groups, 639 to the intervention group and 643 to the control group. As women were allocated four to five weeks prior to their booking visit, a number cancelled their bookings and did not attend. This was most commonly due to miscarriage or attendance at another hospital. There was no significant difference between the number of women lost from each group ($p=0.95$). The final sample comprised 1 089 women, 550 in the STOMP group and 539 in the control group (Figure 4.2).

Figure 4.2: Flow-chart describing progress of women in the study from eligibility through to acceptance of allocated group.

Registered or eligible participants
n=1 283

Random allocation

STOMP group (n=640) | Control group (n=643)

Removed from sample (n=90)
Reasons: miscarriage (n=44); moved to another area (n=46)

Removed from sample (n=104)
Reasons: miscarriage (n=62); moved to another area (n=42)

Final sample (n= 550) | Final sample (n=539)

Agreed to receive STOMP as allocated (n=483) 88%

Reasons for refusal: anxious about giving information (n=5); rather come to hospital-based clinic (n=39); not interested (n=11); wanted birth centre (n=12)

Agreed to participate in satisfaction survey as allocated (n=507) 94%

Reasons for refusal: anxious about giving information (n=9); not interested (n=23)

2 women received STOMP care

Data collected[a] (n=550) | Data collected[a] (n=539)

[a]Clinical outcome data were collected on all women in the final sample.

Consent rates for all language groups were high; 90 per cent of women from both Chinese and Arabic speaking backgrounds and 92 per cent of women from English speaking and other NESB backgrounds agreed to participate.

4.7.1 Demographic data

There were no statistically significant differences between the STOMP and control groups on all demographic variables measured at study entry. Women were of similar age, height, and weight and were of comparable gestation at their booking visit (Table 4.2).

Table 4.2: A comparison of age, height, weight and gestation at booking visit by allocated group.

	STOMP n=550 mean [SD]	Control n=539 mean [SD]	p
Age (years)	28.20 [5.4]	27.9 [5.2]	0.4
Height (cm)	162.5 [12.1]	163.3 [16.4]	0.4
Weight (kg)	61.5 [15.1]	61.1 [12.8]	0.7
Gestation at booking visit (weeks)	15.5 [3.7]	15.2 [3.6]	0.2

Differences between groups were compared using independent *t-tests*. Height and weight were not recorded for all women. Gestation at booking was not recorded for one woman in the control group.

STOMP and control women did not differ in their country of birth (Table 4.3).

Table 4.3: Country of birth by allocated group.

Country of birth	STOMP group n=550 Number (%)	Control group n=539 Number (%)	Total n=1 089 Number (%)
English speaking	258 (46.9)	259 (48.1)	517 (47.5)
Chinese speaking	90 (16.4)	93 (17.3)	183 (16.8)
Arabic speaking	86 (15.6)	88 (16.3)	174 (16.0)
Other NES	116 (21.1)	99 (18.4)	215 (19.7)
Total	550 (100.0)	539 (100.0)	1 089 (100.0)

A chi-squared test was performed to examine differences between allocated groups: χ^2 (3)= 1.3, p=0.7

Primary language spoken at home was the means by which women's linguistic diversity was categorised as it was the most useful method to describe the language needs of the women. There were no differences between the STOMP and control group (Table 4.4).

Table 4.4: Language spoken at home by allocated group.

Language spoken at home	STOMP group n=550 Number (%)	Control group n=539 Number (%)	Total n=1 089 number (%)
English	332 (60.4)	314 (58.3)	646 (59.3)
Chinese	87 (15.8)	93 (17.3)	180 (16.5)
Arabic	85 (15.5)	75 (13.9)	160 (14.7)
Other	46 (8.4)	57 (10.6)	103 (9.5)
Total	550 (100.0)	539 (100.0)	1 089 (100.0)

A chi-squared test was performed to examine differences between allocated groups : $\chi^2(3)=2.3$, p=0.5

More than one fifth of the women in each group (21% in STOMP; 22% in control) required an interpreter for their care.

4.7.2 A representative sample

The population from which the STOMP sample was drawn had a high proportion of women for whom English was not their first language. This was discussed in Chapter 1 (sub-section 1.3.2). Country of birth for all women from similar residential areas, who gave birth at the hospital during the same time period, was compared to the women in the STOMP sample to assess the representativeness of the sample. It was not possible to compare the variable used most frequently in this study 'language spoken at home', as this data was unavailable for the hospital population. The comparison of country of birth is displayed in Figure 4.2 and confirms that the intention to proportionally represent cultural diversity across the population sample was successful.

Figure 4.3: Country of birth for the STOMP sample compared with all women who attended the hospital during the same time period.
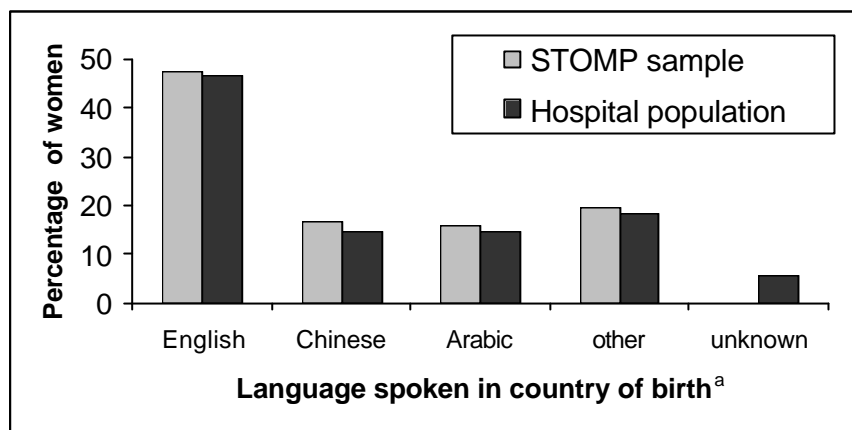
[a]Language spoken at home was not available for the hospital sample so language spoken in country of birth was used. The hospital population was obtained from admission records of all women confined during the same time period as the STOMP sample.

4.8 Choice of outcome measures

The study sought to answer questions relating to a range of clinical outcomes and experiences of women. The same outcome measures were collected on all women in the study.

4.8.1 Clinical outcomes

Outcome measures were chosen for their ability to reflect safety and efficacy in maternity care. Caesarean section rate was chosen as the primary outcome measure as it has notable implications for women and for the cost of health care services. Several studies suggest the caesarean section rate may be reduced with continuity of care and supportive midwifery care in labour (Butler et al 1993; Harvey et al 1996; Rowley et al 1995). Caesarean section rate is also a readily and accurately measured outcome variable.

Other clinical outcomes, for example, onset of labour, mode of delivery, perineal trauma, postnatal complications and readmission to hospital were also collected. These are standard measures of excellence and are used widely by the Australian Council on Health Standards as clinical standards in Australian health care (Australian Council on Health Standards 1997). Neonatal outcomes included admission to special care nursery

(SCN), birth weight and Apgar scores. Apgar scores are a numerical set of criteria for assessing the well being of the baby one and five minutes after birth. The score ranges from 0 to 10 (10 being perfect).

Obstetric intervention during labour and birth was calculated through an audit of the women's medical records using the *Obstetric Procedure Score* devised by Elliot et al (Elliot et al. 1984) and subsequently used by Brown and Lumley (Brown & Lumley 1998). This score takes into account the procedures that occur during labour and birth, with higher scores assigned to more complex interventions such as epidural anaesthesia and caesarean section.

The research team developed a number of questions relating to breastfeeding. Infant feeding in the culturally diverse Australian society is poorly understood (Manderson 1999); (Yelland et al. 1997). Therefore, this study was an opportunity to understand more about breastfeeding intention, initiation and duration. Breastfeeding intention was measured at the first antenatal visit. The midwife conducting the booking visit asked women how they planned to feed their baby. Method of infant feeding on discharge from hospital and at eight weeks was categorised as either breastfeeding (including exclusive and partial breastfeeding) or artificially feeding (formula).

4.8.2 Women's experiences

Data on women's experiences were collected antenatally and postnatally through self-administered questionnaires (Appendix 7: page 260 and Appendix 8: page 269). The questionnaires were translated into Chinese and Arabic. Women in the STOMP and control groups received the same questionnaire.

Translation services were expensive. We were only able to afford Chinese and Arabic translations. The Australian National Association of Accredited Translators and Interpreters completed the translations. The written script for Cantonese and Mandarin is the same, so only one translation was necessary for Chinese-speaking women. Arabic translations posed greater challenges. The subtle nuances of Arabic meant that the gender of the reader and their region of origin slightly altered the interpretation. In some instances, the text was deemed to be offensive to some and inoffensive to others. For example, women from southern Lebanon interpreted some questions differently to those from the north. To help overcome this limitation, a range of bilingual health

workers read all questionnaires and a consensus of what would be acceptable to <u>most</u> women was reached.

The translation of women's responses to open-ended questions into English for analysis was challenging. Accredited translators assisted with this process, however the script or characters used by some women were difficult to translate. For example, some Chinese speaking women wrote in what is known as an 'abbreviated' style of written text. This style is commonly used in Hong Kong and is a shortened version of the more formal characters.

Other pragmatic issues were addressed to ensure that women from NESB were able to complete questionnaires easily. For example, as the text flow for Arabic is from right to left, questionnaires needed to be stapled in the upper right hand corner as opposed to the upper left as was the case with the English and Chinese questionnaires.

Antenatal questionnaire

The antenatal questionnaire was adapted, with permission, from similar questionnaires used in the *Antenatal Care Project* (Sikorski et al 1996), from *Great Expectations* (Green et al. 1988) and the previous Australian studies of team midwifery (Kenny et al 1994; Rowley et al 1995).

The questionnaire included questions about the type of antenatal care, ease of access to visits, waiting time, number of midwives and doctors seen in the clinic and choice of antenatal care in a subsequent pregnancy. These questions were chosen to examine differences in access, equity and perception of antenatal care between the groups. Questions were also asked that related to information sharing and the level of advice and support received from midwives and doctors. Other studies have suggested that continuity of midwifery care leads to greater preparedness for birth and early parenting (Flint et al 1989; McCourt et al 1998), increased satisfaction with psychological aspects of care (Waldenström & Nilsson 1993), and higher participation in decision making (Rowley et al 1995; Turnbull et al 1996). Questions were used to assess whether these occurred with the STOMP model.

The *Cambridge Worry Scale* was also included (Green et al 1988; Green et al. 1993; Stratham et al. 1997). The *Cambridge Worry Scale* examines women's concerns and fears related to pregnancy, health, relationships and socioeconomic issues. Women

were asked to score each item on a scale from 0 (not a worry) to 5 (extremely worried). Six statements related to the baby, seven items to the pregnancy, labour and birth and three about general social concerns. This scale has not been validated for use in Chinese or Arabic-speaking populations.

The Edinburgh Postnatal Depression Scale (EDPS) (Cox et al. 1987) was included to assess any possible impact on women's psychological well being and level of unhappiness or depression. This EDPS was used in two ways: firstly as a screening measure for depression; and, secondly, as a continuous measure of unhappiness. The screening cut-off for potential antenatal depression was 14.5 as recommended by Pope et al (Pope et al. 1999) in a systematic review for the NHMRC in Australia.

Finally, a section at the end of the questionnaire gave women the opportunity to write "anything (good or bad) about your antenatal care or anything else you would like us to know". It was hoped that this qualitative data would reveal additional aspects of the antenatal experience of the women.

The antenatal questionnaire was pilot tested with 10 women in the antenatal clinic. These were women who were not involved in the study. Most of these women took between 10 and 15 minutes to complete the questionnaire and their comments about improving the content and clarity were included in the final questionnaire. For final distribution, the antenatal questionnaires were printed on coloured paper, as this is believed to improve response rates (Allen et al. 1996).

Postnatal questionnaire

The postnatal questionnaire was again adapted, with permission, from the *Antenatal Care Project* (Sikorski et al 1996), *Great Expectations* (Green et al 1988) and the previous Australian studies (Kenny et al 1994; Rowley et al 1995).

Questions asked about the amount of information women felt they had been given before the birth and whether they had an opportunity in the antenatal period to discuss their preferences for the management of labour and birth (Sikorski et al 1996). They were also asked if they would have liked more time to discuss their preferences. Answers to these questions were captured by a categorical response. Women were then asked whether the amount of information they received antenatally on eight topics was adequate. The topics included: pain relief in labour; induction; complications during

labour; infant feeding; and, care of the new baby. Women rated each of the eight items as either "I knew enough" or "I would have liked to know more". The overall score (treated as a continuous variable) reflected the women's 'need for more knowledge'.

Two questions related to the woman's sense of personal control during labour. One asked whether she 'felt in control of what was being done to her' and the other, whether she 'felt in control of the way she managed herself' (Sikorski et al 1996). These two questions used a Likert scale and were combined to form a 'sense of control' score. These were included to test the STOMP model's impact on women's sense of control. Previous research has shown that women who have a strong sense of personal control felt more satisfied with their birth experience (Green et al 1998a).

Questions relating to continuity of care and carer were included as uncertainty remains about the importance of continuity of carer in labour as discussed in Chapter 2 (page 23). These questions were included to develop a greater understanding of continuity of care and carer, especially in a public hospital setting with a team of six midwives. Asking women whether they had a 'known' midwife in labour assessed continuity of <u>carer</u>. Women who answered in the affirmative were then asked whether a known midwife 'made a difference'. Women who did not have a known midwife in labour were asked whether they 'would have liked to have had a known midwife'.

Women were asked to rate their experience of childbirth using a scale from one to ten (Green et al 1988). The clarification for this question was: "ten out of ten would mean an absolutely wonderful experience that could not have been better, zero out of ten would mean a thoroughly unsatisfactory experience with nothing good to be said for it".

A shorter version of Cambridge Worry Scale, as used in the *Antenatal Care Project* (Sikorski et al 1996), and the EDPS (Cox et al 1987) was included. The cut-off score of 12.5 for the EDPS was used as suggested by Cox (Cox et al 1987) and validated in Australian research (Boyce et al. 1993). The EDPS was also used as continuous measure of unhappiness. This scale has been validated for use in Chinese and Arabic-speaking populations.

Three questions regarding breastfeeding duration were included in the questionnaire. Women were asked whether they had breastfed their baby. The three possible responses were either: no, not at all; yes, but now I have completely stopped; or, yes, and I am still breastfeeding. Women who had initiated breastfeeding, but have since

weaned, were asked when this had occurred. Women who had weaned were asked to describe the reasons for this decision.

An open ended section at the end of the questionnaire invited women to write make "any comments (good or bad) about your maternity care, your childbirth experiences or anything else you would like us to know".

The emotional impact of completing such a questionnaire, particularly during a potentially vulnerable period, concerned the research team. We were concerned that if a woman was depressed or distressed, and this was apparent on their returned questionnaire, we would have no ethically sound method in which to contact her and ensure appropriate follow-up services were in place. We were committed to preserving the confidentiality that we had assured women, but were also concerned with the clinical ramifications of being unable to act in the instance of a profoundly depressed woman returning a questionnaire which clearly illustrated her distress. As a compromise, in the final section of the questionnaire, the following paragraph was included:

> "New parenthood can be a stressful time as well as a rewarding time. If any of these questions has made you feel sad or depressed or worried, please talk to your early childhood nurse or your doctor. They will be happy to help you talk about your concerns or may be able to help in other ways. If you prefer, we can arrange for someone from the hospital or your nearest early childhood centre to contact you. This will be completely confidential. Would you like someone to contact you?" (the woman could indicate that this was required and leave her telephone number)

When women answered 'yes' to this question, they were contacted by the researcher, usually within 24 hours. When necessary, the health care interpreter service assisted the researcher to contact women from NESB.

Twenty women from the STOMP group (6.3%) and 19 women from the control group (6.3%) requested a telephone call and all were contacted by the researcher.

Five postnatal women, who were not involved in the study, reviewed the postnatal questionnaire for understanding, logical sequencing and clarity. Their comments on improvement were included in the final revisions. The questionnaires were also printed on coloured paper as had occurred for the antenatal questionnaires.

4.9 Data collection

Data collection commenced in June 1997 and continued until April 1999.

4.9.1 Clinical data

Clinical outcomes were collected by auditing the medical records of women. A data collection sheet (see Appendix 5) was developed to collect information on the variables of interest. The data collection sheet was pilot tested with 50 records and adjusted to ensure that the sequence was correct and the data were available and readily collectable from the audit of medical records. The research midwives attended the medical records department to collect data. The author of this dissertation collected the majority of the clinical data (88%).

Data were extracted from the range of documents stored within the woman's medical record including the 'booking' history, antenatal care record, midwifery and medical notes during labour, birth and the postnatal period, ultrasound reports and cardiotocograph recordings. The medical records of neonates were reviewed only if the baby was admitted to the SCN.

The number and type of caregivers was also taken from the medical records. The number of antenatal visits was ascertained from the antenatal card of both groups. Staff signatures were examined to determine the number of different midwives and doctors each woman had seen during antenatal care. Initiation of breastfeeding and infant feeding on discharge was obtained from women's medical records.

Availability of records

Clinical data was collected for all 1 089 women. Medical records were unavailable for only seven women, one from the STOMP group and six from the control group (0.7% of the final sample). Despite numerous searches by the medical records department and the researcher, these records were not found. Clinical data for these seven women were collected from the hospital's Obstetrical Database, which collects data on labour and birth outcomes. The only clinical data that was unavailable for these seven women was the number of antenatal visits.

4.9.2 Women's experiences

Women's experiences were collected using questionnaires in one of three languages. When women consented to the trial, they were asked in which language they preferred to receive questionnaires (English, Chinese or Arabic). Women from other NESBs received an English questionnaire.

Antenatal questionnaires

Antenatal questionnaires were distributed to consenting women between 36 and 38 weeks of pregnancy. Women were provided with envelopes to insert their completed questionnaires in and were asked to place them in specially marked boxes in the clinics.

Nine hundred and forty-seven antenatal questionnaires were distributed to the 992 women who had consented to participate, giving a distribution rate of 95 per cent. Mean gestation at return of antenatal questionnaires was 36 weeks for both groups. The response rate for all questionnaires is expressed as a proportion of questionnaires completed out of those distributed. Using this calculation, the response rate to the antenatal questionnaire was 86 per cent. Women in the STOMP group were significantly more likely to return antenatal questionnaires than women in the control group (Table 4.5).

Table 4.5: Distribution and response to antenatal questionnaire.

	Consenting women	Distributed	Returned	Response rate[a] [return/dist]
STOMP	485	452	412	91%
Control	507	488	401	81%
Total	992	940	813	86%

[a]The response rate is expressed as a proportion of women who returned questionnaires by the number of women who received a questionnaire. A chi-squared was used to examine differences in response rate between allocated groups. $\chi^2(1)=17.1$, $p<0.0001$.

English-speaking women were significantly more likely to return their antenatal questionnaire compared with women from other language groups (Table 4.6).

Table 4.6: Distribution and return of antenatal questionnaire by language group.

Language	Consenting	Distributed	Completed	Response rate[b] [comp/dist]
English	600	570	504	88%
Chinese	160	152	129	84%
Arabic	144	138	113	81%
Other [a]	88	80	67	84%
Total	992	940	813	86%

[a]Women from 'other' language groups received a questionnaire in English and utilised interpreters for completion. [b]The response rate is expressed as a proportion of women who women who returned questionnaires by the number of women who were distributed a questionnaire. A chi-squared test was used to examine differences in response rate between language groups: $\chi^2(3)= 9.6$, p=0.02.

Fifty-two women (33 from STOMP group and 19 from control group) were not given a questionnaire. This represented five per cent of the available sample. The reasons are displayed in Table 4.7.

Table 4.7: Reasons why women were not given an antenatal questionnaire.

	STOMP group n=33	Control group n=19	Total n=52
Missed in the clinics	23	11	34
Premature birth	1	2	3
Transfer to another centre	2	2	4
Transfer to the RAP team	3	1	4
Unknown	4	3	7

Postnatal questionnaires

Postnatal questionnaires were mailed to women at eight weeks postpartum. A letter was sent with the questionnaire (in English, Chinese or Arabic) thanking the women for their participation and explaining the procedure for completion and return. The

confidential nature of their responses was reiterated. After two months, women who had not responded were sent another questionnaire with a reminder letter.

In total, 970 women were sent postnatal questionnaires. Twenty-one (six from the STOMP group and 15 from the control group) were returned marked, 'not known at this address'. These women were removed from the sample of distributed questionnaires. The reminder letter and questionnaire was sent to the 464 women, with a 153 of these women subsequently responding. In total, 658 women returned postnatal questionnaires, giving a response rate of 69 per cent. The response rate between the groups was not statistically different (Table 4.8).

Table 4.8: Distribution and response to postnatal questionnaire by allocated group.

	Consent	Distributed	'Return to sender'	Final distribution	Returned	Response[a] [ret/final dist]
STOMP	485	478	6	472	326	69%
Control	507	497	15	482	332	69%
Total	992	975	21	954	658	69%

[a]The response rate is expressed as a proportion of women who returned questionnaires by the number of women who received a questionnaire in the final distribution. A chi-squared test was used to examine differences in response rate between allocated groups: $\chi^2(1)=0.8$, p=0.8.

Twenty-two women were not sent postnatal questionnaires (2 per cent of the total eligible sample) and this was equally divided between STOMP and control groups. Four women were not sent a questionnaire because of stillbirth, known neonatal death or a serious neonatal illness. The reason for the remainder of missed follow-up (n=18) is unknown but it is likely that they were an unintentional omission.

Chinese and English speaking women were more likely to return completed questionnaires than Arabic or other language speakers. The language groups for those women who were sent questionnaires are displayed in Table 4.9.

Table 4.9: Distribution and response to postnatal questionnaire by language group.

Language	Consent	Distribute	'Return to sender'	Final distribution	Returned	Response rate [ret/final dist]
English	600	592	11	581	422	73%
Chinese	160	157	3	154	117	75%
Arabic	144	138	3	138	63	46%
Other [a]	88	85	4	81	56	68%
Total	992	975	21	954	658	69%

[a]Women from 'other' language groups received a questionnaire in English. The response rate is a proportion of women who women who returned questionnaires by the number of women who received a questionnaire in the final distribution. A chi-squared test was used to examine differences in response rate between language groups: c^2 (3)=44.3, p<0.0001.

4.8.3 Time of questionnaire completion

Most women (70%) were between eight and 12 weeks postpartum when they completed their questionnaire. Thirty-six women (5.5%) completed their questionnaire at six and seven weeks and 22 women (3.4%) completed it at greater than 24 weeks postpartum. The mean number of postpartum weeks at completion of the questionnaire was 10.9 [SD 4.8] for STOMP women and 11.9 weeks [SD 5.3] for control women. The difference is due to the greater number of STOMP women who replied earlier.

4.10 Data management and quality assurance

Systems to ensure the quality of the research were instigated into the study at number of points, including at data collection and data entry.

4.10.1 Data collection

During the development phase of the form for the collection of clinical data, the two research midwives worked together to ensure the accuracy of the data collection process. A definition was written for each variable to ensure that interpretations were consistent (see Appendix 6, page 250). These definitions were developed from existing research and current standard policies and protocols within NSW.

4.10.2 Data entry

Data entry commenced in January 1998 and continued until April 1999. Clinical data were entered into a Microsoft Access 97 database. Data were entered in a three month period in early 1999. The researcher entered 47 per cent of the records with the two clerical assistants entering the remainder (36 per cent and 17 per cent respectively). Queries (usually missing data) were checked by the researcher and the medical or computer records for the woman rechecked if necessary.

Data from the antenatal and postnatal questionnaires were entered into a Statistical Package for the Social Sciences (SPPS) database. One of the clerical assistants entered these data over 12 months.

Default values were available for the majority of the data fields. Random checks of the data were also carried out at regular intervals by the researcher, looking for incorrect data and 'outliers'. Data considered suspicious were rechecked with the original datasheet and the woman's medical or computer records if the researcher was unsure of accuracy.

All records were double-checked for accuracy on a primary variable as recommended by the Guidelines for Good Clinical Research Practice (Therapeutic Goods Administration 1991). Mode of delivery was chosen as the primary variable. All 1 089 records were audited against original data sheets with only one error detected. Finally, the list of enrolled women was compared against the main database to ensure that all women were accounted for.

4.11 Analysis

4.11.1 An intention to treat analysis

Primary analyses were performed on an 'intention to treat' basis. This meant that all women in the final sample were included and data analysed according to the group to which the women were randomly allocated to, irrespective of whether they actually received the intervention.

Intention to treat analysis is an important aspect of randomised controlled trials in health care settings. Any other form of analysis can give misleading results, and in some instances, can lead to practices being erroneously implemented, with undesirable

consequences for the patient (Newell 1992). An intention to treat analysis is the only analysis that can confidently be assumed to be free from selection bias. This method ensures that questions are answered as to whether this intervention works in typical circumstances as opposed to ideal circumstances (Chalmers 1989).

4.11.2 An overview of the analysis

Data were analysed using the Statistical Package for Social Sciences (SPSS). The α level was set at 0.05 as has been the case in most other studies of this nature (Hundley et al. 1994; Kenny et al 1994; Rowley et al 1995; Turnbull et al 1996; Waldenström et al 1997). Odds ratios (OR) with 95% confidence intervals (CI) are presented where appropriate. Confidence intervals that include 1.0 show that that the intervention was no more effective than standard care (Brown 1999). Assumptions associated with the various statistical tests were checked before the tests were applied.

Specific primary and secondary analyses will be described in each of the chapters that report the results of the study (Chapters 5-9).

4.11.3 Evaluation of perinatal deaths

Each perinatal death was independently and 'blindly' reviewed and classified using the Maternal/Fetal Antecedents of Perinatal Mortality. This classification system was modified from Whitfield et al (Whitfield et al. 1986) and has been used in Australian research (Forbes & King 1990). An independent obstetrician conducted the review. This obstetrician did not work at the hospital and was unaware of the study, the intervention, the allocated groups or the aim of the review. The medical records of the eight women and infants were photocopied. Evidence of the model of care they had received was deleted from these photocopies using 'liquid paper' (Tipex). No other information was deleted from the records.

4.12 Potential measurement bias

As this was an unblinded trial there was potential for measurement bias. The women randomly allocated to the intervention group were aware that they were being studied and that their experiences would be used to support the continuation or cancellation of the project. This may have influenced some women to be overly enthusiastic about the STOMP service. Equally, discontented control group women might have been overly

negative about their experience with the hospital in an attempt to encourage change. It was hoped that the Zelen design would reduce disappointment bias, although this is difficult to quantify.

It was not possible to mask the data collectors to the woman's allocation. Whilst this may be a limitation of the trial, it is a common problem in research into health services. In an effort to reduce this bias, records of women in the control group could not be differentiated by clinicians from other women receiving standard care but not participating in the study. We also attempted to reduce bias by blinding the allocation of the woman from the reviewer of the eight perinatal deaths.

4.13 Project management

A working party was established prior to the onset of the project. Membership of the working party included the major stakeholders in this new model of care. This included: the clinical midwife consultant who coordinated the teams; two research midwives; midwifery managers from the postnatal ward, birth centre, delivery suite and antenatal clinic; staff specialist obstetrician; early childhood services liaison nurse; and, representatives from the ward and team midwives. This working party met monthly throughout the study, from December 1996 to January 1999.

The terms of reference for the working party were to: provide a forum for exchange of information and ideas regarding the implementation and integration of the STOMP program; develop, conduct and implement the evaluation of the STOMP program; and, provide a forum to address issues arising from the STOMP program that could not be resolved at ward level.

Minutes were distributed to the senior managers within the maternity unit. The minutes were placed in the 'communication folders' in all areas. Staff members were encouraged to access this ongoing information. The working party reported to the St George Hospital Maternity Services Research and Development Steering Committee, which met every two months and monitored a number of projects.

4.14 Summary

This chapter has described the methods that were used in the STOMP study, including: the setting; sample; system of random allocation; recruitment and consent process; outcome measures; and, data collection methods. A commitment was made to recruit a

representative sample of women from NESB which meant a number of strategies were used including translations, health care interpreters and ethnic obstetric liaison midwives. The Zelen design assisted in the recruitment of a representative sample as selection bias was reduced.

The following five chapters (5-9) present the results of the study. Chapter 5 presents the clinical outcomes of women and neonates in the study with a particular emphasis on caesarean section rate.

Chapter 5 Clinical outcomes of labour and birth

5.1 Introduction

Significant reductions to rates of perinatal morbidity and mortality have been made in the past 100 years, however, this decline cannot be entirely attributed to an improved maternity service. Improved living standards, including sanitation, clean water and nutrition as well as higher levels of education (particularly for girls), and health services with access to antibiotic agents and operative technologies, have improved the physical health of mothers and babies (Tew 1990). While improvements to perinatal health have been considerable, concern remains in many countries, including Australia, about the high rates of obstetric intervention, particularly caesarean section rates (NHMRC 1996; Senate Community Affairs References Committee 1999). Continuity of midwifery care has been shown to reduce interventions in labour, particularly augmentation of labour, use of analgesics and electronic fetal monitoring (Hodnett 1999). Other research has suggested that continuity of midwifery care may also reduce the caesarean section rate (Harvey et al 1996; Rowley et al 1995).

This chapter specifically examines the impact of the primary outcome variable, caesarean section rate, on women. The argument presented in this chapter illustrates the reasons why caesarean section rates are an important consideration in maternity care. The chapter then presents the maternal and neonatal clinical outcomes from the study. Subsequent chapters (Chapters 6 and 7) address the experiences of women. Chapter 8 considers the costs of providing care from the perspective of the health system.

5.2 Caesarean section: risks and costs

Australia has one of the highest caesarean section rates in the western world (NHMRC 1996; Wagner 1994a). The national rate in 1999 exceeded the rate in the USA, long regarded by comparable countries as unjustifiably high (Senate Community Affairs References Committee 1999). In 1987, the mean caesarean section rate in NSW was 15.9 per cent (NHMRC 1996). This had risen to 19 per cent by 1998 (NSW Health 2000).

The optimal caesarean section rate is not known. The World Health Organisation (WHO) has recommended a rate of no more than 15 per cent (World Health Organisation 1985). The Department of Health in the USA adopted this figure as a goal for the year 2000 (US Department of Health and Human Services 1991). The Australian government has also identified 15 per cent as a possible goal. In 1999, the *Senate Inquiry into Childbirth Procedures* recommended "that the Commonwealth Government work with state governments to decide a target rate for caesarean sections, moving towards the target of 15 per cent" (Senate Community Affairs References Committee 1999), p. 107). The cautious tone in which this recommendation is framed is indicative of the challenges associated with such a move.

Only a few countries have achieved the rate recommended by WHO. The Netherlands and Sweden have managed to keep their caesarean section rate below 15 per cent (Senate Community Affairs References Committee 1999; Smulders 1999). Australia's caesarean section rate ranges from 16.5 to 25.4 per cent depending upon the state or territory (Day et al 1999b). In the USA, rates between 20 and 25 per cent have been reported (Notzon et al. 1994; Taffell et al. 1991). In China, the rate of caesarean section has increased from 4.7 to 22.5 per cent over the past 30 years (Cai et al. 1998). Research in 19 Latin American countries, found only seven countries with caesarean section rates below 15 per cent (Belizán et al. 1999). The remaining 12 countries, which accounted for 81 per cent of births in the region, had caesarean section rates that ranged from 17 to 40 per cent. Using the WHO recommended rate of 15 per cent, Belizán and Althabe (1999) estimated that over 850 000 unnecessary caesarean sections were performed annually in the region.

5.2.1 Risks to the mother

While a caesarean section is considerably safer now than in the past, it still carries the risks associated with major abdominal surgery. Maternal mortality after caesarean section is es timated to be significantly higher than after vaginal birth. Infection, pulmonary embolism, anaesthetic accidents and haemorrhage are the principal causes of mortality. Maternal morbidity associated with caesarean section has been reported to be 5 to 10 times greater than with vaginal birth (Shearer 1993).

Caesarean section also has long term implications for women. A review of more than 65 000 births over a 10 year period in Ireland, found an association between a history of

caesarean section and emergency peripartum hysterectomy (Greene et al. 1997). While peripartum hysterectomy was an uncommon operation, Greene et al (1997), estimate that it was 18 times more likely in women with a history of caesarean section compared with those who have previously had vaginal births. Caesarean section is also a risk factor for major postpartum haemorrhage (Coulter-Smith et al. 1996), ectopic pregnancy and placental problems, such as abruptio placentae and placenta previa (Hemminki & Merilainen 1996).

Psychological health can also be affected by a caesarean section. An association has been found between emergency caesarean section and subsequent maternal psychological problems (Boyce & Todd 1992; Fisher et al. 1997). Research by Creedy (Creedy 1999) in Queensland has identified a strong correlation between obstetric intervention (including caesarean section) and post traumatic stress disorder. It has also been suggested that caesarean sections leave women frightened about future childbirth (Jolly et al. 1999). Jolly et al (Jolly et al 1999) reported that 26 per cent of women who underwent a caesarean section five years previously, were still frightened about future childbirth. This compared with only 10 per cent of women after a normal birth. This fear had contributed to involuntary infertility, with 30 per cent of women post-caesarean section electing not to have additional children. A negative response to caesarean births, including fear, disappointment, anger and lowered self esteem, has also been identified in earlier research (Cranley et al. 1983; Hillan 1992b; Hillan 1992a). These negative responses may reflect the difference between expectation and the actual experience, or they may represent a reaction to the complications that made the caesarean necessary (Hillan 2000). Nonetheless, it seems possible that a rising caesarean section rate will contribute to an increase in psychosocial morbidity.

5.2.2 Risks to the neonate

While caesarean sections are usually performed to benefit the fetus, they still carry risks for the infant. Caesarean birth following an uncomplicated pregnancy is a risk factor for adverse neonatal outcome. Adverse outcome includes the possible need for oxygen therapy and mechanical ventilation (Annibale et al. 1995). The risks to the neonate remain even after pregnancy-related complications are considered (Bobadilla & Walker 1991). Bobadilla and Walker (Bobadilla & Walker 1991) reported that neonatal mortality

was 2.5 times higher after caesarean section than vaginal birth even after controlling for birth weight, gestational age, maternal characteristics and complications.

In the 1980's, elective repeat caesarean birth of fetuses who were healthy before birth accounted for up to nine per cent of admissions to neonatal intensive care units. The most common reason for admission was respiratory distress syndrome (Bowers et al. 1982). Respiratory distress syndrome commonly occurs in preterm infants whose lungs are too immature to expand properly, however 41 per cent of the infants who developed respiratory problems in the Bowers et al (1982) study were thought to be full term. A significant reduction in respiratory distress seems to be possible if elective caesarean sections are performed after 39 weeks gestation, although this does not remove the risk entirely (Morrison et al. 1995).

Other research has highlighted the risk of respiratory distress for full term infants born by elective caesarean section. Respiratory distress was reported in 30 per cent of infants when the elective caesarean section was performed before the onset of labour compared with 11 per cent of those born after the commencement of labour (Cohen & Carson 1985). These findings have been confirmed more recently with research that found that the incidence of respiratory morbidity was almost three times higher in infants born by caesarean section before the onset of labour, compared with during labour (Morrison et al 1995). The reason for some of development of respiratory distress in the neonate may be related to release of catecholamines during labour (Lagercrantz & Slotkin 1986). Catecholamines are associated with changes at birth that facilitate lung function and increase blood flow to vital organs. Babies born by caesarean before labour have lower catecholamine levels at birth compared with those born vaginally (Shearer 1993).

5.2.3 Costs

Caesarean sections use more health care resources than normal vaginal deliveries (Lee 2000). In the UK it has been estimated that each one per cent increase in caesarean section rate costs the National Health Service over £5 million per annum (Lancet 1997). In Australia, a caesarean section (using Diagnostic Related Groups, the recognised national standard for hospital funding) costs the health system approximately A$1 500 more than a normal vaginal birth (Harper 1999). A detailed cost analysis of caesarean sections is presented in Chapter 8 of this dissertation.

The cost implications of a trial of labour versus an elective caesarean have been also examined. Traynor and Peacemen (Traynor & Peaceman 1998) compared the hospital costs incurred by women with one previous caesarean section who underwent a trial of labour with the costs incurred by women who had an elective repeat caesarean section in the USA. The study found that a trial of labour was associated with a 14 per cent reduction in hospital costs and a 31 per cent reduction in length of stay compared with elective repeat caesarean section. Shorten et al (Shorten et al. 1998) conducted a similar study in Australia. She reported that, as long as the rate of vaginal delivery after trial of labour was high (in the order of 68 per cent), a trial of labour was less expensive than elective caesarean section.

Social and emotional costs must also be considered. A longer hospital stay with the associated separation from the family and a more lengthy recovery period after the birth of the baby both contribute to direct and indirect costs. A community that is conscious of rising costs associated with health care cannot afford to be complacent about the increased costs associated with a procedure that is not always necessary or medically indicated.

Caesarean births carry risks to the infant and the mother and are an expensive intervention that should only be performed when necessary. This next section discusses some of the reasons behind the rising caesarean section rate and suggests strategies to reduce the rate without comprising maternal and neonatal health. A discussion of these issues is important, as the primary hypothesis in the STOMP study was that the intervention would result in a reduction in caesarean section rate.

5.3 Reasons for rising caesarean section rates

The most common reasons for emergency caesarean section are dystocia, prolonged labour and fetal distress. The criterion for the diagnosis of these conditions can be unclear and there is variability between clinicians and hospitals (Enkin et al. 1998). The most common reason for an elective caesarean section appears to be a previous caesarean section despite evidence to the contrary. For example, *Effective Care in Pregnancy and Childbirth*, the widely acclaimed compilation of systematic reviews of evidence in maternity care, states that "previous caesarean section is rarely an adequate indication [for elective caesarean section] by itself" (Enkin et al 1998), p. 319).

While many caesarean sections are carried out for unequivocal indications, such as placenta previa or the transverse lie of the fetus, it appears that some caesarean sections are performed for ambiguous indications and could be considered 'unjustified' or not medically indicated. For example, one study from Colombia in South America reported that 81 per cent of primary caesareans performed at four different hospitals were 'unjustified' (Gomez & Carrasquilla 1999). Showalter and Griffin (Showalter & Griffin 1999) suggest that the increase in caesarean section rates in Latin America reflects an improvement in medical services, education and possibly better monitoring for detecting fetal distress. It has been suggested that the increase in rate of caesarean section worldwide is justified because it has reduced perinatal mortality (Bottoms et al. 1980). This claim has been widely disputed with repeated research failing to find any significant correlation between variations in caesarean section rates and perinatal mortality (Wagner 1994b); (O'Driscoll & Foley 1983); (Bergsjo et al. 1983); (Shearer 1993); (Lomas & Enkin 1989); (van Roosmalen 1989)).

A woman's request for elective caesarean section is increasingly seen as a valid and reasonable indication. Some obstetricians are advocating 'caesarean section on demand' as a choice for women (Mackenzie 1999; Paterson-Brown 1999; Paterson-Brown & Fisk 1997). It is unclear how many women are requesting elective caesarean without medical reason as various studies report different results. The proportion of women who request elective caesarean section in the absence of medical indication ranges from seven to twenty-seven per cent depending on the population and the study (Graham et al. 1999; Quinlivan et al. 1999; Wilkinson et al. 1998). A survey of 206 obstetricians in London reported that 17 per cent would opt for a caesarean section for no medical reason (Al-Mufti et al. 1997). A similar survey in The Netherlands, however reported that only eight out of 567 obstetricians (1.4%) would opt for an elective caesarean in an uncomplicated pregnancy (van Roosmalen 1999).

It has been suggested that socioeconomic status and private health insurance contributes to the rising caesarean section rate in Australia (King 1993). In Latin America, a clear positive correlation has been found between socioeconomic indicators and caesarean section rate (Belizán et al 1999). Significant correlation between caesarean section rates, gross national product and the number of doctors per 10 000 population was found with a higher proportion of caesarean sections in private hospitals compared with public or social security hospitals. In Latin America, as in many other

regions, women who attend public hospitals are more likely to be single, less educated, adolescent, and have more medical and social problems than women attending private hospitals (Belizán et al. 1998). The medical justification for the higher rates in private hospitals is, therefore, difficult to argue (Belizán et al 1999).

In Australia in 1997, the average caesarean section rate in privately insured women was 27 per cent compared to 17 per cent in non-insured women in public hospitals (Day et al 1999a). This disparity between public and private intervention rates was one of the particular areas of interest in the Commonwealth Government's *Senate Inquiry into Childbirth Procedures* (Senate Community Affairs References Committee 1999). The report (1999) referred to the difference as being "particularly disturbing" (p. 82). The difference has again been highlighted in recent Australian research, which reported higher rates of obstetric intervention in low-risk women attending private hospitals compared with public hospitals (Roberts et al. 2000).

Other factors have also been reported, some of which may relate to socioeconomic and insurance status. Fear of litigation is believed to have contributed to increased caesarean sections rates in the USA, the UK (Kitzinger 1998); van Roosmalen & van der Does 1995; (Macfarlane & Chamberlain 1993; van Roosmalen & van der Does 1995) and in Australia (Molloy & Richardson 1994). Individual obstetric styles of practice have also been shown to significantly influence the rate of caesarean section (Goyert et al. 1989). Caesarean section rates are higher in countries where doctors supervise the majority of births (Macfarlane & Chamberlain 1993), whereas those countries with a strong commitment to midwifery care for most women (like The Netherlands) have managed to retain a low caesarean section rate (van Roosmalen & van der Does 1995). Socio-cultural conventions, for example, the widespread use of epidural anaesthesia for labour pain in many developed countries, also impacts on the rate of emergency caesarean section (van Roosmalen & van der Does 1995).

5.4 A model of care as strategy to reduce the caesarean section rate

The STOMP model of care was designed to improve outcomes for women and their infants. Caesarean section rate was chosen as the primary outcome as it has important implications for women. Continuity of midwifery care has been shown to reduce interventions in labour, particularly augmentation of labour, analgesic use and electronic fetal monitoring (Flint et al 1989; Kenny et al 1994; Rowley et al 1995; Waldenström &

Nilsson 1997). Harvey et al (Harvey et al 1996) reported a reduction in caesarean section rate in Canada. In Australia, Rowley et al (Rowley et al 1995) demonstrated a trend towards a reduced elective caesarean section rate in high risk women. In the USA, supportive nurse-midwifery care in labour was associated with a reduced caesarean section rate (Butler et al 1993). Continuous support in labour has also been associated with less use of analgesia, fewer instrumental births and caesarean sections and a decreased need for augmentation of labour (Hodnett 2000b). The STOMP model had a strong midwifery focus, as this seems to be a factor in lowering caesarean section rates (van Roosmalen & van der Does 1995).

5.5 The primary research question of the study

The primary research question of the STOMP study was:

- Does the STOMP model result in comparable maternal and neonatal outcomes compared with standard care?

The findings relating to this question are presented in the remainder of this chapter in relation to the variables of interest including: baseline characteristics; antenatal complications and admission; events during labour; mode of birth; perineal outcome and neonatal birth weight; admission to the SCN; and, Apgar scores.

5.6 Method

The study design, sample size calculation, method of random allocation, outcome measures and data collection method are described in Chapters 3 and 4.

5.6.1 Data collection

Data were collected from medical records.

5.6.1 Analysis

All women in the final sample were included on an intention to treat basis. To examine differences between the STOMP and control groups, categorical variables were analysed using chi-squared tests, unless the expected cell size is less than five when a Fisher's exact test was applied. Continuous variables were analysed using Student t tests. Logistic regression (Hosmer & Lemeshow 1989) was used to control for factors that affect the caesarean section rate. The factors included: age; height; parity; history

of a previous caesarean section; and, presence of gestational diabetes, pre-eclampsia or antepartum haemorrhage (Dougherty & Jones 1988; Harlow et al. 1995; Martel et al. 1987; Turcot et al. 1997). Logistic regression was used to examine factors associated with neonatal admission to the SCN.

Odds ratios (OR) are presented where appropriate in this chapter. The OR estimates the change in odds of membership in the target group for a one-unit increase in the predictor (Wright 1997). Confidence intervals around the point estimate are presented. Confidence intervals that do not include 1.0 are statistically significant at the α level of 0.05.

The study was too small to detect significant differences in perinatal mortality. Each perinatal death was independently and 'blindly' reviewed and classified as described in Chapter 4 (page 82). Perinatal mortality was defined as being a stillbirth (an infant of at least 20 weeks gestation or 400 grams birth weight) or a neonatal death (the death of a live born infant within 28 days of life) (NSW Health Department 1998a). The purpose of the independent review was to determine the cause of death and whether the type of care had contributed. Each perinatal death was allocated a category and a cause of death (for example, avoidable or unavoidable) and the time of death for stillbirths was noted (that is before the onset of labour or during the intrapartum period).

5.6.2 Sample

The final sample comprised of 1 089 women, 550 in the STOMP group and 539 in the control group (see Figure 4.1, page 66). Eighty-eight per cent (483/550) of women in the STOMP group received their allocated model of care. Two women in the control group received STOMP care as described in Chapter 4 (section 4.7, page 63).

5.7 Results

5.7.1 Baseline characteristics

Both groups were similar in demographic characteristics and had comparable past medical and obstetric histories (Table 5.1). Using chi-squared tests and t-tests, it was evident that there were no statistically significant differences in past medical or obstetric history, although slightly more women in control group had a history of a previous caesarean section.

Table 5.1: Baseline maternal characteristics by allocated group.

	STOMP	Control	p[a]
	n=550	n=539	
	Number (%)	Number (%)	
Mean age in years [SD]	28.2 [5.4]	28 [5.2]	0.4
Mean booking gestation in weeks [SD}	15.5 [3.7]	15.2 [3.5]	0.2
Country of birth:			0.7
• English speaking	258 (46.9)	259 (48.1)	
• Chinese speaking	90 (16.4)	93 (17.3)	
• Arabic speaking	86 (15.6)	88 (16.3)	
• other NESB	116 (21.1)	99 (18.4)	
Nulliparous	253 (46)	248 (46)	1.0
Married or defacto relationship	520 (94.5)	508 (94.2)	0.8
Employed out of the home	276 (50.2)	258 (47.9)	0.4
Tertiary education	156 (28.3)	139 (25.8)	0.7
Past obstetric history:			
• Significant postpartum haemorrhage	7 (1.3)	8 (1.5)	0.8
• Caesarean section	33 (6.0)	44 (8.2)	0.2
• Pre-eclampsia	28 (5.1)	21 (3.9)	0.3
• Gestational diabetes	10 (1.8)	15 (2.8)	0.3

Baseline characteristics include age; gestation at booking; country of birth; parity; employment out of the home; tertiary education; and past obstetric history. [a]Independent sample t-tests were used to test for differences in age and gestation at booking visit and χ^2 tests were used to test differences between groups in other variables.

5.7.2 Maternal outcomes

Most women concluded their pregnancy at term with a mean gestation of 39 weeks (min-max 21–42) in both groups. Almost all women had their babies at the study hospital. Two women in the STOMP group (0.4%) and three from the control group

(0.6%) were transferred to other hospitals because they required a higher level of perinatal and neonatal specialist care.

Antenatal complications

More women from the control group were admitted to hospital during the antenatal period. There were no significant differences between the allocated groups in attendance at the Day Assessment Unit (DAU) or in the frequency of antenatal complications, including gestational diabetes and pre-eclampsia (Table 5.2).

Table 5.2: Antenatal admission to hospital, attendance at DAU and frequency of obstetric and medical complications by allocated group.

Complications	STOMP group n=550 Number (%)	Control group n=539 Number (%)	OR (95% CI)[b]
Antenatal admission	53 (9.6)	72 (13.4)	1.4 (0.99-2.1)
Attendance at DAU	27 (4.9)	30 (5.6)	1.1 (0.6-1.9)
Complications:			
• Antepartum haemorrhage	9 (1.6)	14 (2.6)	0.06 (0.2-1.4)
• Pre-eclampsia	33 (6.0)	34 (6.3)	0.9 (0.6-1.5)
• Gestational diabetes	42 (7.6)	37 (6.9)	1.1 (0.7-1.7)
• Threatened preterm labour	8 (1.5)	12 (2.2)	0.6 (.03-1.5)
• IUGR	9 (1.6)	11 (2)	0.8 (0.3-1.9)
• Other[a]	53 (9.6)	67 (12.4)	0.7 (0.5-1.1)

[a]Other includes: cholestasis, polyhydramnios, depression, placenta previa. [b]Odds ratios (OR) and 95% confidence intervals (CI) were calculated to examine differences between groups.

Small numbers of women in each group (10 from STOMP and 11 from control) developed serious risks through the pregnancy and were transferred to the Risk Associated Pregnancy (RAP) team. These women remained in their randomly allocated group for the analysis.

Outcomes of labour and birth

There were no significant differences in most events during labour with a similar use of induction of labour, analgesia and augmentation between the allocated groups. STOMP women who underwent a labour were significantly less likely to have had continuous electronic fetal monitoring applied (Table 5.3).

Table 5.3: Induction of labour, analgesic use, augmentation of labour, and electronic fetal monitoring by allocated group.

	STOMP n=529[a] Number (%)	Control n=505[a] Number (%)	OR (95% CI)[b]
Induction of labour	125 (23.6)	109 (21.6)	1.1 (0.8-1.5)
Analgesia:			
• Nitrous oxide	364 (68.8)	324 (64.3)	1.2 (0.9-1.5)
• Narcotic (pethidine)	160 (30.2)	136 (27)	1.2 (0.9-1.5)
• Epidural/spinal block	139 (26.3)	148 (29.4)	0.8 (0.6-1.1)
Augmentation of labour	227 (42.9)	200 (39.6)	1.1 (0.9-1.4)
Electronic fetal monitoring	252 (47.6)	275 (54.5)	0.7 (0.6-0.9)*

[a]Women booked for elective caesareans were excluded from this analysis. [b]Odds ratios and 95% CI were calculated to examine differences between allocated groups. *$p<0.05$.

The most common indication for an induction of labour (IOL) was prolonged pregnancy. One third of control women (n=36) and 28 per cent of STOMP women (n=35) who underwent an IOL had this as the primary indication. Nine women in the STOMP group and three in the control group had 'woman's request' as the indication for IOL.

There was a significant difference in the caesarean section rate between the groups, 13.3 per cent (73/550) in the STOMP group and 17.8 per cent (96/539) in the control group (Table 5.4).

Table 5.4: Proportion of normal birth, forceps/vacuum extraction and caesarean sections by allocated group.

	STOMP n=550 Number (%)	Control n=539 Number (%)	OR (95% CI)[a]
Normal vaginal birth	402 (73.1)	374 (69.4)	1.1 (0.8-1.4)
Forceps/Vacuum extraction	71 (12.9)	63 (11.7)	1.1 (0.7-1.5)
Total caesarean section	73 (13.3)	96 (17.8)	0.7 (0.5-0.9)*
• Elective CS	21 (3.8)	34 (6.3)	
• Emergency CS	52 (9.5)	62 (11.5)	

[a]Odds ratios (OR) and 95% CI were calculated to examine differences between groups. *p<0.05.

Logistic regression was used to determine the predictors of a reduced caesarean section rate. The odds of a women having a caesarean section from the STOMP group was lower than that for a woman in the control group after considering the factors that are known to contribute to an increased risk of caesarean section (Table 5.5).

Table 5.5: Logistic regression with caesarean section as the dependent variable.

Variable	P	OR	95% CI
Group (STOMP versus control)	0.02	0.6	0.4-0.9
Parity	<0.0001	0.2	0.1-0.3
Obstetric risk factor	0.008	1.9	1.2-3.0
Age	<0.0001	1.1	1.0-1.1
Height	0.42	1.0	0.9-1.0
Previous caesarean section	<0.0001	33.9	17.2-67.0

Factors included in the model were allocated group (STOMP vs control), parity (nulliparity vs multiparity), age (continuous measure), height (continuous measure), obstetric risks (gestational diabetes, pre-eclampsia or antepartum haemorrhage vs none), previous caesarean section (previous caesarean vs no previous caesarean).

One third of STOMP women with a previous caesarean section (11/33) underwent an elective caesarean section in this pregnancy compared with 41 per cent of control

women (18/44). There was only one documented request for an elective caesarean section in the absence of medical indications. This was from a primiparous woman in the STOMP group and an elective caesarean was performed.

There were no significant differences in the number of women who had episiotomies or perineal tears. Table 5.6 presents the perineal outcomes of women who had a vaginal birth.

Table 5.6: Perineal outcome for women who had vaginal births.

	STOMP n=476 Number (%)	Control n=441[a] Number (%)
Intact perineum	119 (25.0)	102 (23.0)
Graze: perineal or labial	47 (9.9)	41 (9.3)
Episiotomy	64 (13.4)	66 (14.9)
First or second degree laceration	234 (49.2)	223 (50.3)
Third degree laceration	12 (2.5)	9 (2.0)
Total	476 (100.0)	441 (100.0)

[a] The perineal outcome for 2 women in the control group was unknown. A χ^2 test was performed to examine differences between groups. $\chi^2(5)=3.2$, p=0.6.

Primiparous women were more likely to have an episiotomy and less likely to have an intact perineum compared with multiparous women. One tenth of primiparous women had an intact perineum compared with one third of multiparous women. These outcomes were not significantly different between the groups.

Rates of primary postpartum haemorrhage (PPH) and retained placenta were similar between the groups. In the STOMP group, 5.6 per cent (n=31) of women had a PPH compared with 4.8 per cent (n=26) in the control group ($\chi^2 (1)= 0.02, p=0.6$). Three women (0.5%) from the STOMP group and five women (0.9%) from the control group had a retained placenta requiring surgical removal.

Postnatal outcomes

The mean postnatal length of hospital stay was slightly reduced in the STOMP group (4.9 days versus 5.1 days) but this difference was not significant. More women in the STOMP group utilised the domicillary midwifery program, also known as 'early discharge' (43% versus 35%, *OR 1.4, 95% CI 1.1-1.8, p=0.003*).

Twenty-one women (3.8%) from the STOMP group and 14 (2.6%) from the control group were re-admitted at a mean of 3 weeks postpartum. The most common reasons were retained products of conception or endometritis (seven women from each group) and mastitis (five from the STOMP and three from the control group) and because the baby was admitted to hospital (three from the STOMP and one from control groups).

5.7.3 Neonatal outcomes

In total 1 099 neonates were born to the 1 089 women in the study, with 10 sets of twins. There were no differences between the groups in mean birth weight (Table 5.7). Twelve STOMP infants (2.2%) and 13 control infants (2.4%) had Apgar scores of less than 7 at five minutes ($c^2(1)=0.6, p=0.8$).

Table 5.7: Neonatal birth weight and Apgar scores by allocated group.

	STOMP n=550 Mean [SD]	Control n=539 Mean [SD]	p[a]
Birth weight (grams)	3 375 [521]	3 357 [543]	0.6
Apgar score 1 minute	8.1 [1.7]	7.9 [1.7]	0.1
Apgar score 5 minute	8.9 [1.0]	8.8 [1.1]	0.5

[a]An independent sample t-test was used to examine differences between groups.

Eighty (14.5%) neonates from the STOMP group and 102 (18.9%) from the control group were admitted to the SCN but this difference was not significant (*OR 0.75, 95% CI 0.5-1.1*). In a logistic regression, the most important factors determining neonatal admission were gestation less than 37 weeks (*OR 21.4, 95% CI 10.8-42.5*), maternal antenatal risk factors (*OR 3.5, 95% CI 2.3-5.3*) and caesarean section (*OR 1.6, 95% CI 1.03-2.5*). Neonates born to women in the STOMP group were admitted to the SCN for

a shorter time than control group neonates (mean length of stay in days: 4.2 versus 6.0).

Eight infants died during the perinatal period (four from each group) with no deaths in the 10 twin pregnancies. Six of the infants were stillborn (four in the STOMP group and two in the control group) with two early neonatal deaths in the control group, giving a perinatal mortality rate of 7.3 per 1 000 births. A summary and review of the perinatal deaths is presented in Table 5.8. The only potentially avoidable perinatal death was Case 1. This woman was a 32 year multipara with two previous uneventful pregnancies that resulted in normal vaginal births at term with normal birth weights. She received antenatal care at the STOMP clinic and attended regularly. Her fundal height (measurement of uterine size and growth) at 28 weeks gestation was recorded at 27cm, at 31 weeks it was 31 cm and at 34 weeks it was 33cm, a total increase of six cm in six weeks. These last three recordings were by the same midwife. Fetal heart sounds were heard at all visits and fetal movements reported by the woman. Her blood pressure was normal throughout the pregnancy. She presented at 36 weeks with no fetal movements for two days and a fundal height of 28 cm. A fetal death in utero was diagnosed and induction of labour undertaken. A stillborn female (birth weight 1 395g) was born after a short labour. The autopsy reported an infant with moderate skin maceration and blistering. Weight and measurements were equivalent to 31 weeks. The infant had no dysmorphic features but the placenta showed extensive infarction. All maternal pathology investigations were normal.

A detailed description of each of the eight perinatal deaths can be found in Appendix 9.

5.8 Discussion

The results suggest that this collaborative model of continuity of care can result in satisfactory clinical outcomes for women. Fewer women in the STOMP group were admitted to hospital in the antenatal period, although the numbers of complications were similar between the groups. STOMP women were less likely to have electronic fetal monitoring in labour or to have a caesarean section. Fewer STOMP neonates were admitted to the SCN although this was not statistically significant. There were four perinatal deaths in each group, however the study had insufficient power to test differences in this outcome. STOMP women were more likely to leave hospital early and have domicillary midwifery follow up at home.

5.8.1 Intervention rates

While the caesarean section rate in the STOMP group is reduced, the 95% confidence interval of the OR is close to 1. The upper limit of this confidence interval suggests that a 10 per cent reduction in caesarean section rate is possible while the lower limit suggests that a 50 per cent reduction is possible. These are important clinical differences with implications for health services and women. It is possible that the reduced caesarean section rate is due to the difference in previous caesarean section rates in the baseline characteristics. However, a logistic regression analysis controlling for previous caesarean section and other factors, indicated that the STOMP model did influence the rate of caesarean section.

The baseline difference in previous caesarean section was unexpected. While the random allocation schedule was stratified for parity, in future research it may be necessary to stratify for previous caesarean section as well to ensure the equal distribution of this characteristic.

It is also possible that the reduced caesarean section rate is a result of the research process rather than the model per se. The primary outcome measure was not included in the consent forms and women were not aware that this was an outcome that was being carefully monitored. STOMP midwives and the obstetrician and registrars involved were aware that caesarean section rate was an important outcome of the study. This may have impacted on their usual practice.

The reduction in the rate of elective caesarean section may have occurred because of the nature of the relationship that the STOMP women developed with their midwives and obstetrician. The clinicians (midwives and doctors) who provided STOMP care believed that the consistent relationship developed with women during the antenatal period encouraged women to attempt a labour rather than elect surgery. Clinicians also felt that women were more confident to undertake trial of labour because they would have a STOMP midwife providing care during labour. The collaboration between midwife and obstetrician may have also increased the confidence of women and encouraged them to attempt a labour.

While continuity of care may have affected elective caesarean section rates, more women in the STOMP group underwent an IOL, and more (although the numbers are small) requested an IOL in the absence of medical indications. It is possible that the

relationship STOMP women had with their clinicians made them more able to request an IOL and in turn, it was more likely to be fulfilled and documented as such. The obstetrician, who provided most of the obstetric care in STOMP, is an advocate of IOL as a woman's choice as evidenced in a recent publication (Homer & Davis 1999). This philosophy probably also impacted on the rate of IOL and more accurate documentation of the indication for the IOL. Conversely, it is possible that control group women felt less able to make such a request for an IOL, or, their clinicians were less likely to document 'woman's request' as the indication for IOL.

The reduction in the rate of emergency caesarean section (although slight) might be attributable to continuity of midwifery care during labour and also the reduced use of electronic fetal monitoring, a known risk for caesarean section (Thacker & Stroub 2000). However, other expected differences in clinical outcomes during labour due to the STOMP model (for example, less induction or augmentation of labour and reduced use of epidural analgesia) were not found. Differences in caesarean section rates have not been demonstrated in other trials of continuity of midwifery care although other outcomes, like epidural analgesia and induction of labour, have been reduced in the continuity of care groups (Waldenström & Turnbull 1998). The reasons why some outcomes are similar (or even increased) between the groups, while the caesarean section rate is reduced in the STOMP group, are unclear.

The study had adequate power to detect clinically important differences in the caesarean section rate. It did not have sufficient power to detect differences between elective and emergency caesarean section rates individually. This limitation means it is difficult to examine differences between the types of caesarean section. Results can only be suggestive. Further research needs to be conducted in this area to understand more about the impact of continuity of care on elective and emergency caesareans and the factors that contribute to these interventions.

The STOMP model was trialed in a sample of non-insured women. It is unknown what effect the model would have on the caesarean section rate in privately insured women. Discussions are being held with the aim of implementing and evaluating a similar model in a private hospital in Sydney.

5.8.2 Transfer to standard care

The collaborative model of care meant that women did not need to be transferred to the standard model of care if they developed pregnancy-related complications. Nearly all women in the STOMP group who developed complications (n=154, 28%) were able to continue to receive antenatal care in the community-based setting. Only a small proportion of women from each group (2 per cent) were transferred to the RAP team which catered for women at risk. The collaborative approach also meant fewer antenatal women were admitted to hospital despite very similar rates of pregnancy-related complications.

Other models of maternity care, catering for low risk women, have transferred women to standard care when complications arose. In the study by Turnbull et al (Turnbull et al 1996), almost one third of women were permanently transferred from midwife-managed care, mainly for clinical reasons. The birth centre trial in Sweden also had high rates of transfer to standard care: 13 per cent antenatally and a further 19 per cent during labour (Waldenström et al 1997). It is possible that these high rates of transfer to standard care in these studies meant that clinical effects were diluted.

5.8.3 Perinatal mortality and morbidity

The perinatal mortality rate of 7.3 per 1 000 births reported in this trial is comparable with other Australian data. In 1996, the perinatal mortality rate in Australia was 8.5 per 1 000 births (Day et al 1999b). In New South Wales, during the period 1993-97, the rate ranged from 8.8 to 9.6 per 1 000 births (NSW Health Department 1998a).

All perinatal deaths were reviewed independently. Most of the deaths occurred prior to the onset of labour. The one death assessed to be 'potentially avoidable' was due to undiagnosed intrauterine growth retardation. However, the measurement of symphysiofundal height is not an accurate predictor of intrauterine growth retardation (Weiner 1994). From the clinical measurements documented it would appear that fetal growth was occurring throughout the pregnancy. It is likely that the course of the pregnancy, and the eventual outcome, would not have been any different if this woman had received standard care.

While there were equivalent numbers of perinatal deaths in each group in the STOMP study, it is still not possible to make definitive assertions about the impact of this model

of care on perinatal health. A trial with a sample size in the order of 10 000 would probably be needed to show a difference in perinatal mortality between the models of care. Waldenström and Turnbull's (Waldenström & Turnbull 1998) systematic review of continuity of midwifery care trials, which included 9 148 women, showed a difference in perinatal mortality bordering on statistical significance (OR 1.6; 95% CI 0.99 to 2.59). The authors acknowledge that this result may have been due to insufficient power or related to the inconsistent definitions of perinatal death used across the trials.

Continued monitoring and evaluation is necessary in any model of care, whether new or established. The ongoing multidisciplinary peer-review process needs to continue in order to ascertain contributing factors in the case of perinatal deaths. Further research and inclusion of all trials of new models of midwifery care in a subsequent systematic review are necessary to ensure that women are not exposed to unnecessary risk.

5.8.4 Admission to SCN

In the study, more neonates in the control group were admitted to the SCN. This was not statistically significant, however the admission rates of 14.5 in the STOMP group and 18.9 per cent in the control group are of concern. Similar trials have reported mean admission rates of 6.1 per cent in continuity of care models and 8.9 per cent in standard care (Waldenström & Turnbull 1998).

The higher rates of SCN admission in the control group are related to the higher rate of caesarean section. It is questionable whether in the absence of other complications or morbidity, caesarean section is an appropriate indication for admission to SCN. If this was the case we will expect to see spiraling rates of admission to SCN with the increasing caesarean section rate. It is possible that a low threshold for transfer to SCN may exist, probably enhanced by the close proximity of the delivery suite to the SCN and by protocols which do not discourage transfer. Admission rates may also reflect the range of obstetric risks in the sample. Nonetheless, the admission rate is too high. Unnecessary separation of mother and baby has been reported to contribute to a delay in the establishment of breastfeeding (Klaus & Kennell 1982) and has cost implications for health services. The cost analysis presented in Chapter 8 highlights the substantial costs associated with SCN admission.

5.9 Summary

This chapter presented evidence suggesting that caesarean section, while considerably safer than in the past, is an intervention that still carries risk and should be used judiciously. A number of factors contribute to the rising caesarean section rate in many countries, including risk status, socio-economic status, private health insurance and the obstetricians' fear of litigation. Some women indicate a personal preference of elective caesarean section rather than vaginal birth, although the proportion in this study was small. The personal and economic costs associated with caesarean are not inconsequential. These include: maternal and neonatal morbidity; social and emotional costs; separation from the baby; and, the delayed return home. Economic costs are discussed in Chapter 8.

Continuity of midwifery care has been suggested as a means to improve the clinical outcomes for women. The STOMP study hypothesised that a community-based continuity of care model provided collaboratively by midwives and obstetricians would reduce the overall caesarean section rate. The results from the clinical aspect of the study suggest that the STOMP model can decrease the caesarean section rate. Most women who developed complications during pregnancy were managed in a community setting and did not require transfer to standard care. These issues will be discussed again in Chapter 10. Chapter 10 also considers the implications that this research has for maternity care in Australia.

Chapter 6 presents the experience of women who received antenatal care in the community-based clinics (the STOMP model) compared with standard care in a hospital-based setting.

Table 5.8: Perinatal mortality review of the eight perinatal deaths that occurred in the study.

Case	Group	Gestation	Stillbirth (SB) or neonatal death (NND)	Timing	Reason for death (Whitfield et al 1986)
1	STOMP	36	SB	Pre labour	Intrauterine growth restriction: placental pathology.
					Potentially avoidable (possibly small at 31-34 weeks whivh was not detected)
2	STOMP	31	SB	Pre labour	Non-immune hydrops: fetal abnormality cardiovascular system.
					Unrelated to the model of care received
3	STOMP	40	SB	Pre labour	Unexplained.
					Unrelated to the model of care received
[a]4	STOMP	40	SB	Intrapartum	Intrapartum asphyxia.
					Unrelated to the model of care received
5	Control	39	SB	Unknown	Unexplained.
				?pre-labour	Unrelated to the model of care received
6	Control	23	NND	12 hours	Preterm labour (possibly cervical incompetence).
					Unrelated to the model of care received
7	Control	21	SB	Unknown:	Antepartum haemorrhage: abruption.
				?pre labour	Unrelated to the model of care received
8	Control	40	NND	12 hours	Acute chorioamnionitis and E coli pneumonia.
					Unrelated to the model of care received

[a]Case 4 was a woman who was offered STOMP care but chose to receive standard care through the antenatal clinic. An independent obstetrician, who was blinded to the women's allocated group, undertook the review. The purpose of the review was to determine whether the care received contributed to the death.

Chapter 6 The experience of community-based antenatal care compared with hospital-based care

6.1 Introduction

This chapter outlines the influences that contribute to women's dissatisfaction with antenatal care. The STOMP model was designed to provide an improved antenatal service for women by locating antenatal care in the community and providing continuity of care and carer. This chapter presents the findings from the questionnaires that addressed women's experiences with antenatal care.

6.1.1 Dissatisfaction with antenatal care

Most antenatal services in the Australian public health system are provided in hospitals. Women are seen by a variety of clinicians, including: midwives; obstetricians; junior medical staff; and, midwifery and medical students. Criticisms of hospital antenatal clinic services in Australia and elsewhere are common and were discussed in depth in Chapter 2. Briefly, the criticisms include prolonged waiting times, lack of continuity of care, conflicting advice and rushed staff (Laslett et al 1997; NSW Health Department 1989; Senate Community Affairs References Committee 1999; Victorian Department of Health 1990; Williamson & Thomson 1996). Women have also reported dissatisfaction when their 'worries are not taken seriously' (Laslett et al 1997). Length of the antenatal visit is another factor that predicts dissatisfaction. Dye and Woitowycz (Dye & Wojtowycz 1999) reported women's satisfaction with antenatal care decreased as the time they spent with care givers was reduced. Practical problems, for example, difficulty in finding a place to park the car around the hospital, also contribute to dissatisfaction with antenatal care (Everitt et al 1995).

6.2 Women's experiences of STOMP care in the antenatal period

Many of the factors that contribute to dissatisfaction were considered during the development and implementation of the STOMP model. The STOMP model aimed to improved the experiences of women with antenatal care. A number of elements were included in order to achieve this aim. For example, women were given specific appointment times with 20 minutes allocated for each appointment. It was hoped that

this would reduce waiting time and would mean that midwives did not feel rushed and could provide adequate support and reassurance for women. The six team midwives were divided into two groups to increase the probability of receiving continuity of carer. Community-based clinics were located near to car parking and public transport to reduce practical difficulties with access to care.

The experiences of women who received the STOMP model of antenatal care were compared with the experiences of women who received standard care. The question was:

- Are community-based antenatal services, established as an outreach of a teaching hospital, associated with a better experience for women?

'Better experiences' included reduced waiting time, easier access to the clinic and a higher perceived quality of care. Variables of interest included the type of antenatal care, number of visits, waiting time for appointments, perceived quality of care, ease of access, continuity of carer and worry, unhappiness and potential for antenatal depression.

6.3 Methods

The study design, sample size calculation, method of random allocation, outcome measures, data collection method and distribution and return of questionnaires are described in Chapter 4. Chapter 4 also described the recruitment and consent rates of participants (Figure 4.1, page 66).

6.3.1 Data collection

The model of antenatal care women received and the number of antenatal visits were ascertained from the audit of antenatal records. Other data were collected from the questionnaires.

6.3.2 Analysis

The first analysis examined differences between responders and non-responders to the questionnaire. Chi-squared tests were used for categorical data (nulliparity, language, need for interpreter, residential area and allocated group). Student t-tests were used for continuous data (age, gestation at completion of questionnaire, mean number of antenatal visits).

Chi-squared tests were then used to examine differences between the allocated groups in waiting time, acceptability and the suitability of the clinics. Two questions were used to assess transport and parking issues at antenatal visits. Responses rated the journey from being 'very easy' to 'very difficult, and rated the ease of finding a car park from being 'easy' to 'very difficult'. These ratings were added together to give a 'difficulty of access to antenatal care' score. Questions, relating to the number of midwives and medical carers seen, were measured as continuous responses. Six questions, relating to the perception of the quality of antenatal care received were added to give a continuous score that reflected this perception. These two continuous responses were analysed using t-tests. Women were asked what option of care they would choose in any subsequent pregnancies. This is reported using descriptive statistics. Women who responded that they 'did not plan any further pregnancies' were excluded from this analysis.

The Worry Scale (Stratham et al 1997) was used to assess the level of worry and represented continuous data. The EPDS (Cox et al 1987) was analysed in two ways. Firstly, as a categorical measure of screening for depression, with the threshold at greater than or equal to 14.5 (Pope et al 1999). Differences between allocated groups were examined using a chi-squared test. Secondly, the EDPS was used as a continuous measure of 'unhappiness'.

The final question elicited open-ended responses. Where necessary, these were translated into English and recorded verbatim. A simple content analysis was performed to categorise the responses. Examples from the open-ended responses are presented with the relevant sections in the chapter (study numbers are presented). Open-ended responses are presented as a percentage of respondents to the questionnaire.

Not all women responded to each question in the questionnaire. This means that the denominator varies on some percentages.

6.3.3 Sample

Eighty-six per cent of women returned antenatal questionnaires, 412 (91 per cent) from STOMP and 401 (81 per cent) from the control group (Table 4.5, page 77). The mean gestation at completion of antenatal questionnaires was 36 weeks for both groups (min-max 25-42). One hundred and ninety-nine women in the STOMP group (48%) and 136 control women (34%) in the control group responded to the open-ended question.

Chapter 6: Experiences of antenatal care

Women who completed the antenatal questionnaire were more likely to be nulliparous, not require an interpreter and attended more antenatal visits than those who did not complete questionnaires. There were no significant differences between responders and non-responders in group, age or residential area. Slightly more English-speaking women returned questionnaires, however this was not statistically significant (Table 6.1).

Table 6.1: Characteristics of responders to antenatal questionnaire compared with non-responders.

		Responder n=811 Number (%)	Non-responder n=278 Number (%)	p[a]
Mean age [SD]		27.9 [5.3]	28.3 [5.5]	0.3
Parity	Nulliparous	398 (49.0)	103 (37.3)	0.001
	Multiparous	415 (51)	173 (62.7)	
Allocated group	STOMP	412 (50.7)	138 (50.0)	0.8
	Control	401 (49.3)	138 (50.0)	
Residential area	Rockdale	472 (58.1)	162 (58.7)	0.9
	Hurstville	341 (41.9)	114 (41.3)	
Primary language	English	405 (49.8)	112 (40.6)	0.07
	Chinese	131 (16.1)	52 (18.8)	
	Arabic	123 (15.1)	50 (18.5)	
	other	154 (18.9)	61 (22.1)	
Interpreter needed	yes	162 (19.9)	72 (26.1)	0.03
	no	651 (80.1)	204 (73.9)	
Mean number of antenatal visits [SD]		8.2 [2.4]	6.9 [2.8]	<0.001

[a]Differences in parity, allocated group, residential area, primary language and interpreter need were examined using a χ^2 test. Independent sample t-tests were used to examine differences in age and number of antenatal visits.

6.4 Results

6.4.1 Antenatal care

Eighty-seven per cent of women allocated to the intervention group received the STOMP model of care in the community and sixty-two per cent of women allocated to the control group received antenatal care in the hospital antenatal clinic. Women who refused the offer of STOMP care choose to attend the antenatal clinic (8%) with a smaller proportion attending the birth centre (2.5%), GP shared care (1.5%) or the midwives clinic (0.5%). Table 6.2 illustrates the model of antenatal care received by women.

Table 6.2: Type of primary antenatal care received by allocated group.

Primary antenatal care	STOMP group[a] n=550 Number (%)	Control group[b] n=539 Number (%)
STOMP clinic	481 (87.5)	2 (0.4)
Hospital antenatal clinic	44 (8)	335 (62.2)
Birth centre	14 (2.5)	53 (9.8)
Midwives Clinic	3 (0.5)	67 (12.4)
GP Shared Care	8 (1.5)	90 (16.7)
Total	550 (100.0)	539 (100.0)

[a]Women allocated to the STOMP group but who refused the offer of STOMP, were able to choose from the standard care options available. [b]Two women in the control group received STOMP care. This was an unintentional protocol violation.

Sixteen per cent (n=93) of women who attended STOMP also chose GP shared care in combination with STOMP, which meant antenatal visits were shared between the STOMP clinic and the GP.

6.4.2 Number of antenatal visits

STOMP women attended one more antenatal visit than control group women (Table 6.3).

Table 6.3: Number of antenatal visits recorded on the antenatal record.

	STOMP	Control
	n=549 [a]	n=531 [a]
Mean number of visits [SD]	8.3 [2.2]	7.4 [2.8]
Median number of visits	9	8
Min-max	1-16	1-15

[a]Antenatal cards were unavailable for 8 women (one STOMP and seven control). An independent samples t-test was used to compare the allocated groups: t(1079)=5.9, p<0.0001.

6.4.3 Waiting time for antenatal appointments

Women in the STOMP group reported that they waited less time for antenatal appointments. Eighty per cent of STOMP women reported waiting less than 15 minutes compared with twenty-three per cent of women in the control group (Table 6.4).

Table 6.4: Waiting time for antenatal appointments by allocated group.

	STOMP	Control
	n=412	n=397
	Number (%)	Number (%)
Less than 15 minutes	332 (80.6)	90 (22.7)
15 to 30 minutes	74 (18.0)	137 (34.5)
30 to 45 minutes	4 (1)	82 (20.7)
Greater than 45 minutes	2 (0.5)	88 (22.2)

A χ^2 test was used to examine differences between the groups: $\chi^2(3)=310$, p<.0001.

Women were asked if the waiting time was acceptable. Three quarters of STOMP women (n=306) reported that it was 'always acceptable' compared with just over one quarter of control women (n=110). Only six per cent of STOMP women (n=25) felt the waiting time was 'occasionally or never' acceptable compared with almost one third (30%) (n=119) of control women ($c^2(1)=77.8, p<.0001$).

Nineteen STOMP women (5%) made direct comments about the reduced waiting time and increased convenience. All these comments were positive, for example:

During my pregnancy, I felt very good. Every time I went to the clinic I didn't need to wait a long time. Compared to hospital. It is much better (#2059).

Appointments are always on time and you never feel have to hurry (#2158).

I've found the community clinic to be very convenient for me. There is less waiting time than hospital clinics and all midwives are very friendly and make you feel at ease (#1189).

Antenatal care has been great. It's been quick and easy without waiting for hours (#2004).

In contrast, there were no positive comments about waiting time from the 16 control women (4%) who made comments about this aspect of care, for example:

The waiting time bothers me sometimes (#2218).

If you have an appointment at a certain time, it would be more appreciated if we were seen at that preferred time especially if our husband are with us they become very impatient in the waiting period and don't become encouraged to come along again due to long waiting time (#2461).

6.4.4 Access to antenatal care

Women in the STOMP group reported that access to antenatal care, in terms of transport and car parking, was easier (*t (636)=13.6, p<.0001*). Women in the STOMP group were also more likely to find the times and days of the community-based antenatal clinic suitable than did control group women. Three quarters (n=306) of the STOMP group reported that "all the times and days were convenient" compared with just over half (n=229) of the control group (*c^2(2)= 25.1, p<.0001*).

Only one STOMP woman (0.2%) made a negative comment about access:

Parking is very hard to get. Please convey to the government as to the importance of this (# 1362).

Six control women (1.5%) commented on the lack of parking at the hospital. These comments were all negative, for example:

Parking is a problem because it is very hard to find two hour parking so that I can wait until I am seen by the midwife/doctor (#2038).

Parking [is] an absolute horror (#2195).

6.4.5 Quality of antenatal care

STOMP women reported a higher 'quality' of antenatal care compared with control women. The mean 'quality of antenatal care' score for STOMP women was 28.9 [*SD 3.6*] compared to 26.4 [*SD 4.2*] for control women (*t (595)=8.1, p<.0001*). 'Quality' included: having adequate time to ask questions and to seek advice; obtaining reassurance and emotional support; and, having midwives and doctors who listened, explained issues and remembered women from one visit to the next.

One hundred and sixty-six women from the STOMP group (40%) expressed this perceived quality of care in their comments, for example:

[STOMP] clinic is an excellent program and hope it will continue indefinitely. The midwives are very caring, treat you as an individual and make you feel your pregnancy is special. They are very informative, enthusiastic, good listeners. After the long waits at the hospital and being one of 30-40 women waiting, it is nice to be treated so well (#1004).

Throughout my pregnancy I've found the midwives at [STOMP] clinic to be exceptionally well informed & most supportive. It has been a pleasure to take part in the STOMP program & I wouldn't hesitate participating again in future pregnancies (#1202).

I am really enjoying the STOMP program. What I like most: short waiting period, child friendly waiting room (ie toys), more personalised care – feel more like a person and less like a "number". As I had my previous child at the hospital antenatal clinic, I can compare the two and I would definitely do this program again. Keep up the good work (#2521).

Seventy-eight women from the control group also expressed satisfaction with their care (19%) for example:

I am very grateful to your hospital's enthusiasm and antenatal care. Every midwife and doctor is so careful, very detailed in caring which make me feel very relieved before the baby is born (#1581).

For a hospital under such demand for antenatal care – who can complain. Well done to the ever patient midwives. This is my second pregnancy and have returned with no hesitation that myself and my baby will be well cared for (#2578).

Thirteen of these positive comments from the control group were from women who attended the birth centre, for example:

Decided to go to birth centre and were much happier. All midwives we saw were pleasant and we never felt rushed or anxious about going to appointments (#1228).

The midwives at the birthing centre have been very helpful with information and have encouraged my questions. I have been able to make appointments at times which suit me and have not had to wait long at all for my appointment (#1446).

There were no positive comments made about GP shared care.

Women in both STOMP and control groups made negative comments or stated some form of dissatisfaction about their care. More control women made negative comments. Seven STOMP women (2%) made comments like:

Why don't I ever see a doctor? (#2350).

Weekly appointments after week 36 would be good. This is standard procedure and gives us security (#1123).

Seventeen control group women (4%) responded negatively, including comments like:

I was treated like another number. I'd like to be told about my condition at the checkup instead of interpreting what is being written on the yellow card. This is vital for peace of mind (#1587).

The hospital lost my record twice and made me feel very anxious I was made to wait longer and longer to see a doctor & also made me feel very uncomfortable and anxious at each antenatal checkup (#2431).

6.4.6 Continuity of care and carer

STOMP women reported 3.7 [*SD 1.2*] midwife carers in the antenatal period compared with the control group who reported 3.2 [*SD 1.9*]. STOMP women reported seeing less doctors in the antenatal period (*1.5 [SD 1.1] versus 2.1 [SD 1.5*]).

Most women reported that it was important for them to see the same person or people (that is, continuity of carer) at each antenatal visit. This was significantly more important for women in the control group than the STOMP group (Table 6.5).

Table 6.5: Importance of continuity of carer during antenatal care by allocated group.

	STOMP group n=406 Number (%)	Control group n=394 Number (%)
Yes, it is important	222 (54.7%)	253 (64.2%)
No, it is not important	28 (6.9%)	31 (7.9%)
Does not matter	156 (38.4%)	110 (27.9%)

A χ^2 test was used to examine differences between the groups: χ^2 (2)=9.9, p=0.007.

Five STOMP women (1%) expressed concern in their written comments about meeting too many midwives antenatally and not developing a relationship with one or two of them. For example:

> The team of midwives have been very helpful to me and have given the support and assurance needed. The only problem is having different ones every few weeks. I can't seem to feel as though I am developing a rapport with one of them due to constant swapping. I want to feel comfortable with the midwife during labour and know her well (#1501).

> Would have liked to establish a relationship with all staff or else consistent one or two [midwives]. It felt strange meeting once here or there (#1491).

Two STOMP (0.5%) women expressed ambivalence between antenatal continuity of carer and planning for a known midwife in labour, for example:

> It would be nice to see the same person but it is also good to know everyone before you go into labour (#1392).

Ten control group women (2%) expressed a desire for continuity of care. For example:

> I would like to have the same doctor or the same midwife. This would help understand my progress better (#1291).

All the midwives I had met had been nice and friendly, but still I think it is very, very important to be able to meet just the same midwife during the whole pregnancy/ visits (#2548).

My midwife was great! I just wish my midwife could be there for me when labour begins to deliver the baby. I would feel much more comfortable and safe with her being with me (#1519).

6.4.7 Antenatal worry and depression

Independent samples t-tests were used to examine differences between the allocated groups in levels of worry and unhappiness. Control women expressed significantly more worry than STOMP women did (*t (742)= -2.1, p=0.03*). There was no significant difference in level of unhappiness between the allocated groups (Table 6.6).

Table 6.6: Mean levels of antenatal worry and unhappiness by allocated group.

	STOMP	Control	p[c]
	mean [SD]	mean [SD]	
Antenatal worry[a]	45.2 [15.1]	47.6 [15.2]	0.03
Antenatal unhappiness[b]	8.4 [5.2]	8.7 [5.5]	0.5

[a]Antenatal worry was measured using the Cambridge worry scale. [b]Antenatal unhappiness was measured using the total score from the EDPS. [c]Independent sample t-tests were used to examine differences between groups.

Furthermore, there was no significant difference in the number of women who scored above the antenatal screening cut-off on the EDPS. Twelve per cent (n=49) of women in the STOMP group and sixteen per cent (n=59) of women in the control group scored above the threshold for depression. A chi-squared test showed that this different was not statistically significant (*c^2 (1)=1.8, p=0.2*).

6.4.8 Preferred model of care in a subsequent pregnancy

Twenty-seven per cent of women in both groups (STOMP n=110; control n=107) stated that they had 'no further pregnancy planned'. These women were excluded from further analysis on this question. Seventy-seven per cent of women in the STOMP group reported that they would choose STOMP care for a future pregnancy. Only 30 per cent

of women in control group reported that they would choose antenatal clinic care. (Table 6.7).

Table 6.7: Preferred model of care in a subsequent pregnancy by allocated group.

	STOMP n=291[a] Number (%)	Control n=280[a] Number (%)
Hospital antenatal clinic	17 (5.8)	84 (30.0)
Midwives' clinic	33 (11.3)	117 (41.8)
Shared care with GP	17 (5.8)	71 (25.4)
Community-based care (STOMP)	224 (77.0)	8 (2.9)
Total	291 (100.0)	280 (100.0)

[a]Women who stated that they had no further pregnancy planned were excluded from this analysis (STOMP n=110; control n=107). A χ^2 test was used to examine differences between groups: $\chi^2(3)=325$, $p < 0.0001$.

6.5 Discussion

The findings presented in this chapter suggest that women who attended community-based antenatal clinics staffed by known midwives and an obstetrician had positive experiences. Women attending the STOMP clinics waited less time for their appointments, had improved access to antenatal care, worried less about their babies and perceived that their antenatal care was of a higher quality than women attending standard hospital-based services. Quality of care included being listened to, having adequate time to discuss concerns and problems, receiving enough information and advice and receiving emotional support. These are all factors that have been identified as being determinates of satisfactory antenatal care (Brown & Lumley 1994; Green et al 1998a; Hirst et al 1998; McCourt et al 1998; MORI (Market and Opinion Research International) 1993; Proctor 1998; Wilcock et al 1997).

6.5.1 Number of antenatal visits

Control women had fewer antenatal visits. This is likely because a greater proportion of women in the control group chose GP shared care. The overall number of antenatal

visits per woman is lower than most antenatal visit schedules. Antenatal visit schedules refers to the number and timing of antenatal visits throughout the pregnancy. Australian research has reported that most Victorian hospitals specify 13 antenatal visits, assuming the baby is born at term (Brown et al 1999). In the UK, the traditional schedule seems to be similar. Skiroski et al's (Sikorski et al 1996) study of reduced visits compared the traditional schedule of 13 visits with a schedule of seven visits for nulliparas and six for multiparas. Following the Sikorski et al (Sikorski et al 1996) study, the St George Hospital implemented a slightly reduced schedule of visits for multiparas (10 visits) that was essentially tailored towards the needs of the woman. This schedule has not been tested but has operated for more than three years with no apparent adverse consequences. The antenatal visit schedule at St George Hospital may partially explain the reduced number of visits in both the STOMP and control groups.

The use of GP shared care may have also impacted on the number of antenatal visits recorded in medical records. Women did not carry their entire medical record, which meant GPs were not able to record antenatal visits on the hospital record.

6.5.2 Continuity of care and carer

STOMP women reported seeing more midwives than those who attended standard hospital-based care despite the model being designed to improve the probability of receiving continuity of midwifery carer. Women in the control group saw less midwives because they saw more doctors. The fewer doctors seen by STOMP women is because there was usually only one obstetrician or obstetric registrar at the clinic and women were only reviewed by the obstetrician when necessary. In the hospital-based clinic, women were more likely to be reviewed by a number of obstetricians and obstetric registrars at antenatal visits.

In designing STOMP, we had to decide between either providing continuity of midwife carer during the antenatal period with possibly, an 'unknown' midwife at the birth or providing continuity of care antenatally with a higher probability of continuity of carer during labour. The STOMP model was ultimately designed to provide continuity of carer during the antenatal period whereas previous models in Australia (Kenny et al 1994; Rowley et al 1995) had aimed towards the continuity of care during this time. The mean number of midwives seen by women in the STOMP group was 3.7. This was slightly higher than hypothesised (2-3), although less than in previous models of continuity of

care. Kenny et al (1994) reported that each woman saw a mean of 5.5 different midwives during the antenatal period. Despite the higher than expected number of midwives, women in the STOMP group reported positive experiences. Only a small proportion of women in the STOMP group (1%) wrote comments about their dissatisfaction with seeing a number of midwives in the antenatal period.

More than one third of STOMP women reported that seeing the same person at most of their antenatal visits "did not matter". For these women, continuity of carer was possibly less important than a 'good' midwife who listened and was knowledgeable and supportive. It is possible that small teams of midwives make it easier to support, facilitate and develop the factors that exemplify 'good' midwifery. Models of care, like STOMP, may be a strategy to provide women with effective and satisfying antenatal care without the emphasis being placed on 'knowing' the midwife in labour.

6.5.3 Community-based care

In the UK, community-based antenatal services provided by GPs and midwives are common, whereas in Australia this system is uncommon. There has been anecdotal concern in Australia that community-based services (provided by hospital-based midwives) would impinge on the traditional domain of GPs. Hospital-salaried midwives providing antenatal care in the community could be in direct competition to GPs who currently provide antenatal care. Direct competition may result in financial losses for GPs.

Fleissig et al (Fleissig et al. 1997) evaluated the impact of a new model of community-based maternity care on GPs. Most GPs who responded to this research were satisfied with the new arrangement with only a minority feeling that their workload, clinical practice or communication with obstetric teams, including midwives, had altered. While the STOMP study did not evaluate the impact on GPs (professionally or financially), our experience suggests that there were no major consequences of the STOMP model on GPs. Women were able to choose GP shared care and their decision was supported and encouraged. For example, 16 per cent of women in the STOMP group chose GP shared care in addition to STOMP care. General practitioners were involved in many of the early discussions about the STOMP model. A GP representative was on the Steering Committee that guided all the projects in the maternity unit. Regular

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presentations were made at GP meetings and articles were placed in the GP newsletter.

Research will need to be conducted into the impact on GPs if models such as STOMP are to be widely implemented. GPs fulfil an important role in women's and family health issues and should not be alienated during childbearing. An exploration of new models of care where midwives and GPs work more closely together, as has occurred in the UK, may reduce some of the concerns related to GP shared care (Brown et al 1999). A model of community-based antenatal care was unsuccessfully attempted in Sydney in the early 1990's (Jones 1999). Perhaps it is now appropriate to test a new model of antenatal care where midwives and obstetricians (who are funded by the hospital) provide care in collaboration with GPs.

6.5.4 Preferred model of care in a subsequent pregnancy

Sixty-two per cent of women in the control group chose to attend the hospital antenatal clinic, staffed by midwives and doctors. When women in the control group were asked to nominate their preferred model of care in a subsequent pregnancy, 30 per cent nominated the hospital antenatal clinic and 42 per cent nominated the midwives' clinic. Seventy-seven per cent of women in the STOMP group nominated the STOMP clinic as their preferred option with a further 11 per cent nominating the midwives' clinic. These findings suggest that many women find that midwives provide acceptable care. This study and others (Giles et al 1992) suggest that the care they provide is well liked and leads to comparable outcomes.

6.6 Summary

This chapter has discussed the main factors that lead women to express dissatisfaction with antenatal care and has highlighted the strategies that have been shown to improve the experience for women. Continuity of care, choice of type of care and place of delivery, and the right to control over their bodies at all stages of pregnancy and birth are the important aspects that contribute to increased women's satisfaction. Prolonged waiting times, rushed caregivers and conflicting advice are determinates of dissatisfaction.

The STOMP model was designed to address some of these issues. The antenatal service was located in the community close to transport and parking facilities. Women

were given specific appointment times and had 20 minutes allocated to each visit. Midwives were arranged in small groups to provide continuity of carer. Results from the women's antenatal questionnaires show that a community-based antenatal service is accessible, convenient and women believe they receive a higher quality of antenatal care compared with women who received standard care. Whilst continuity of carer was not achieved to the extent anticipated, the ability to provide more woman-focussed care (for example, informed, supportive and personalised care) seems to have been enhanced. Locating services in the community eases transport and parking difficulties and results in reduced waiting times. These issues will be discussed again in Chapter 10 along with the implications of this research on Australian maternity care.

Chapter 7 compares and contrasts women's experiences of the STOMP model of care with standard care during labour, birth and the postnatal period.

Chapter 7 Experiences of care during labour, birth and the postnatal period

7.1 Introduction

The STOMP model was designed to improve the experience of labour, birth and the postnatal period. This chapter presents the results of the questionnaire that asked women about their experiences of during labour, birth and postnatal period.

7.1.1 Dissatisfaction with care during labour, birth and the postnatal period

A positive experience during childbirth seems to be determined by: the nature and quality of information (Fleissig 1993; Waldenström & Nilsson 1993); the amount of control over care (Hundley et al 1997); (Green et al 1990); and, the existence of a trusting relationship with midwives (Tinkler & Quinney 1998). The opportunity to 'have an active say in decisions made during labor and birth' and having caregivers during labour who are perceived as helpful have been identified as important factors in positive experiences during labour (Brown & Lumley 1998; 1994). Obstetric intervention predicts a negative childbirth experience (Brown & Lumley 1994); (Seguin et al 1989); (Jacoby 1987). Continuity of care and carer during labour are also linked with positive experiences. Chapter 2 (see page 23) has described some of the dilemmas between providing continuity of carer over consistency of care.

Postnatal care is also an important component of care as it impacts on the physical, social and emotional health of women and is another area where negative experiences have been reported. Chapter 2 discussed the influences of dissatisfaction with postnatal care, including: fragmentation of care; conflicting advice; lack of rest; busy, rushed staff; inadequate time to ask questions; and, the provision of inappropriate or non-individualised advice (Audit Commission 1998; Ball 1994; Ball 1989; Cooke & Stacey 2000).

7.2 The experiences of women during labour, birth and the postpartum periods

The focus of STOMP care during labour and birth was continuity of care, although the probability of receiving continuity of carer was higher compared with standard care. It was hoped the relationship that women had with the STOMP midwives would: facilitate

feeling 'in control' during labour; provide a process for having adequate information; and, provide caregivers who were helpful and supportive. It was suggested that the STOMP model would result in reduced obstetric intervention, particularly a reduced caesarean section rate, and that this would contribute to a more positive experience for women. In the postnatal period, women had continuity of care from STOMP midwives both in hospital and at home. It was also hoped that continuity would lead to less conflicting information and more individualised care being provided.

Experiences with the STOMP model for labour and postnatal care were compared with the experiences of women who received standard care. The research question was:

- Did the STOMP model improve women's experiences during labour, birth and the postnatal period?

The hypothesis was that the new model (STOMP), which incorporated continuity of care and of carer, would result in a better experience for women. This better experience would include improved information, an increased opportunity to discuss preferences for childbirth and a higher feeling of personal control during labour. A secondary analysis aimed to identify the important predictors of a positive experience during childbirth. Worry, unhappiness and potential for postnatal depression are also examined in this chapter.

7.4 Methods

The study design, sample size calculation, method of allocation and method of data collection are described in Chapter 4.

7.4.1 Data collection

Data on continuity of <u>care</u>, that is, whether a woman had a STOMP midwife present during labour and birth, were collected from the medical records. The obstetric intervention score (Brown & Lumley 1998) was also obtained from medical records. Other data were collected through a questionnaire mailed to women eight to ten weeks postnatally.

7.4.2 Analysis

The first analysis examined differences between responders and non-responders to the questionnaire. Chi-squared tests were used for categorical data (primiparity, language,

need for interpreter, residential area, allocated group, mode of birth, domiciliary care and breastfeeding on discharge). A Student t-test was used to evaluate continuous data (age).

Women were asked if they had an opportunity to discuss their preferences for labour and birth management. This response represented categorical data and was analysed using a chi-squared test. Eight questions related to having adequate knowledge about eight aspects of labour and birth (including, analgesic option, induction of labour, caesarean section and looking after a new baby). Chi-squared tests were used to examine differences between groups. The eight items were also added together to obtain a 'need for more knowledge' score which was a continuous measure. This measure was reserved to represent 'adequate knowledge' and was used in a linear regression to estimate predictors of a better experience and 'control' during labour. 'Control' during labour and birth and the 'rating of childbirth experience' were measured as continuous responses and again analysed using independent sample t tests.

A number of questions examined the experience of continuity of carer in labour. These were measured as categorical responses and analysed using chi-squared tests. The importance of continuity of carer in labour was examined in a secondary analysis. Women were categorised into two groups: continuity of carer in labour and unknown carer in labour, regardless of allocated group. Independent sample t-tests were used to determine the impact of continuity of carer on rating of the childbirth experience and sense of personal control in labour.

Linear regression was used to estimate the most important predictor of a positive experience of childbirth. Covariates in this model included: allocated group; opportunity to talk about preferences; adequate knowledge; sense of control; and, amount of intervention. Linear regression was also used in a secondary analysis to determine the factors that influenced 'control' during labour and birth. Covariates in this model included: allocated group; opportunity to talk about preferences; adequate knowledge; and, amount of intervention.

The Worry Scale (Stratham et al 1997) produced continuous data. Differences between allocated groups were examined using an independent samples t-test. The EPDS (Cox et al 1987) was analysed using two methods. Firstly, as a categorical measure of screening for depression, with the threshold at greater than or equal to 12.5 as

recommended for postnatal women (Boyce et al 1993). A chi-squared test was used to examine differences between groups. Secondly, the EDPS was used as a continuous measure of 'unhappiness' and an independent samples t-test was used.

The final question, where women were invited to write anything good or bad about their maternity care experiences, elicited open-ended responses. Where necessary, these responses were translated into English. A content analysis grouped responses into common themes, for example positive and negative responses about overall care, postnatal care and continuity of care. Examples from the open-ended responses are presented within the relevant sections in the chapter (study numbers are presented with quotes). Open-ended responses are presented as a percentage of total respondents to the questionnaire.

Not all women responded to each question in the questionnaire. This means that the denominator varies for some of the percentages.

7.4.3 Sample

Sixty-nine per cent of consenting women (n=658) responded to the postnatal questionnaire. This response rate was not significantly different between the groups (Table 4.8; page 78). Women responded at a mean of 11.5 weeks postpartum. More than half of the women responded to the open ended question (STOMP=184 [56%]; Control=178 [54%]).

Women who responded to the questionnaire were slightly older on average (by one year), more likely to speak English or Chinese than Arabic or other languages and to not require an interpreter compared with non-responders. Responders were also more likely to be primiparous. There were no differences between responders and non-responders in allocated group, residential area, type of birth, use of domicillary midwifery services and infant feeding on discharge. These findings are displayed in Table 7.1.

Table 7.1: Characteristics of responders to postnatal questionnaire compared with non-responders.

		Responder n=658 Number (%)	Non-responder n=431 Number (%)	p
Mean age [SD]		28.4 [5.3]	27.4 [5.4]	0.003
Parity	Primiparous	336 (51.1)	165 (38.3)	<0.001
	Multiparous	322 (48.9)	266 (61.7)	
Allocated group	STOMP	326 (49.5)	224 (52.0)	0.4
	Control	332 (50.5)	207 (48.0)	
Residential area	Rockdale	370 (56.2)	264 (61.3)	0.1
	Hurstville	288 (43.8)	167 (38.7)	
Primary language	English	337 (51.2)	180 (41.8)	<0.001
	Chinese	120 (18.2)	63 (4.6)	
	Arabic	70 (10.6)	104 (24.1)	
	other	131 (19.9)	84 (19.5)	
Interpreter needed	yes	126 (19.1)	108 (25.1)	0.02
	no	532 (80.9)	323 (74.9)	
Type of birth	Normal	459 (69.8)	317 (73.5)	0.4
	Caesarean	107 (16.3)	62 (14.4)	
	Instrumental	92 (14.0)	52 (12.1)	
Domicillary care	yes	249 (37.8)	178 (41.3)	0.3
	no	409 (62.2)	253 (58.7)	
Infant feeding	BF	566 (86.3)	350 (83.5)	0.2
	Artificial	90 (13.7)	69 (16.5)	

Differences in parity, allocated group, residential area, primary language, interpreter need, mode of birth, use of domiciliary care and infant feeding on discharge were examined using χ^2 tests. Independent sample t-tests were used to examine differences in age.

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7.5 Results

7.5.1 Discussion of personal preferences

A significantly larger proportion of women from the STOMP group reported that they had an opportunity to talk about their preferences for labour and birth (Table 7.2).

Table 7.2: The opportunity to talk about labour and birth preference.

	STOMP n=325 Number (%)	Control n=332 Number (%)
Yes, I talked quite a lot	93 (28.6)	61 (18.4)
Yes, I talked about it briefly	157 (48.3)	132 (39.8)
No, I did not talk about my preferences	19 (5.8)	59 (17.8)
No, I had no preferences	56 (17.2)	80 (24.1)

A χ^2 test was used to examine differences between groups: $\chi^2(3)=33.8$, p<.0001.

7.5.2 Knowledge about labour, birth and a new baby

STOMP women were more likely to report that they knew enough about induction of labour, pain relief, caesarean section, complications in labour and infant feeding compared with control women. There were no significant differences between the groups in their need for knowledge about baby care and the early postnatal period (Table 7.3).

Table 7.3: Aspects of labour, birth and the postnatal period that women wanted more information on by allocated group.

	STOMP n=325 Number (%)	Control n=332 Number (%)	p[a]
Pain relief options	56 (17.6)	107 (33.2)	<0.0001
Induction of labour	116 (36.8)	163 (51.1)	<0.0001
Caesarean section	139 (44)	177 (49.3)	0.009
Complications in labour	154 (48.6)	185 (57.1)	0.03
Events immediately after birth	134 (42)	153 (44.6)	0.18
The first few days after birth	114 (36)	135 (41.5)	0.14
Infant feeding	114 (35.6)	259 (40)	0.02
Looking after a new baby	111 (34.6)	131 (40.2)	0.13

[a]χ^2 tests were used to examine differences between groups.

7.5.3 Continuity of care and carer during labour and birth

The majority of women in the STOMP group (n=435, 79%) had continuity of <u>care</u>, that is they had a STOMP midwife present during labour and birth. Twenty-one per cent of the STOMP group and twelve per cent of the control group had only one midwife care for them throughout labour and birth ($c^2(1)=6.5, p=0.01$).

Sixty-three per cent of women in the STOMP group reported continuity of <u>carer</u> (they had a midwife they considered that they knew) compared with twenty-one per cent of women in the control group ($c^2(1)=120.4, p<0.0001$). Of the control group women who reported continuity of carer in labour, 33 (49%) had attended the hospital antenatal clinic and 16 (24%), the birth centre for antenatal care. Of the women who reported <u>having</u> continuity of carer in labour, most (89%) indicated that they liked this experience. Overall, few women (8%) felt that it 'did not make a difference', although a greater proportion of women who gave this response were from the control group (Table 7.4).

Table 7.4: The opinion of women who reported having continuity of carer regarding whether they valued this experience.

	STOMP n=198[a] Number (%)	Control n=65 [a] Number (%)
Liked continuity of carer	180 (90.9)	53 (81.5)
Did not like continuity of carer	6 (3)	4 (6.2)
Didn't think it made a difference	12 (6.1)	8 (12.3)
Total	198 (100.0)	65 (100.0)

[a]Only women who reported having continuity of carer during labour were included in this cross-tabulation. A Fisher's exact test was used to examine differences between groups, as the observed frequency of one cell was less than 5: Fisher's exact test=4.1, p=0.1.

Of the women reported not having continuity of carer, the majority reported that they would have liked this experience. Around one quarter of women from both groups, indicated that they did not want continuity of carer (Table 7.5).

Table 7.5: The opinion of women who did not report continuity of carer during labour regarding whether they would have liked to have this experience.

	STOMP n=113[a] Number (%)	Control n=241[a] Number (%)
Did not want continuity of carer	32 (27.4)	64 (25.1)
Would have liked continuity of carer	81 (69.2)	177 (69.4)
Total	113 (100.0)	241 (100.0)

[a]Only women who reported not having continuity of carer during labour were included in this cross-tabulation. A χ^2 test was used to examine differences between groups: $\chi^2(1)=0.12$, p=0.8.

Twenty STOMP women (6%) wrote about their positive experience of continuity of carer:

> *It was great to always go to the same clinic with the same six midwives. It was also very good to know the midwife before having the baby (#1162).*

> *Childbirth was a good experience for me, especially since I know the midwives that looked after me, I feel safe and trusted them (#1514).*

Four STOMP women (1%) who had an unknown labour midwife expressed disappointment in their written responses, for example:

> *When I did get into labour to give birth, the midwife "On call" called in sick and a midwife in [the] labour ward delivered my baby. I was disappointed because I was looking forward to [having] a midwife I got to know deliver this baby (#2026).*

One women from the STOMP group (0.3%) was positive about continuity of care, even though she did not 'know' the midwife who provided care:

> *During my labour I hadn't met the midwife that delivered my daughter but she was great! My labour wouldn't have been such a beautiful experience if it wasn't for the [STOMP] midwives - who prepared me very well (#1038).*

Only one STOMP woman (0.3%) expressed disappointment with the known labour midwife:

> *I found the idea of knowing the midwife prior to labour a very good one but would like to be able to choose which midwife I had as the one I had I wasn't the most comfortable with (#1521).*

Seven control women (2%) expressed a desire for fewer midwives antenatally and a known labour midwife, for example:

> *It would have been nice to have been able to see the same midwife every clinic appointment and to have the same midwife attend the birth. Instead I had a different midwife every time which meant a lot of the information given was repeated (#1373).*

> *Generally my care via the hospital was good. I do wish I hadn't seen so many midwives prior to the birth (#1253).*

7.5.4 Sense of control and rating of childbirth experience

An independent sample t-test was used to examine differences in sense of control during labour and rating of childbirth experience by allocated group. STOMP women reported a significantly higher sense of control during labour and birth ($t(608)=2.7$, $p=0.005$). Women in the STOMP group also gave their childbirth experience a higher

rating than women in the control group, although this did not have statistical significance (*t(629)=1.9, p=0.05*).

One hundred and two women in the STOMP group (31%) made positive comments about their care. For example:

> *The STOMP program made a huge difference both before and during the birth of my child (#2333).*

> *The care and help of the midwives before and during the birth of my baby helped make the pain and trauma of giving birth a wonderful experience (#1242).*

> *I feel that the care which I received during my pregnancy and labour was wonderful. All the midwives were extremely supportive and encouraging right up to the day we left the hospital. At all of my visits to the clinic, all of my questions and concerns were fully discussed and I always left feeling reassured and confident (#1275).*

Seventy-two women in the control group (22%) also made positive comments about their care:

> *I would like to thank the maternity ward for all the care and good help they attended to me when required. This has helped make the birth of my baby and recovery of my caesarean a much easier and faster process (#1194).*

> *I found the whole experience very satisfying. A great experience (#1291).*

7.5.5 The impact of continuity of carer on birth experience and sense of control

In a secondary analysis, the experiences of women who reported continuity of carer during labour were compared with those who did not. Women were categorised into two groups: continuity of carer or unknown carer. Independent sample t-tests were used to examine differences in rating of the childbirth experience and sense of 'control' in labour. Women who had continuity of carer during labour had a higher sense of 'control' (*t(628)=3.1, p=0.02*) and a more positive birth experience (*t(607)=2.4, p=0.002*) compared with women who had an unknown carer.

7.5.6 Predictors of a better experience during labour and birth

Linear regression was used to estimate the predictors of a better experience using the rating of childbirth as the dependant variable. Included in the model were: allocated

group; opportunity to talk about preferences; adequate knowledge; sense of control; and, obstetric intervention score.

A higher sense of control and lower level of obstetric intervention during labour and birth were the most important positive predictors of a better experience. The STOMP model, opportunities to discuss preferences and having adequate information did not predictor a better experience (Table 7.6).

Table 7.6: Predictors of a better experience during labour and birth.

	Standardised Beta (unadjusted) [a]	Standardised Beta (adjusted)	t	p	95% CI upper	lower
(Constant)			7.08	0.000	2.76	4.88
Allocated group	0.07	0.007	0.16	0.88	-0.40	0.47
Talked about preferences	0.002	-0.04	-0.99	0.32	-0.95	0.31
Adequate knowledge[b]	0.15	0.069	1.58	0.12	-0.02	0.15
Sense of control[b]	0.37	0.355	7.99	0.000	0.46	0.76
Intervention score[b]	-0.24	-0.154	-3.56	0.000	-0.11	-0.03

Linear regression was used, with the rating of childbirth as the dependant variable: R^2= 0.2, F (5)=21.5, p<.0001. Included in the model were: allocated group (STOMP vs control); opportunity to talk about preferences (yes vs no); adequate knowledge; sense of control; and, obstetric intervention score. [b]These variables were represented by continuous data. [a]An unadjusted analysis was also performed with each variable individually entered.

Two control group women specifically commented on their need for control:

> *[I] would have liked to have had more control during childbirth. I requested pain relief more than once and was told it wouldn't be long to go. But I pushed for an hour and still no pain relief. I wish I had discussed pain relief more at the start of the labour (#2048).*

> *I would like to have had more say during my labour. All the decisions seemed to be made for me and my husband was pushed to the side for most of the labour (#2163).*

7.5.7 Predictors of 'control' during labour and birth

As 'control' was an important predictor of a positive experience, linear regression was used to estimate the characteristics of care which predicted this experience. The

opportunity to talk about preferences and having adequate knowledge predicted 'control' during labour and birth with a positive slope. Obstetric intervention also predicted 'control', but with a negative slope. The allocated group did not predict 'control' during labour and birth (Table 7.7).

Table 7.7: Predictors of 'control' during labour and birth.

	Standardised Beta (unadjusted) [a]	Standardised Beta (adjusted)	t	p	95% CI upper	95% CI lower
(Constant)			22.3	0.000	4.6	5.5
Allocated group	0.11	0.054	1.20	0.23	-0.10	0.43
Talk about preferences	0.14	0.115	2.5	0.01	0.11	0.83
Adequate knowledge[b]	0.23	0.180	4.01	0.000	0.05	0.15
Intervention score[b]	-0.22	-0.198	-4.50	0.000	-0.08	-0.03

Linear regression was used with 'control' as the dependant variable: R^2= 0.11, F (4)=14.2, p<.0001. Included in the model were: allocated group (STOMP vs control), opportunity to talk about preferences (yes vs no), adequate knowledge and obstetric intervention score. [b]These variables were represented by continuous data. [a]An unadjusted analysis was also performed with each variable individually entered.

7.5.7 Postnatal care

Postnatal care elicited the greatest number of negative comments in the open-ended section of the questionnaire. Thirty-one (17%) STOMP and 41 (23%) control women made specific negative comments about postnatal care, particularly the inconsistent advice given by midwives and the lack of support and follow-up. This was not significantly different between the groups. For example:

Although the level of care postnatally was given with care and professionalism, I did find advice and information given to be very inconsistent and opposing from midwife to midwife causing much confusion [STOMP] (#1491).

[the] STOMP program was fine up to and including childbirth, but as for post-natal care, it fell apart at the seams [STOMP] (#2008).

I was very happy with the care that I received but I got confused about the advice I got from some midwives [Control] (#1396).

7.5.8 Worry, depression, unhappiness

There were no differences between the allocated groups in postnatal worry or unhappiness (Table 7.8). Fifteen per cent of women in both groups scored above the threshold for postnatal depression on the EDPS using the cut-off of 12.5.

Table 7.8: Mean levels of postnatal worry and unhappiness by allocated group.

	STOMP mean [SD]	Control mean [SD]	p[c]
Postnatal worry [a]	12.8 [9.1]	13.3 [9.8]	0.5
Postnatal unhappiness[b]	6.1 [5.0]	6.4 [5.1]	0.4

[a]Postnatal worry was measured using the Cambridge worry scale. [b]Postnatal unhappiness was measured using the score from the EDPS. [c]Independent sample t-tests were used to examine differences between groups.

7.6 Discussion

The results of this component of the study suggest that the STOMP model had benefits for women. Women in the STOMP group: felt more able to discuss their preferences for labour and birth with their caregivers; were better informed about various aspects of labour and birth; and, felt more in control during labour. The majority of STOMP women (79%) had continuity of <u>care</u> during labour and birth, and almost two thirds of STOMP women (63%) had continuity of <u>carer</u> during labour. The majority of women who had continuity of carer during labour liked the experience. Postnatal care was the area that received most negative responses from women in both groups. The STOMP model did not impact on subsequent levels of worry, unhappiness or depression.

7.6.1 The effect of continuity of care and carer

Almost 80 per cent of women in the STOMP group experienced continuity of care, that is, one of their team midwives was present, during labour and birth. This proportion was in line with the expectations of the new model of care. More than 60 per cent of STOMP women reported continuity of carer during labour. This is reasonable considering this was a team of six midwives and it was acknowledged that not all women would have a known midwife in labour.

Positive experiences of childbirth were associated with a higher sense of control during labour and a lower level of obstetric intervention. Control, in turn, was positively associated with an opportunity to talk about preferences and adequate knowledge about labour, birth and the postnatal period. The STOMP model of care resulted in a higher sense of 'control' during labour and birth, although the experience of childbirth was not rated significantly higher. Women in the STOMP group were more likely to report an opportunity to discuss preferences and feel that they had adequate knowledge about aspects of labour and birth. It is possible that women who have a high sense of personal 'control' are more likely to seek information and opportunities for discussion about their preferences. Alternatively, these factors may lead to a higher sense of 'control'.

Twenty-one percent of women in the control group reported continuity of carer during labour. This confounded the effect of the STOMP model on the rating of childbirth and women's sense of control. In the secondary analysis, women who had continuity of carer during labour rated their intrapartum experience more highly and scored higher on the sense of control score. As this latter analysis is not on an intention to treat basis, it should be interpreted with caution. The results suggest that continuity of carer has tangible benefits. Continuity of carer can be increased through models of care such as STOMP.

Provision of continuity of carer also impacts on the midwives who provide the care. This study was not designed to examine the impact of continuity of carer on midwife satisfaction and on sustainability. Research by Sandall (Sandall 1997) reported that continuity and control was as important to midwives in their clinical practice as they were to childbearing women. The capacity to develop meaningful relationships with women was a factor in reducing burnout and increasing sustainability (Sandall 1997). A study of midwives, GPs and obstetricians in the UK found that, while all the professional groups favoured greater continuity in antenatal and intrapartum carer, midwives were the most enthusiastic with GPs being the least (Sikorski et al. 1995).

A qualitative study (known as, the *Study about Maternity Carers Beliefs and Attitudes* or *SAMBA*) was conducted in conjunction with the research reported in this dissertation. Experiences of midwives and other caregivers were explored in a series of focus

groups and interviews over two years. Analysis of these data will shed light on the impact on continuity of care and carer on midwives.

7.6.2 Postnatal care

The STOMP model was designed to reduce the level of conflicting advice that women received in the postnatal period. However, inconsistent advice was reported from women in both groups suggesting that the STOMP model did not alleviate this issue. Postnatal care was the most difficult service to provide in the STOMP model. One midwife from each STOMP team was rostered onto the postnatal ward each day to provide care for women in the hospital and those at home. The midwife reviewed all the STOMP women in the ward, provided necessary care, planned the care for the remainder of the day and then they went into the community to provide the domiciliary service for women at home. The midwives on the ward cared for the STOMP women while the STOMP midwives were away. Midwives on the ward also provided care to STOMP women during the evening and night when STOMP midwives were not rostered to provide postnatal care.

This disrupted style of care may account for some of the dissatisfaction that STOMP women felt towards postnatal care. It is also possible that postnatal care was less valued by STOMP midwives for two reasons. Firstly, it was disruptive and difficult to provide. Secondly, it was seen as the least exciting component of maternity care. There is a balance to be found in the provision of postnatal care as part of a package of continuity of care. If there were more midwives in the team, it would be possible for team midwives to staff the postnatal ward on a 24 hour basis. This would result in less continuity of carer and probably increase the level of inconsistency reported. An alternative is to have smaller teams, in a caseload model like the One-to-One model in the UK (McCourt et al 1998) where two or three midwives provide care for a smaller group of women.

Duration of care also impacts on the midwives' ability to provide effective and support postnatal care. The mean duration of postnatal care in the study was five days. This contrasts to the duration of postnatal care provided in the UK, where women are visited by midwives at varying intervals up to the 10th day, and to the 28th day as needed (Garcia & Marchant 1999). Uncertainty exists about the constitution of effective clinical

care as most of the research in maternity care has focussed on the antenatal and intrapartum phases (Cooke & Stacey 2000; Garcia & Marchant 1999).

Postnatal care is an important component of maternity care and should not be omitted just because it is problematic to provide. Additional research needs to be conducted into the content and organisation of postnatal care and how effective care can be provided to women within a public health system.

7.7 Summary

This chapter has reviewed the elements that lead to dissatisfaction with care during labour and birth. It appears that 'having an active say in decisions made during labour', feeling 'in control' and having caregivers who are perceived as helpful and supportive are associated with a more positive experience. The STOMP model was designed to facilitate these experiences. It was hypothesised that continuity of care and carer would be a mechanism to promote these important aspects of care.

The results have demonstrated that the STOMP model is associated with more positive experiences of childbirth compared with standard care. Postnatal care is the area that still requires more research and development, as it appears not to meet the needs of women. Chapter 10 will return to these issues and discuss the implications for midwifery, particularly within the Australian context.

The next chapter presents the cost analysis. This analysis compares the cost of providing STOMP care with standard care.

Chapter 8 A cost analysis

8.1 Introduction

Anecdotes suggest that one of the perceptions preventing the widespread implementation of new midwifery models of care in Australia is cost. Within the current climate of cost containment, many midwifery managers and hospital administrators seem unable to consider introducing a new model of care because "the budget does not allow for it" or "we need additional funds". Chapter 8 presents the cost analysis which was conducted in conjunction with the STOMP study. The cost analysis is made from the perspective of the health care provider and evaluates costs borne by the organisation, for example, salaries and wages of staff and goods and services. Personal costs to women, for example, child care, travel, parking, time away from work, have not been included. The chapter reviews the various economic evaluations that have been conducted in the provision of maternity care. Then the procedures used to determine each component of resource use in the STOMP and standard care models are described. The results are presented as mean cost per woman. Sensitivity analyses were performed to evaluate the robustness of the results.

8.2 Economic evaluations in the provision of maternity care

Maternity care is a significant user of resources in public hospital systems. In Australia, more than 250 000 babies are born annually (Day et al 1999a). The majority of care for pregnancy and birth in Australia takes place in the public hospital system. In NSW, 83 per cent of women had their babies in public hospitals in 1998 (NSW Health 2000). Cost of providing maternity care is therefore an important consideration in the design and implementation of new services.

8.2.1 Models of continuity of midwifery care

Economic analyses of new models of maternity or midwifery care are uncommon. The trial of team midwifery at the John Hunter Hospital in Australia used Australian national cost weights for diagnostic-related groups (AN-DRGs) for the cost analysis (Rowley et al 1995). AN-DRGs are a means of reimbursing hospitals according to the services they provide (Leeder 1999). Using AN-DRGs, Rowley et al (Rowley et al 1995) concluded

that the team approach was associated with a reduction in costs per woman. Only mean costs were presented. Information on the precision of the mean cost difference observed was not presented. This resulted in some challenge to the conclusion that the costs of providing the intervention were less than the costs of providing standard care (Barber & Thompson 1998). Problems also exist with the use of the AN-DRG system to cost overall maternity care. AN-DRGs can only address acute inpatient maternity care and do not account for antenatal clinic services or domiciliary care. They are also limited in their capacity to determine and refine costs, particularly for adverse events (Phelan et al. 1998; Rigby et al. 1999) and outpatient care (Lee et al. 1998).

A cost analysis was also conducted in the other randomised controlled trial of team midwifery conducted in Australia (Kenny et al 1994). The cost of providing antenatal care was similar between the groups. Costs during labour and birth were only calculated on statistically significant outcomes, for example, forceps delivery and episiotomy, and not for total care. Postnatal care costs included hospital-based length of stay and number of domiciliary visits. Overall, the team midwifery care represented a cost saving compared to standard care, although the variability of the mean costs was not given. Sensitivity analyses were not conducted so it is difficult to determine if this cost saving would remain if the statistically significant birth outcomes were altered.

A cost analysis accompanied the large randomised controlled trial of continuity of midwifery care conducted by Turnbull et al (Turnbull et al 1996) in Scotland. Young et al (Young et al. 1997) measured the costs of providing midwife-led care compared with shared care and found no significant differences in the median costs of antenatal and intrapartum care. Postnatal care was associated with higher costs in the midwife-led group.

These three studies demonstrate that there are inadequacies in our understanding of the costs associated with models of midwifery care. Further research is necessary to provide hospital managers with information about the cost implications of new models of care.

8.2.2 Models of antenatal care

Antenatal care offers the greatest scope for economic analysis of maternity care because alterations can be made more readily. For example, the location of the service can be varied and different health care professionals can provide care (Twaddle &

Young 1998). Ratcliffe et al (Ratcliffe et al. 1996) reported significant cost reductions when antenatal care was provided by GPs and midwives in the community. Gravely and Littlefield (Graveley & Littlefield 1992) compared the costs of providing three antenatal services in their non-randomised study in the USA. The antenatal services were: a physician-led clinic; a mixed staffing clinic (doctors, nurse practitioner and nurse aide); and, a community-based clinic (staffed by clinical nurse specialists) for low risk women. While there were no significant differences in clinical outcomes between the three groups, the community-based clinic was significantly cheaper to operate than the other options (Graveley & Littlefield 1992).

Altering the ratio of midwives to doctors in antenatal care provision can also contribute to a reduction in costs. In Australia a significant proportion of women with uncomplicated pregnancies receive antenatal care from the most expensive caregivers, that is, obstetricians, and to a lesser extent, GPs (Leap & Cornwell 1999). The trial by Giles et al (Giles et al 1992) demonstrated that significant cost savings can be made when midwives, instead of doctors, provide antenatal care for low risk women. Young et al (Young et al. 1997) have also assessed the impact of midwife-led care in the antenatal period on women and their families in terms of cost and satisfaction with the accessibility of care. In this research (Young et al 1997), women receiving midwife-led care had slightly lower costs and higher levels of satisfaction with the accessibility of care.

8.2.3 Models of intrapartum care

Few studies seem to have formally examined the economic implications of different models of care for labour and birth, although some have compared the costs of providing care during labour in different settings. For example, Hundley et al (Hundley et al. 1995) compared the cost of providing care in a separate midwife-managed birthing unit with a consultant-led labour ward. The costs of establishing the midwife-managed birthing unit resulted in higher costs compared with the labour ward. Sensitivity analyses showed no clear benefit in location of care (Hundley et al 1995). In contrast, Walker and Stone (Walker & Stone 1996) in the USA, retrospectively compared the costs of labour care provided in a free-standing birth centre with two hospital-based models of care. Care in the free-standing birth centre was found to cost less than care in the two hospital-based models. The usefulness of this study in an

Australian setting is limited as the professional fee structure in the USA quite different. Uncomplicated home births are the least expensive model of care. Anderson and Anderson (Anderson & Anderson 1999) estimated that an uncomplicated vaginal birth costs 68 per cent less at home than in a hospital.

While home birth and free-standing birth centres may be cost effective models of care, they are not available or desirable to all women. Cost effective models of care that are accessible to all women need to be developed and evaluated.

8.2.4 Models of postnatal care

Economic analyses of postnatal care have predominately focussed on reducing length of hospital stay with or without early discharge programs. Early discharge or domiciliary midwifery programs have been widely established as 'cost effective' alternatives to hospital-based care. Debate continues over the validity of these conclusions (Brumfield 1998; Cooke & Barclay 1999; Grullon & Grimes 1997). Scott (Scott 1994) analysed the costs of early discharge in three Sydney hospitals and reported that two of the early discharge programs used more resources than standard care with the reverse scenario occurring in the third. Another study in NSW by Shorten (Shorten 1995), contributed to the debate. Shorten (1995) concluded that early discharge was less expensive than the standard hospital stay when the costs of community-based (including medical) care were included in the analysis. Despite the ongoing debate on the cost effectiveness, acceptability and long term benefits of early discharge, the average postnatal length of stay continues to fall (Cooke & Barclay 1999; NHMRC 1996). As length of hospital stay decreases, cost savings from early discharge are also likely to decrease.

8.2.5 The STOMP model

It was hypothesised that the STOMP model of care would be cost neutral, that is, it would cost no more to provide than current standard care. Antenatal care was provided in the community, a decision undertaken primarily to reduce personal costs to women associated with access to care including inconvenience, transport difficulties, parking problems and long waiting times. These personal and social costs have not been costed in monetary terms. Instead, they are presented qualitatively in Chapter 6. Obstetric interventions have associated costs, both directly and indirectly. The clinical

outcomes presented in Chapter 5 have significant implications on the cost of providing care and are included in this cost analysis.

The cost analysis was conducted to provide hospital managers with data that would assist their decisions about service provision. Data were collected on AN-DRGs for all women in the study, however due to the limitations and lack of sensitivity of these measures, they were not used in the analysis.

The cost of providing STOMP care to each woman was compared with the cost of providing standard care. The question was:

- From the perspective of the health system, did the STOMP model cost more or less to provide than the standard model?

8.3 Methods

A broad cost analysis was undertaken from the perspective of the health system (Drummond & Stoddart 1984). In a cost analysis, an examination of the comparative costs of the two alternatives is undertaken. This information enables the health care providers to determine whether the model of care is sustainable from an economic perspective.

This analysis presented in this chapter compared the cost of providing the STOMP model of care with the cost of providing standard care for the 1 089 women in the study. All costs are presented in Australian dollars.

8.3.1 Data collection

The resources used to provide antenatal, intrapartum and postnatal care for each woman in the trial were calculated for each aspect of care, including salaries and wages, goods and services and maintenance. The components of care were: antenatal clinic; antenatal admission; day assessment unit; labour and birth; hospital-based postnatal care; domiciliary postnatal care; and, admission of neonates to the SCN. STOMP midwives also incurred an on-call cost.

Salaries and wages were calculated at market prices (Robinson 1993). In this case, the 1997 NSW industrial award rates including 'on-costs' (sick leave, annual leave, long service leave and superannuation) were used. Midwifery care was calculated at the level of an 8th year midwife, which was the average at the hospital. Medical officers

were costed at the average year of service (2nd year for residents and 4^{h} year for registrars). Consultant obstetricians were costed at their hourly rate. Other personnel, including midwifery managers, clerical staff, enrolled nurses and porters were costed at their current level and grading.

8.3.2 Analysis

Costs associated with all aspects of care were calculated and presented as the mean cost per woman per group. Ninety-five per cent confidence intervals were used to represent the variability of mean. Describing the variability of mean costs per woman requires acknowledgement that the data may be highly skewed (Barber & Thompson 1998). This is because small subsets of 'patients' incur particularly high costs. The usual method of calculating the standard error (via the standard deviation) may result in a biased estimate of this statistic.

It has been suggested that the standard error should be calculated using a non-parametric technique known as bootstrap resampling (Barber & Thompson 1998). Bootstrapping enables the estimation of the variability of statistics (such as means) without making any assumptions about the underlying distribution of data (Efron & Tibshirani 1993). It was unlikely that the cost data in the study were normally distributed. Bootstrapping was therefore used to estimate the variability of mean costs (standard error and 95% confidence intervals). Ten thousand bootstrap replications were used to calculate these results.

Sensitivity analyses were performed on sub-sections of the analysis. The first sensitivity analysis examined the impact of admission to SCN on total costs between the allocated groups. The second sensitivity analysis evaluated the impact of the assumptions surrounding the efficiency of the STOMP clinics. Finally, the rates of obstetric intervention in the STOMP group were varied to determine the cost difference. This analysis allowed the estimation of the caesarean section rate that would nullify cost savings from the STOMP model.

8.3.3 Economic assessments

Antenatal clinics

Salary and wage costs incurred in conducting a hospital-based and community-based STOMP clinic were calculated and divided by the number of women usually seen per

clinic (50 per hospital-based clinic; 30 per community-based clinic) to obtain an average cost per visit per woman per site. These averages were then multiplied by the number of visits per woman to obtain a cost of antenatal care per woman.

Hospital-based antenatal clinic

Each hospital-based clinic was staffed by five midwives and one resident, registrar, consultant doctor, enrolled nurse, nurse manager and appointments clerk. The midwives, enrolled nurse, clerk and manager attended the clinic for four hours, which included initial setting up and cleaning and restocking at the conclusion. The resident and registrar attended the clinic for three hours and the obstetrician for two hours. A registrar checked all pathology and ultrasound reports prior to each clinic (30 minutes). During the study the antenatal records were stored in three filing cabinets in the delivery suite. Hospital porters transported these cabinets to and from each antenatal clinic. Clerks retrieved and replaced antenatal records (Table 8.1).

Table 8.1: Salary and wages expended to conduct the hospital-based antenatal clinic.

Description	No	Time (hours)	$ per hour	Cost $
Midwives	5	4	27.73	554.60
Resident medical officer	1	3	51.55	154.65
Registrar	1	3	66.67	200.01
Registrar to check results	1	0.5	66.67	33.34
Consultant obstetrician	1	2	155.75	311.50
Clerk	1	4	12.73	50.92
Enrolled nurse	1	4	15.02	60.08
Nurse manager	1	4	33.28	133.12
Porters to move files	2	1	13.7	27.40
Clerk to retrieve files	1	0.75	12.73	9.55
Clerk to replace files	1	0.75	12.73	9.55
Total				1 544.71

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Average cost per woman (50 women per clinic)[a]	30.89

Salaries and wages were calculated at NSW industrial award rates including 'on-costs' (sick leave, annual leave, long service leave and superannuation). [a]The total cost was divided by the number of women who usually attend each clinic session (50) to obtain the average cost per woman.

Community-based clinic

The community-based STOMP clinic was organised differently to the hospital-based clinic. One STOMP midwife was responsible for preparation of the antenatal records, usually the day before the clinic. Preparation involved: retrieving all the necessary antenatal records; checking that pathology and ultrasound reports were available; following up results that were unavailable or missing; and, contacting the consultant or registrar about the time that they were likely to be needed at the clinic. Preparation also included travel to the clinic. Preparation usually took four hours.

The obstetrician attended each clinic for approximately two hours. Women who required obstetric review were booked in at similar times to ensure his/her time was used efficiently. The obstetrician alternated attendance at the clinic with an obstetric registrar. The obstetric registrar usually spent a longer period of time in the clinic (up to 4 hours) being less familiar with the routine, the women and with, in general, less clinical experience.

The STOMP midwives travelled to the community sites in a leased hospital vehicle. Costs for the hospital vehicles were calculated on a daily basis that accounted for annual lease, petrol, insurance, servicing and maintenance. These data were obtained from St George Hospital's transport department and were based on an average cost per small vehicle (Table 8.2).

Table 8.2: Description of resources required to lease a vehicle.

Description	Cost
	$
Car leasing ($220/month)	2 640
Petrol ($40/week)	2 080
Insurance	550
Registration	460
Emergency road service	42
Servicing	100
Total	5 872
• Vehicle cost per week[a]	112.92
• Vehicle cost per day[b]	22.58

[a]Cost per week was calculated (52 weeks per year). [b]It was assumed that vehicles were used for five days per week.

While the round-trip travelling time to each community-based facility was only 30 minutes, the midwives had the vehicles for up to six hours per clinic. The 'cost per day' was therefore used for travel expenses.

The cost to provide STOMP clinics were based on two clinics. This was because in any one week, the consultant obstetrician attended one session and the registrar attended the other. Rather than spilt the costs of each attendance it was simpler to calculate the overall costs for a week rather than for one session. STOMP catered for 60 women per week (Table 8.3).

Table 8.3 Salary and wages expended to conduct two community-based STOMP clinics.

Description	No	Time (hours)	$ per hour	Cost $
Midwives	4 MW	5	27.73	554.60
Consultant obstetrician	1	2	155.75	311.50
Registrar	1	3	66.67	200.01
Preparing for clinic	2 MW	8	27.73	221.84
Putting files away and follow up	2 MW	2	27.73	55.46
Cleaning up time	2 MW	2	27.73	55.46
Vehicle		2 days	22.58	45.16
Total per week				1 444.03
Cost per woman (60 women per week) [a]				24.07

Salaries and wages were calculated at NSW industrial award rates including 'on-costs' (sick leave, annual leave, long service leave and superannuation). [a]The total cost was divided by the number of women who attended each week (60) to obtain the average cost per woman.

Additional costs to establish the community-based clinic

The sites for the STOMP clinics were both owned and operated by the NSW Health Department. The early childhood centre, where the Rockdale Clinic was situated, was part of the St George Hospital and Community Services. The NSW Health Department funded the family planning clinic where the Hurstville STOMP team operated. These affiliations meant that the STOMP clinics were not required to pay rent or contribute to operating costs. Negotiations at the commencement of the project meant that days and times for clinics were chosen on the basis that they were mutually acceptable. Staff at the early childhood centre and the family planning clinic believed that locating the STOMP clinics in their facilities would be beneficial.

A small amount of additional equipment was purchased to set up the STOMP clinics. This included: two portable examination beds for the Rockdale clinic ($400 each); two automated urine-testing machines ($850 each); two small cases to transport records and other paperwork ($50 each); two hand-held fetal heart rate 'doppler' machines

($895 each); and, twelve long range 'pagers' for the midwives ($395 each). Other equipment, for example, sphygmomanometers, stethoscopes and two other fetal heart rate doppler machines were obtained from within existing resources in the antenatal clinic. It was not necessary to purchase this equipment as it was simply shifted from the antenatal clinic to the STOMP clinics. Consumables were used from the normal antenatal service budget thus not attaching additional costs to the organisation. These initial 'set up' costs ($9 130) were not included in the overall analysis as they were used for longer than the period of this study.

In the first year of the implementation of STOMP, a clinical midwifery consultant provided training, mentoring and leadership to support the midwives. This was a developmental role and was reduced over time. The costs of this role were not included in the cost analysis.

Other antenatal costs

Almost all antenatal women attending St George Hospital had an obstetric ultrasound at 18 weeks gestation and pathology tests in the first trimester (estimation of haemoglobin; blood group, rhesus factor and antibody screening; hepatitis B and syphilis screening; rubella titre; and, urine microscopy) and at 28 weeks gestation (estimation of haemoglobin and antibody screening). Other costs included urine testing, which was performed at each visit using an automated machine. As these practices were the same in each group these costs were not included in the analysis.

Capital costs and cleaning costs were not included in the analysis. Stationery costs (including progress notes and checklists) and linen were also not included as they would have been involved regardless the model of care.

Neither model of care offered antenatal education as a routine component. Antenatal education was offered at the hospital but women paid $50 for a series of classes which were usually held in the evenings. The cost of providing antenatal education was not included.

Antenatal admission to hospital

The cost of a day in a hospital bed in an antenatal ward was $216 in 1997 and 1998 (St George Hospital average cost 1997-8). This incorporates midwifery and medical care,

goods and services and repair and maintenance. Costs related to antenatal admissions were calculated on the number of days in hospital for each woman (Table 8.4).

Table 8.4: Antenatal days in hospital by group.

Days in hospital	STOMP n=550 Number (%)	Control n=539 Number (%)
0	498 (90.5)	472 (87.6)
1	18 (3.3)	27 (5.0)
2	17 (3.1)	19 (3.5)
3	9 (1.6)	7 (1.3)
4	2 (0.4)	3 (0.6)
5	1 (0.2)	6 (1.1)
6	2 (0.4)	0 (0.0)
≥ 7	3 (0.6)	5 (1.0)

Antenatal admission to a Day Assessment Unit

The day assessment unit (DAU) was a clinic for antenatal women who need more intensive monitoring but do not require admission to hospital. At St George Hospital the DAU was conducted three days per week from 9am to 1pm. One midwife coordinated the DAU and spent approximately six hours per day in the clinic. This time accounted for preparation, conduct of the four hour session, follow up of results and tidying up at completion. Each woman had a cardiotocograph (CTG) and blood tests (different pathology tests were collected at the first and subsequent visits) at each visit. An obstetrician and physician reviewed all women each day. Different charges were made for first and subsequent visits. The first visit fee for an obstetrician in the DAU was $55.95. The first visit fee for the physician was $98.65. Subsequent visit fees for both specialists were $28.05.

The total cost of providing care for each group was divided by the number of visits to obtain an average cost per woman per visit per group (Table 8.5).

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Table 8.5: Day assessment unit costs by group.

Description	$ per service	STOMP[a] $	Control[b] $
Midwife for 6 hours with 4 women per session	41.25	3 052.50	2 145.00
Cardiotocograph	24.00	1 776.00	1 248.00
Pathology tests:			
• first visit (FBC, UECs, LFTs, urate)	37.56	1 014.12	1 126.80
• subsequent (FBC, AST, urate)	36.95	1 736.65	812.90
Obstetrician:			
• first visit	55.95	1 510.65	1 678.50
• subsequent	28.05	1 318.35	617.10
Physician:			
• first visit	98.65	2 663.55	2 959.50
• subsequent	28.05	1 318.35	617.10
Total		14 390.17	11 204.90
Average costs per visit[c]		194.46	215.48

[a]Women in the STOMP group made 27 first visits and 47 subsequent visits. [b]Women in the control group made 30 first visits and 22 subsequent visits. [c]The total cost is divided by the total number of visits to obtain a cost per visit per group.

Intrapartum care

Intrapartum care was based on four categories of birth outcome: normal vaginal delivery; assisted vaginal delivery (forceps, vacuum extraction or breech); elective caesarean section; or, emergency caesarean section. The level of care and resources required for each category was different. This method is known as 'product costing' (Hindle 1993).

Cost per birth outcome was made independent of the allocated group. The proportions of each category of birth outcome were taken from the clinical outcomes that were presented in Chapter 5. The birth outcomes are repeated here (Table 8.6).

Table 8.6: Birth outcome by group.

	STOMP	Control
	n=550	n=539
	Number (%)	Number (%)
Normal birth	402 (73.1)	374 (69.4)
Complicated vaginal birth[a]	75 (13.6)	69 (12.8)
Emergency caesarean section	52 (9.5)	62 (11.5)
Elective caesarean section	21 (3.8)	34 (6.3)

[a]Complicated vaginal birth included forceps and vacuum extraction and vaginal breech birth.

Costing was based upon an uncomplicated normal vaginal birth. This included: midwifery care; clerical and managerial support within the delivery suite; and, goods and services, including gloves, linen and cleaning (Table 8.7). The assumption of 10 hours of midwifery care per woman was based on data currently used within the hospital to calculate staffing requirements and costs of providing care. This time includes direct care as well as telephone support and advice, liaison with team members, transfer and restocking. Background costs, that is, costs of providing a service even though it was not specifically required (for example, obstetric and paediatric cover) were also included. All other assumptions were based on the usual estimates within the hospital.

Table 8.7: Resources used in a normal vaginal birth.

Description	Cost/birth $
Salaries and wages	
Nurse manager @$32.04/hr x 38hrs x 50 women per week	28.91
Midwife 8th year (+26% on costs) @ $27.75 per hr x 10hrs	277.50
RMO (background) 2nd year (+53.65% on costs) @ $36.44 per hr x 10min	6.07
Registrar (background) 4th year (+97.89% on costs) @ $66.67 per hr x 10min	11.28
Consultant (background) @ $155.75 per hr x 10 min	25.96
Paediatric cover (background) @ $36.44 per hr x 10 min	6.07
Clerk (+1.34% on costs) @12.73 per hr x 20hrs x 50 women per week	5.09
Goods and services	
Consumables (gloves etc)	13.50
Linen, laundry, cleaning	10.00
Meals, food supplies	8.00
Depreciation on equipment	10.50
Total	414.49

Salaries and wages were calculated at NSW industrial award rates including 'on-costs' (sick leave, annual leave, long service leave and superannuation). All other costs were based on assumptions used at St George Hospital. The same costs were applied to both groups.

Additional costs were included for women who had a normal birth but required obstetric care (STOMP n=206; control n=220) and/or paediatric care (STOMP n=51; control n=65). Obstetric care was most commonly attended for perineal suturing (30 minutes) and was provided by an obstetric resident medical officer (RMO). Paediatric care was usually to attend the birth and assess the neonate (20 minutes). This care was also provided by a RMO. In these instances, the background costs were removed and the additional costs added.

As the number of women who had epidural analgesia during a normal labour and birth was similar between the groups (STOMP n=51; control n=56), the cost was not included in the normal birth resources.

The costs for a complicated vaginal birth, elective caesarean or emergency caesarean section used the baseline resources for a normal birth with additional costs. For example, it was assumed that an obstetric registrar, anaesthetist and paediatric registrar would provide care and a consultant obstetrician and paediatrician would be on-call. There was an increased use of goods and services, such as an epidural anaesthetic and an intravenous line (Table 8.8 and Table 8.9).

Table 8.8: Resources used in a complicated vaginal birth.

Description	Cost/birth
	$
Salaries and wages	
Nurse manager @$32.04/hr x 38hrs x 50 women per week	28.91
Midwife 8th year (+26% on costs) @ $27.75 per hr x 10hrs	277.50
RMO 2nd year (+53.65% on costs) @ $36.44 per hr x 30min	18.22
Registrar 4th year (+97.89% on costs) @ $66.67 per hr x 1hr	67.67
Consultant (background) @ $155.75 per hr x 1hr	155.75
Paediatric cover @ $36.44 per hr x 20 min	12.15
Consultant paediatrician on call @ $7.60 per hr	7.00
Clerk (+1.34% on costs) @12.73 per hr x 20hrs x 50 women/week	7.60
Anaesthetist for epidural analgesia @ $125	125.00
Goods and services	
Consumables (gloves, IV lines, catheters, IV fluids etc)	52.00
Linen, laundry, cleaning	30.00
Meals, food supplies	8.00
Pharmacy (medications)	51.40
Depreciation of equipment	10.50
Total	863.30

Salaries and wages were calculated at NSW industrial award rates including 'on-costs' (sick leave, annual leave, long service leave and superannuation). All other costs were based on assumptions used at St George Hospital. The same costs were applied to both groups.

Operating theatre costs were included for women who underwent emergency or elective caesarean sections. These were taken from estimates made by the hospital (Table 8.9 and 8.10).

Table 8.9: Resources used in an emergency caesarean section.

Description	Cost/birth$
Salaries and wages	
Nurse manager @$32.04/hr x 38hrs x 50 women per week	28.91
Midwife 8th year (+26% on costs) @ $27.75 per hr x 10hrs	277.50
RMO 2nd year (+53.65% on costs) @ $36.44 per hr x 1hr	36.44
Registrar 4th year (+97.89% on costs) @ $66.67 per hr x 2hrs	135.34
Consultant @ $155.75 per hr x 1hr	155.75
Paediatric registrar @ $66.45 per hr x 1hr	66.45
Consultant paediatrician on call @ $7.00 per hr x 1hr	7.00
Clerk (+1.34% on costs) @12.73 per hr x 20hrs x 50 women per week	7.60
Goods and services	
Consumables (gloves, IV lines, catheters, IV fluids etc)	52.00
Linen, laundry, cleaning	30.00
Meals, food supplies	8.00
Pharmacy (medications)	51.40
Depreciation of equipment	10.50
Operating theatre costs	930.00
Anaesthetist for epidural anaesthesia	295.00
Recovery room	109.00
Total	2 212.49

Salaries and wages were calculated at NSW industrial award rates including 'on-costs' (sick leave, annual leave, long service leave and superannuation). All other costs were based on assumptions used at St George Hospital. The same costs were applied to both groups.

The 'care during labour' cost was not included for women who underwent an elective caesarean section. Instead, midwifery and medical time to prepare the woman for the operating theatre were substituted.

Table 8.10: Resources used in an elective caesarean section.

Description	Cost/birth
	$
Preparation for theatre	
Midwife 8th year (+26% on costs) @ $27.75 per hr x 2hrs	55.50
Cons umables	10.00
RMO 2nd year (+53.65% on costs) @ $36.44 per hr x 30min	18.22
Salaries and wages	
Registrar 4th year (+97.89% on costs) @ $66.67 per hr x 2hrs	135.34
Consultant @ $155.75 per hr x 1hr	155.75
Paediatric registrar @ $66.45 per hr x 30 min	33.23
Consultant paediatrician on call @ $7.00 per hr x 1hr	7.00
Midwife 8th year (+26% on costs) @ $27.75 per hr x 2hrs	55.50
Goods and services	
Depreciation on equipment	10.50
Operating theatre costs	930.00
Anaesthetist for epidural anaesthesia	295.00
Recovery room fees	109.00
Total	1 826.64

Salaries and wages were calculated at NSW industrial award rates including 'on-costs' (sick leave, annual leave, long service leave and superannuation). All other costs were based on assumptions used at St George Hospital. The same costs were used for the STOMP and control groups.

Postnatal care

The cost of providing postnatal care fell into two general categories: after a vaginal birth (normal or complicated); or, after a caesarean section (elective or emergency). The assumptions used were the same for the STOMP group and the control group. The costs only differed depending on the birth outcome.

The length of time that midwives spent with a woman after a vaginal birth was estimated at 1.5 hours per woman per day (assumed that 3 midwives cater for an

average of 8 women per day with half their time taken in administrative and non-direct clinical duties). These estimates were made from recent research in our unit (Stacey 2000). Medical care was one 30 minute visit by a resident medical officer to authorize discharge from hospital.

The length of time that midwives spent with a woman after a caesarean section increased to 3 hours per day. Medical care increased to 20 minutes per day which included the discharge visit. Again, Stacey (Stacey 2000) made these estimates from recent research. Both groups of women had their babies reviewed (usually once) by a paediatric resident medical officer. Background support included a midwifery manager, a lactation consultant and a clerk. The mean length of stay in hospital after a vaginal birth was 3.5 days (STOMP 3.47 days; Control 3.61 days) and 6.2 days after a caesarean section (STOMP 5.52 days; Control 6.81 days).

Goods and services included meals, consumables, pharmacy, cleaning, linen and laundry. These were greater for women recuperating from a caesarean section compared with those recuperating from a vaginal birth. A small budget for maintenance and repair costs was also included.

The final calculation for hospital-based postnatal care used the *daily* cost multiplied by the number of days in hospitals plus the other costs *per woman* for each category. Using these assumptions, postnatal costs were obtained for a vaginal birth (Table 8.11) and a caesarean birth (Table 8.12).

Table 8.11: Resources used to provide hospital-based postnatal care for a woman after a <u>vaginal</u> birth.

Description		Cost/birth
		$
Daily costs [a]	Midwifery care @ $27.75/hr x 1.5hrs per day	41.63
	Meals ($7 per meal)	21.00
	Subtotal per day	62.63
Other costs [a]	Manager @ $30.35 per hr x 38hrs x 50 women per wk	23.07
	Clerk @ $15 per hr x 38hrs x 50 women per wk	11.40
	Lactation consultant @ $30.35 per hr x 38hrs x 50 women per wk	23.07
	Paediatric review @ $36.44 per hr x 20 min	12.15
	RMO 2nd year (+53.65% on costs) @ $36.44 per hr x 30min	18.22
	Consumables	10.00
	Linen, laundry, cleaning	10.30
	Pharmacy	1.00
	Repair and maintenance	2.00
Total [b]	Cost per woman	111.20

Salaries and wages were calculated at NSW industrial award rates including 'on-costs' (sick leave, annual leave, long service leave and superannuation). All other costs were based on assumptions used at St George Hospital. The same costs were used for the STOMP and control groups. [a]Two categories of costs are included: *daily costs*; and, *other costs*. [b]The *daily costs* are multiplied by the number of days in hospital for each woman. This figure is added to the *other costs* to obtain a 'cost per woman'.

Table 8.12: Resources used to provide hospital-based postnatal care for a woman after a <u>caesarean</u> birth.

Description		Cost/birth $
Daily costs [a]	Midwifery care @ $27.75 per hr x 3hrs per day	83.25
	RMO 2nd year (+53.65% on costs) @ $36.44 per hr x 20min/day	12.15
	Meals ($7 per meal)	21.00
	Subtotal per day	95.40
Other costs [a]	Nurse manager @ $30.35 per hr x 38hrs x 50 women per wk	23.07
	Clerical support @15 per hr x 38hrs x 50 women per wk	11.40
	Lactation consultant @ $30.35 per hr x 38hrs x 50 women per wk	23.07
	Paediatric review @ $36.44 per hr x 20 min	12.15
	Consumables	25.20
	Linen, laundry, cleaning	20.60
	Pharmacy	23.20
	Repair and maintenance	2.00
Total [b]	Cost per woman	140.68

Salaries and wages were calculated at NSW industrial award rates including 'on-costs' (sick leave, annual leave, long service leave and superannuation). All other costs were based on assumptions used at St George Hospital. The same costs were used for the STOMP and control groups. [a]Two categories of costs are included: *daily costs*; and, *other costs*. [b]The *daily costs* are multiplied by the number of days in hospital for each woman. This figure is added to the *other costs* to obtain a 'cost per woman'.

Domiciliary midwifery care

Costs of domiciliary midwifery visits were calculated per woman. The main cost was the salary of the midwife. Each visit involved up to one hour of preparation time, which included visiting the woman on the ward prior to discharge and reviewing and preparing records. The average length of the visit was estimated to be 42 minutes (using 1998 data from domiciliary midwives at St George Hospital). Each midwife used a leased hospital vehicle as described in Table 8.2. It was assumed that each vehicle travelled to four visits per day. Round trip travel time was estimated to be 40 minutes and an

additional 30 minutes was added for completion of records, cleaning equipment and restocking (Table 8.13).

More women in the STOMP group utilised domiciliary midwifery care [STOMP n=240 (43.6%); Control n=187 (34.7%)]. Of women who had domiciliary care, the mean number of visits was 3.4 (STOMP 3.2; Control 3.6).

Table 8.13: Resources expended to provide midwifery care in the community.

Description	Cost
	$
Vehicle (see Table 8.2)	5.65
Preparation up time (up to 1hr)	27.75
Visit time (average 42 min 1997-1998 data)	19.43
Finishing up time (up to 30min)	13.87
Good and services (paperwork, use of scales)	1.00
Travel time (up to 40 min)	18.5
Total per visit	86.20

Salaries and wages were calculated at NSW industrial award rates including 'on-costs' (sick leave, annual leave, long service leave and superannuation). All other costs were based on assumptions used at St George Hospital. The same costs were used for the STOMP and control groups.

Costs of midwifery 'on-call' for STOMP

STOMP midwives provided 24 hour on-call cover for women in labour. This was provided in two 12 hour shifts (8am to 8pm and 8pm to 8am). Midwives were on-call for 12 hour shifts. They were not paid overtime allowances. When they were on-call, they were paid for 8 hours regardless of whether they were called in to work. If they were not called in, then they owed 8 hours on their 'tally sheet', if they were called in for 12 hours, then the additional 4 hours was taken off their tally sheet. Midwives were not on-call on their days off. A more detailed description of the 'tally sheet' system is presented in Appendix 2 (page 233).

On-call costs were calculated using the NSW Nurses Award (1997 and 1998) assuming two on-call shifts ($13.08) per day. Rockdale STOMP midwives were on call from 1 June 1997 to 8 December 1998 (553 days) and Hurstville STOMP midwives were on

call from 12 December 1997 to 8 December 1998 (364 days) to cover the 550 women in the study. The total cost was divided by the number of women to obtain a 'cost per woman' (Table 8.14).

Table 8.14: A description of the on-call costs used by STOMP midwives to provide care during the study.

Time period	Cost
	$
1 June 1997-8 Dec 1998: 2 Rockdale midwives per day	
553 days @ $13.08 per shift	7 233.24
12 Dec 1997-8 Dec 1998: 2 Hurstville midwives on call	
364 days @ $13.08 per shift	4 761.12
Total	11 994.36
Cost per woman[a]	21.81

On-call costs were calculated using the NSW Nurses Award assuming two on-call shifts ($13.08) per day per team. [a]The cost per woman was obtained by dividing the total cost by the number of women in the STOMP group (n=550).

Neonatal admission to Special Care Nursery

The daily cost of a neonatal bed in a Level 2 SCN in 1997 and 1998 was $1700 (St George Hospital data). This incorporates midwifery and medical care, goods and services and repair and maintenance of equipment. Resource costs related to admission to SCN were calculated on the number of days in hospital in each group. Overall, neonates in the control group spent more days in the SCN (STOMP: 80 days; control: 97 days).

As SCN admission uses considerable financial resources, the sensitivity analysis calculated the mean cost per woman when the cost associated with admission to SCN was removed from the analysis. This is presented in section 8.5.

8.4 Results

The costs associated with each of the nine components of care were calculated and are presented as the mean cost per woman by group (Table 8.15). The largest difference in the mean cost was in admission to SCN, although, there were also cost savings in

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antenatal clinic care, antenatal inpatient admissions and intrapartum and postnatal care. STOMP had slightly higher DAU and domiciliary midwifery care. Only STOMP women incurred on-call costs.

Table 8.15: Total cost per woman by the nine components of maternity care by group.

	STOMP	Control	Cost saving
	Mean	Mean	Control-STOMP
	$	$	$
Antenatal clinic	200.45	229.29	28.84
DAU	26.40	20.98	-5.42
Antenatal inpatient	57.84	96.58	38.74
On-call costs	21.81	0.00	-21.81
Labour and birth	704.74	773.57	68.83
Hospital postnatal care	373.75	417.60	43.85
Domiciliary care	121.59	110.53	-11.06
Special care nursery	7 416.25	10 217.53	2 801.28
Total per woman	2 578.70	3 482.79	904.09

Overall, the mean cost of providing care per woman was lower in the STOMP group compared with the control group ($2 579 versus $3 483). Table 8.16 presents these results.

Table 8.16: Total costs by allocated group and cost saving (control minus STOMP).

	STOMP	Control	Cost saving
	n=550	n=539	Control-STOMP
	$	$	$
Total cost per group	1 420 512	1 876 233	455 721
Mean per woman	2 578.70	3 482.79	904.10
Standard Error[a]	227.03	403.42	
95% CI for mean	2 236-2974	2 864-4 188	
Minimum value	532.00	513.00	
Maximum value	70 190.00	133 113.00	

[a]Standard errors and 95% confidence intervals (CI) were calculated using the bootstrap technique.

8.5 Sensitivity analyses

Sensitivity analyses were used to evaluate the robustness of the results in three areas. These were:

- neonatal admission to SCN;
- efficiency of the antenatal clinics; and
- proportion of elective caesarean sections performed.

8.5.1 Neonatal admission to SCN

Neonates from the control group were admitted to the SCN for longer periods compared with the STOMP group. An assessment of the cost per group for infants admitted for greater than seven days shows that control group infants used more resources than STOMP infants (control: $683 220; STOMP: $325 680). It was presumed that admission for longer than seven days was related to prematurity. While the numbers of preterm infants in the two groups was not significantly different, it was clear that admission to SCN skews the overall cost and contributes to the increased variation in costs of the control group. Therefore, the costs of SCN admission were removed from the analysis to determine if a cost saving still existed. Cost savings associated with STOMP were maintained even after the SCN admission costs were excluded. These

mean costs will be used for the subsequent sensitivity analyses as they are a more accurate reflection of the costs of the models of care (Table 8.17).

Table 8.17: Total costs (excluding costs associated with SCN admission) by group.

	STOMP n=550 $^b	Control n=539 $^b	Cost saving Control-STOMP $^b
Total cost per group	827 213	885 133	57 920
Mean cost per woman	1 504	1 643	139
Standard Error[a]	33	50	
95% CI for mean	1 449-1 559	1 563-1 729	
Minimum cost	490	513	
Maximum cost	5 976	16 097	

[a]Standard errors and 95% confidence intervals (CI) were calculated using the bootstrap technique. [b] Costs were rounded to the nearest dollar.

8.5.2 Efficiency of antenatal clinics

The cost analysis was based upon 50 women per hospital-based clinic and 30 women per STOMP clinic. This sensitivity analysis assessed overall cost savings when the efficiency (the number of women per clinic) was altered. When the STOMP clinic saw less than 10 women per week (five women per clinic), STOMP cost more than standard care. Once the STOMP clinic saw more than 10 women per week, it resulted in cost savings when compared with standard care (Figure 8.1). This cost saving barely changed once the STOMP clinics saw greater than 60 women per week.

Figure 8.1: The cost saving when the number of women seen in the STOMP clinic each week is varied.
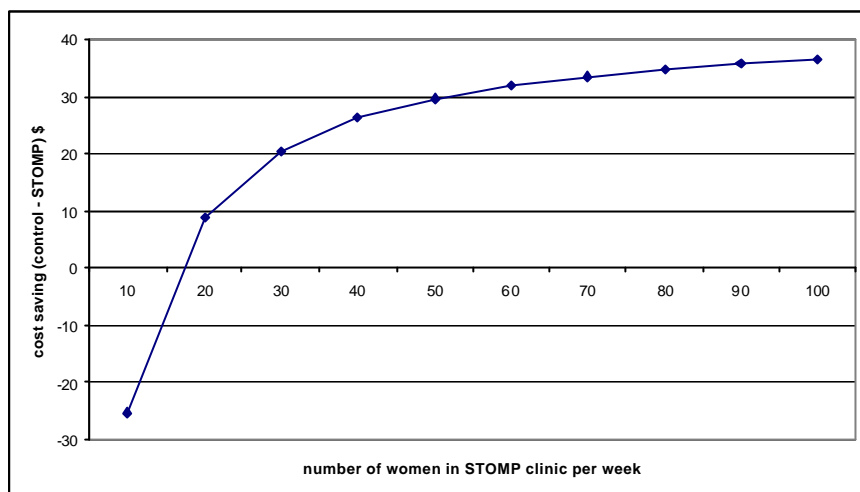
The STOMP clinics currently cater for 60 women per week. STOMP costs less than standard care once more than 10 women are seen per week. The cost saving is minimal once more than 60-70 women are seen per week.

8.5.3 Altered caesarean section rate

It is possible that the cost saving is only because the birth outcomes are different between the groups, particularly the caesarean section rate. To evaluate this, the rates of caesarean section were varied and the cost differences assessed.

Rising caesarean section in STOMP

In order to conduct this analysis, the birth outcomes in each group were converted to proportions. The birth outcomes (normal birth, complicated vaginal birth, elective caesarean section and emergency caesarean section) each have different costs (Tables 8.7-8.10). A ratio of vaginal birth to caesarean section was calculated for each allocated group. This ratio was manipulated to increase the elective caesarean section rate in the STOMP group. The overall cost of STOMP care at each 0.5 per cent increase in elective caesarean section rate was compared with the rate in the control group (17.8%). Postnatal care was adjusted accordingly as the increase in caesarean section rate in the STOMP group altered the costs of postnatal care (Table 8.18 and Figure 8.2).

Table 8.18: Effect on the overall cost when the caesarean rate in STOMP increases incrementally.

Control		STOMP		Cost saving
Total CS[a]	elective CS[a]	Total CS[b]	elective CS[b]	Control-STOMP
%	%	%	%	$
17.8	6.3	13.3	3.8	137.90
17.8	6.3	13.9	4.0	114.21
17.8	6.3	15.6	4.5	79.13
17.8	6.3	17.4	5.0	44.05
17.8	6.3	19.1	5.5	8.98
17.8	6.3	20.9	6.0	-26.10
17.8	6.3	22.6	6.5	-61.18

[a]The rate of caesarean section in the control group was kept stable. [b]The rate of elective caesarean section in the STOMP group was incrementally increased by 0.5%. As a result the total caesarean section rate increased.

Figure 8.2: Cost of two models of care as the caesarean section rate in the STOMP group increases.
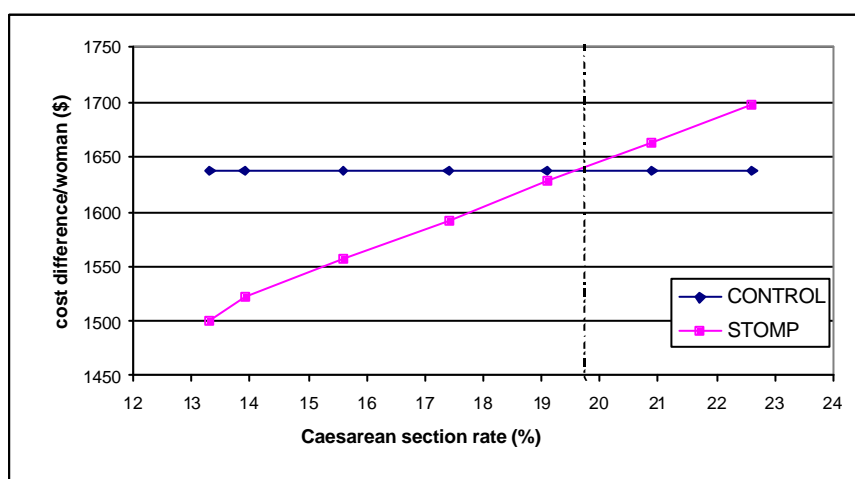
The rate of caesarean section in the control group remains the same (17.8%) as the rate of caesarean in the STOMP group increases. The dotted line represents the point at which the cost saving is lost, that is, when the rate of caesarean section in the STOMP group is around 19.5%.

Table 8.19 and Figure 8.2 illustrate that as the caesarean section rate rises in the STOMP group, the cost saving is reduced. The cost saving was maintained with an increase in caesarean section rate to beyond that of the control group. The caesarean section rate in the STOMP group would have to reach almost 20 per cent (with the control group staying at 17.8%) for the models of care to have similar cost.

Intervention rates

In the second part of this sensitivity analysis, it was assumed that there were no differences in caesarean sections between the groups. The rates of caesarean section obtained in the control group were also applied to the STOMP group. The cost of postnatal care (that is ratio of caesarean to vaginal birth) was adjusted accordingly. This analysis demonstrated that even when the rate of caesarean section was the same in groups, a small cost saving was maintained (Table 8.19).

Table 8.19: Total costs and the cost saving when the birth outcomes are the same in both groups.

	STOMP	Control
Caesarean section rate (%)	17.8	17.8
• elective caesarean section rate (%)	6.3	6.3
Total costs ($)	879 144.37	874 649.98
Mean cost per woman ($)	1 598.44	1 622.73
Cost saving: Control -STOMP per woman ($)		24.28

8.6 Discussion

This cost analysis has demonstrated that there are savings associated with the STOMP model of care. This saving is maintained even when the largest single aspect of resource usage (SCN admission) is removed. The efficiency of the antenatal clinic also alters the cost. However, the cost saving related to this aspect of care was only removed when the STOMP clinics were highly inefficient (five women per clinic). It is important to balance potential cost savings related to increased efficiency with the quality of care associated with adequate time during consultations. Higher efficiency

Chapter 8: A cost analysis

(more women per clinic) means women are likely to be rushed, have a shorter visit and encounter longer waiting times. STOMP care was not associated with these outcomes (see Chapter 6). Sixty women per week (30 per session) appears to provide a balance between cost and quality.

This cost analysis was restricted to an examination of the comparative costs of the alternative treatments (Drummond & Stoddart 1984). The costs are calculated from the perspective of the health system (the provider of the service). Many hospital administrators believe that the introduction of a new model of maternity care is impossible due to constraints on their budget or the need to attract additional funding. This was why a detailed analysis of the costs to the health care system was valuable. It is acknowledged that a broader perspective, that included the costs to the individual and to society, is ideal, this was not the objective of this analysis. Qualitative 'costs' have been presented in earlier chapters that demonstrate the benefits of the STOMP model on other outcomes.

It was plausible that the cost savings demonstrated by the STOMP model are only due to the reduction in caesarean section rates. However, the sensitivity analysis showed that the caesarean section rate in the STOMP group would need be well above the rate in the control group before the cost saving is lost.

The cost analysis makes evident the high costs associated with caesarean sections. Emergency caesareans are more than five times and elective caesareans more than four times the cost of a normal vaginal birth. While it is appreciated that some rate of caesarean section is inevitable (and necessary) in any health system, additional resources will be expended as the rates increase in Australia and elsewhere.

This analysis has simply used the results from a clinical trial to estimate costs of providing maternity care. The original study was not designed for statistical analysis of costs therefore the calculations have been deterministic. The analysis however is a comprehensive description and account of the costs involved in the implementation of a new model of maternity care. A bootstrap resampling technique was used to estimate the variability of mean costs. This reduced the difficulties with skewed nature of the data (Barber & Thompson 1998). The arithmetic mean, standard error and confidence intervals are presented as recommended by Barber and Thompson (1998). Some assumptions may restrict interpretation of the results. For example, the costs of

providing postnatal care were assumed to be the same in the STOMP and the control groups.

The STOMP model currently caters for 25 per cent of women booked into the St George Hospital. It is not clear whether the cost saving demonstrated in this analysis would persist if the STOMP model catered for a greater proportion of women. Further research needs to be conducted to determine the cost efficiency of more widespread implementation.

8.7 Summary

Chapter 8 has presented research concerned with the costs of providing maternity care. Economic analyses of maternity services seem to have been a low priority area. Twaddle and Young (Twaddle & Young 1998) call for more research in this area, especially as scarce resources in public health care systems should be used efficiently.

The STOMP model was established within the current budget of the maternity unit at St George hospital and it was hoped that it would be cost neutral (cost the organisation no more than the current system of care). Results indicate a small cost saving per woman. This confirms that the model is a cost-effective means of providing maternity care with clinical (Chapter 5) and personal benefits for women (Chapter 6 and 7). Chapter 10 discusses the wider implications of these results in the provision of health care in Australia.

The next chapter describes the experiences of women from the three main language groups in the STOMP study and explores the impact of the STOMP model on these women.

Chapter 9 The experiences of women from three diverse language groups

9.1 Introduction

Previous chapters have included the outcomes of women from non-English speaking backgrounds (NESB) in the analysis of the impact and effectiveness of the STOMP model. This chapter presents a secondary analysis investigating the difference in outcomes and experiences between the three main linguistic groups, that is, English, Arabic and Chinese. The chapter also examines whether the STOMP model impacted differently on the outcomes and experiences of women in these language groups. This analysis was conducted because a greater understanding of cultural variation is necessary to plan the provision of culturally acceptable maternity services. Ensuring that the opinions of women from NESB were included was a particular focus of the research presented in this dissertation.

The chapter initially reviews some of the broader issues facing women from NESB in Australia and describes some of the problems identified in the provision of maternity care.

Issues for immigrant women

The first point of contact many immigrant women have with the health system in Australia is when they access maternity services (Cape 1999). Many women from NESB live within nuclear families in Australia. They are relatively isolated from their extended family, who in their country of origin, would typically provide support during the childbearing period (Johnson et al. 1991; Manderson 1999). Recent immigrants tend to have lower socio-economic status compared to the Australian-born population. They are also more likely to be unemployed or working in low status and poorly paid work (Victorian Department of Health 1990). The relative poverty of many new immigrants means that women are reliant on the public health sector for maternity care (Taylor 1999). This places the onus on the public health system to meet the needs of this group of women and provide services that are appropriate and accessible, regardless of language or ethnic background.

Immigrant women experience a number of stressors, including: isolation due to language and culture differences; conflicts between traditional and Australian health care practices; and, lack of support (Locke 1985). Past experiences of trauma and torture contribute to the potential for distress and unhappiness, particularly during the postnatal period (Locke 1985; Paediatric Mental Health Service 1995). The research conducted by Nahas et al (Nahas et al. 1999) with Middle Eastern immigrant women in Sydney attributed high rates of postnatal depression to: loneliness and isolation; a lack of social support; a fear of not being a 'good' mother and wife; and, a lack of understanding about depression and available services.

9.2.1 Barriers to the provision of maternity care for women from NESB

In Australia, as in many other countries, women from NESB experience specific problems with their use of maternity services. They often have to navigate the range of maternity and welfare services, cope with the practical and cultural aspects of childbearing, while also learning English, establishing a home and looking for employment opportunities (Manderson 1999). Cape (Cape 1999) identified: the lack of, or poor command of, English; unfamiliarity with Australian health systems; and, inadequate support networks as being the three most common difficulties facing women from NESB in Australia. Johnson et al (Johnson et al 1991) have defined language as a major barrier to health service delivery. Instances of cross-cultural insensitivity or prejudice have also been reported in the provision of maternity care (Hickey et al 1991). Many women from NESB report problems with maternity services similar to those reported by English-speaking women. For example, crowded antenatal clinics, long waiting times and lack of continuity of care are common to almost all women (Cape 1999; Hickey et al 1991). Language difficulties, lack of support and lack of knowledge about the health system exacerbates these already recognised problems (Cape 1993).

A number of studies have shown that women from minority ethnic and language groups generally receive inadequate information from health care workers (Johnson et al 1991; MORI (Market and Opinion Research International) 1993; Phoenix 1990). Inadequate information can have a significant effect on the long-term health of women. For example, terms such as 'recent immigrants' and 'little English' appeared regularly throughout the *1994 Report on Confidential Enquiries into Maternal Deaths* in the UK,

suggesting that the inability to negotiate the health care system was detrimental to the health of immigrant women (Keirse 1994).

9.3 The experiences of women from Chinese, Arabic and English-speaking backgrounds

Research in Australia has shown diversity in the need, perceptions and experiences of maternity care for women from NESB (Manderson 1994; Rice 1994; Rice et al. 1999a). Summers et al (Summers et al 1997) even suggested that women from ethnic minority communities have different priorities. The STOMP study wanted to better understand the needs of women from NESB who accessed the St George Hospital. The study was not specifically designed to examine differences between language group, but because a diverse and representative sample was recruited it was possible to investigate the experiences of women and to determine whether the STOMP model made a difference. The research question was:

- Did the STOMP model meet the needs of women from non-English speaking backgrounds?

The variables of interest included: the type of antenatal care chosen; antenatal complications; birth outcomes; admission to SCN; quality of antenatal care; opportunity to discuss preferences; the need for more information relating to labour and birth; antenatal and postnatal depression using the EDPS; and, postnatal worry. A number of variables related to infant feeding were also examined, including the intention, initiation and duration of breastfeeding.

9.4 Method

The design of the study, sample size calculations, method of random allocation, outcome measures and data collection methods are provided in Chapter 4.

9.4.1 Analysis

Women were categorised according to language spoken, either English, Chinese (Cantonese and Mandarin) or Arabic. Women from 'other' language groups (n=215), that is, other than English, Arabic or Chinese, were excluded from the analysis in this chapter. These women were too diverse to have a level of meaningful homogeneity

within language group as they spoke a range of languages including Macedonian, Vietnamese, Thai and Spanish.

Descriptive statistics were used to represent the characteristics of women and their clinical outcomes. These statistics were used as cell sizes for some variable groups were too small for statistical analyses (such as chi-squared tests). Variables describing the characteristics of women included age, gestation at booking, need for interpreter, parity, marital status, employment, level of education and type of antenatal care. Variables to describe the clinical outcomes included history of a previous caesarean section, presence of gestational diabetes, type of birth and admission to the SCN.

Continuous variables that were normally distributed were analysed using a two-way analysis of variance (ANOVA) to determine how outcomes differed for the allocated group depending on language group. Continuous data that did not have normal distributions were log-transformed to ensure they were normally distributed (Coakes & Steed 1999). The α level for statistical significance was set at 0.05. Post hoc analyses were carried out using a Bonferroni adjustment to examine group differences. Categorical responses, for example, opportunity to discuss preferences for labour and birth, and antenatal and postnatal depression were analysed with chi-squared tests examining the significance of differences between language groups.

Descriptive statistics were used to represent women's intention to breastfeed as well as breastfeeding initiation and duration. A Kaplan-Meier procedure was used to illustrate duration of breastfeeding by language group. The Kaplan-Meier procedure is a method of estimating time-to-event models in the presence of censored cases. In this analysis, censoring occurred when women reported weaning their infants.

9.4.2 Sample

There were 874 women in this sample. The main language groups were English (n=517), Chinese (n=183) and Arabic (n=174). The language groups were evenly divided between the STOMP and the control groups.

9.5 Results

9.5.1 Demographic data

Chinese-speaking women were older than Arabic or English-speaking women. Twenty-eight per cent of Chinese-speaking women were aged 35 or older compared with eight per cent of English-speaking and seven per cent of Arabic-speaking women. Arabic-speaking women booked into hospital slightly later into their pregnancy (Table 9.1).

Table 9.1: Age and gestation at booking by language group.

	English n=517	Chinese n=183	Arabic n=174
Age [SD]	26.9 [5.0]	32.2 [4.3]	26.6 [5.4]
Age: min–max	16-41	22-44	17-44
Booking gestation [SD]	15.1 [3.6]	14.8 [3.5]	16.3 [4.1]

English and Chinese-speaking women were more likely to be primiparous than Arabic speakers. Arabic-speaking women were of higher parity than the other groups. Chinese-speaking women were more likely to require an interpreter compared to Arabic-speaking women. Chinese-speaking women were also more likely to report having a tertiary education than other women. Fewer Arabic-speaking women reported working outside the home. Marital status was similar between language groups (Table 9.2).

Table 9.2: Descriptive variables by language group.

	English	Chinese	Arabic
	n=517	n=183	n=174
	%	%	%
Interpreter needed	0	73.2	39.1
Primiparous	52.0	44.8	29.9
Married/defacto	91.5	97.8	95.4
Employed outside the home	60.5	41.0	18.4
Tertiary education	35.0	51.3	30.4

The proportion of women in the sample who were primiparous, married, employed outside the home, with a tertiary education and requiring an interpreter by language group. Responses were represented by categorical variables and are presented as percentages

Slightly more women in the control group had a history of a previous caesarean section (as described in Chapter 5, page 93). This variable was evenly distributed across language groups.

9.5.2 Clinical outcomes

Antenatal care

Most women allocated to the STOMP group received the new model of care (87%), and most allocated to the control group received antenatal care in the hospital-based antenatal clinic (66%) as described in Chapter 6. Arabic and Chinese-speaking women were less likely to choose the birth centre or the midwives' clinic for antenatal care. Slightly higher proportions of Arabic and Chinese-speaking women from the control group chose GP shared care (Table 9.3).

Table 9.3: Antenatal model of care by language group and allocated group.

	STOMP[a]			Control[b]		
	English	Chinese	Arabic	English	Chinese	Arabic
	n=332	n=87	n=85	n=314	n=93	n=75
	%	%	%	%	%	%
STOMP clinic	88.6	83.9	89.4	0.3	0	1.3
Antenatal clinic	5.1	14.9	8.2	52.5	82.8	62.7
Birth centre	4.2	0	0	14.6	0	9.3
Midwives' clinic	0.6	0	0	19.4	0	2.7
GP shared care	1.5	1.1	2.4	13.1	17.2	24

[a]Women who refused the offer of STOMP, were able to choose their type of care. [b]Women in the control group were able to choose their model of antenatal care. Results are presented as percentages.

Antenatal complications

The incidence of antenatal complications (including antepartum haemorrhage, pre-eclampsia, preterm labour) was similar between allocated groups. More Chinese-speaking women developed gestational diabetes compared with English and Arabic speaking women regardless of allocated group (Table 9.4).

Table 9.4: Incidence of women with gestational diabetes by allocated group and language group.

	STOMP			Control		
	English	Chinese	Arabic	English	Chinese	Arabic
	n=332	n=87	n=85	n=314	n=93	n=75
	%	%	%	%	%	%
Gestational diabetes	5.1	24.1	2.4	3.2	19.4	6.7

The response was represented by a categorical variable and is presented as a percentage of the sample.

Birth outcomes

Statistical analyses were not used to compare differences in birth outcomes as cell sizes were small. Results are simply described and presented graphically.

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There appeared to be an interaction between language and allocated groups. Figures 9.1 to 9.4 presents the birth outcomes of women in the three language groups and the effect that the STOMP model had on these outcomes.

Normal birth was more common in Arabic-speaking than English or Chinese-speaking women regardless of allocated group. The STOMP model increased the rate of normal birth in English-speaking women, but did not appear to influence Arabic or Chinese-speaking women (Fig 9.1).

Figure 9.1: Proportion of normal births by allocated and language group.
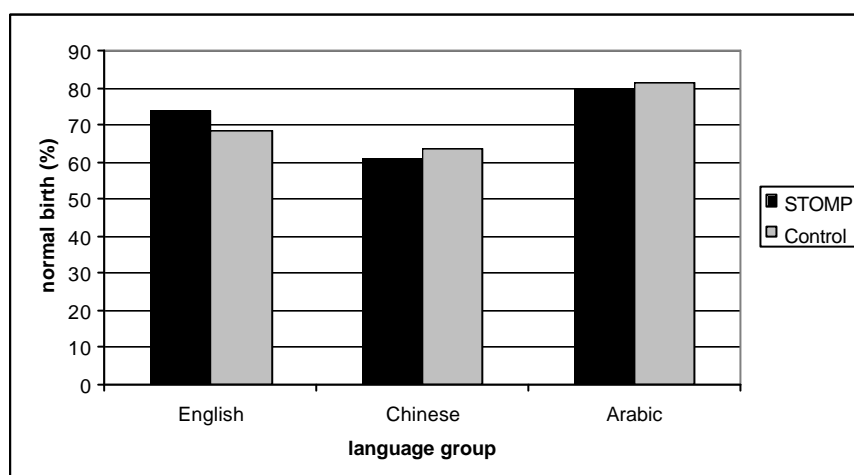
Number of women who had a normal birth: English STOMP n=197; English control n=177 Chinese STOMP n=56; Chinese control n=57; Arabic STOMP n=72; Arabic control n=70.

There was a small decrease in the rate of elective caesarean section in English and Arabic-speaking women but a larger decrease in Chinese-speaking women. The elective caesarean section rate in Chinese-speaking women was more than seven per cent less the STOMP group compared with the control group (Fig 9.2).

Figure 9.2: Proportion of elective caesarean sections by allocated and language group.
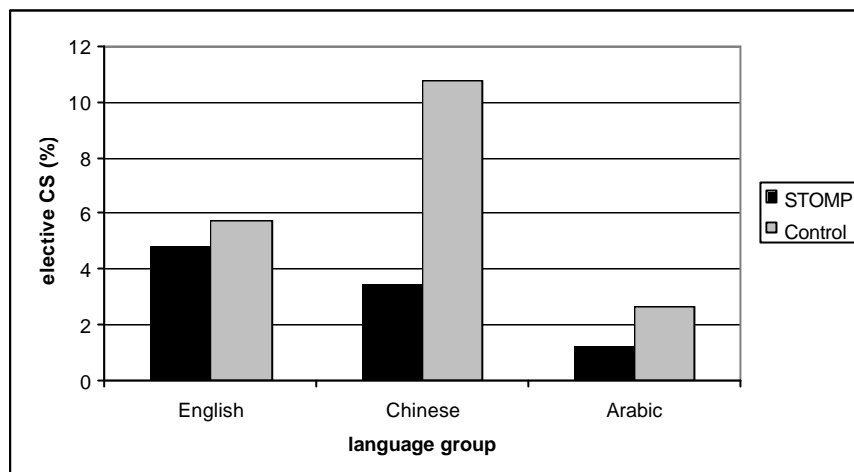
Number of women who had an elective caesarean section: English STOMP n=10; English control n=13; Chinese STOMP n=3; Chinese control n=10; Arabic STOMP n=1; Arabic control n=5.

There was a small decrease in the emergency caesarean section rate in English and Chinese speaking women in the STOMP group. For Arabic women, the reverse occurred with fewer women in the control group having an emergency caesarean section than in the STOMP group (Fig 9.3).

Figure 9.3 Proportion of emergency caesarean sections by allocated and language group.
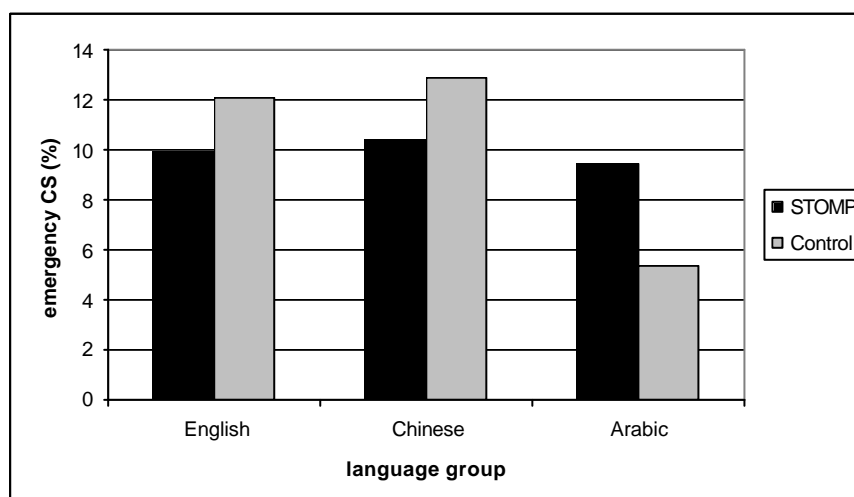
Number of women who had an emergency caesarean section: English STOMP n=22; English control n=32; Chinese STOMP n=8; Chinese control n=14; Arabic STOMP n=7; Arabic control n=5.

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There was a small decrease in rate of instrumental vaginal birth in English-speaking women from the STOMP group. STOMP did not influence the rate in Arabic-speaking women. The rate of instrumental vaginal birth was higher in Chinese-speaking women from the STOMP group compared with the control group (Fig 9.4).

Figure 9.4: Proportion of instrumental vaginal births by allocated and language group.
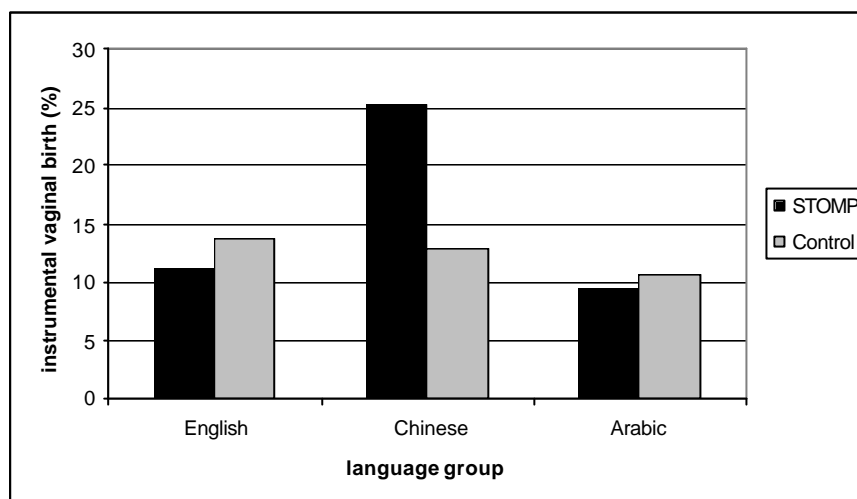
Number of women who had an instrumental vaginal birth: English STOMP n=29; English control n=37; Chinese STOMP n=23; Chinese control n=12; Arabic STOMP n=6; Arabic control n=8.

Admission to SCN was most common in Chinese-speaking women from the control group. Chinese-speaking women from the STOMP group had lower rates of SCN admission, as did, to a lesser degree, Arabic-speaking women. STOMP did not influence the rate of admission to SCN in English-speaking women (Figure 9.5).

Figure 9.5 Proportion of neonates admitted to the SCN by allocated group and language group.
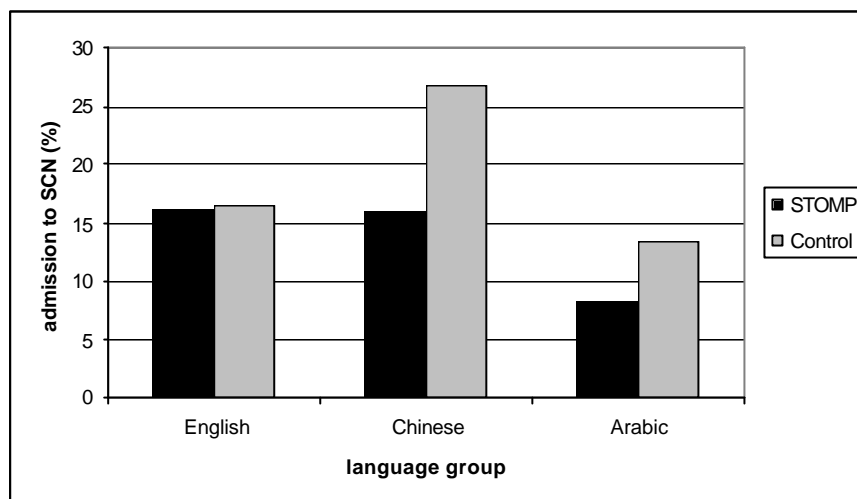
Number of neonates admitted to the SCN: English STOMP n=41; English control n=37; Chinese STOMP n=14; Chinese control n=25; Arabic STOMP n=7; Arabic control n=11.

9.5.3 Experience of antenatal care

Women's experiences with antenatal care were evaluated through a questionnaire distributed at 36 weeks gestation. This process is described in detail in Chapters 4 and 6 and the response rates to the questionnaires are presented in Chapter 4 (Tables 4.5, page 77). The variables of interest were: quality of antenatal care; opportunity to discuss preferences for labour and birth; and, antenatal depression.

Quality of antenatal care

A two-way ANOVA was performed to determine whether there was an interaction between allocated group and language group on quality of antenatal care. There was no significant interaction between allocated group and language ($F(2,467)=1.2, p=0.3$). Rating of quality of care differed due to allocated and language group (*group: $F(1,467)=38.7, p<0.0001$; language: $F(2,467)=53.3, p<0.0001$*). Women in the STOMP group rated their antenatal care higher than those in the control group (*mean diff. 2.5; p<0.0001*). Regardless of allocated group, English-speaking women rated their care the highest and Chinese-speaking women the lowest. Table 9.5 presents this post hoc analysis using a Bonferroni adjustment.

Table 9.5: Quality of antenatal care by language group.

Language		Mean Diff	SE	p	95% CI
English-speaking vs	Chinese-speaking	4.16	0.416	0.00	(3.16, 5.16)
English-speaking vs	Arabic-speaking	1.74	0.457	0.00	(0.65, 2.84)
Chinese-speaking vs	Arabic-speaking	-2.42	0.54	0.00	(-3.73, -1.10)

Quality of antenatal care was measured on a continuous scale. A post hoc analysis using a Bonferroni adjustment was conducted. SE: Standard error, CI: confidence intervals.

Opportunity to discuss preferences for labour and birth

Chinese-speaking women were more likely to report insufficient opportunity in the antenatal period to discuss their preferences for labour and birth. Eighty-six percent (n=100) of Chinese speaking women wanted more time to talk about their preferences compared with 46 per cent (n=192) of English speaking and 52 per cent (n=41) of Arabic speaking women ($c^2(2)= 71$, $p<0.0001$). Regardless of language, women in the STOMP group were more likely to report that they had an opportunity during the antenatal period to talk about their preferences for labour and birth management.

Antenatal depression

Arabic-speaking women were significantly more likely to score above the antenatal threshold (14.5) on the EDPS than Chinese and English-speaking women ($c^2(2)= 28.6$, $p<0.0001$). Twenty-eight per cent of Arabic-speaking women scored above the threshold compared to nine per cent of Chinese and 12 per cent of English-speaking women. The STOMP model did not impact on depression within language groups.

9.5.4 Experiences of care during labour, birth and the postnatal period

Women's experiences with care during labour, birth and the postnatal period were evaluated through a questionnaire distributed at eight to ten weeks postpartum. This process is described in detail in Chapters 4 and 7. The response rates to the questionnaire are presented in Chapter 4 (Table 4.8, page 78). The variables of interest were: the adequacy of information provided about labour, birth and the postnatal period; and, levels of postnatal depression and worry.

Adequacy of information provided about labour, birth and the postnatal period

There was no significant interaction between allocated group and language group on need for more information (*F(2,494)=0.5, p=0.6*). Both allocated group and language group significantly affected the need for more information (*group: F (1,494)=8.3, p<0.0001; language: F(2,494)=54.7, p=0.004*). Women in the STOMP group required less additional information regardless of language. Women from Chinese-speaking backgrounds were most likely to report that they had insufficient knowledge about specific issues relating to aspects of labour, birth and the postnatal period compared to English and Arabic-speaking women. Table 9.6 presents this post hoc analysis using a Bonferroni adjustment.

Table 9.6: Need for more information by language group by language group.

Language		Mean Diff	SE	p	95% CI	
English-speaking vs	Chinese-speaking	-2.80	0.27	0.00	(-3.4,	-2.2)
English-speaking vs	Arabic-speaking	-0.48	0.32	0.41	(-1.3,	0.3)
Chinese-speaking vs	Arabic-speaking	2.31	0.38	0.00	(1.4,	3.2)

'Need for more information' was measured on a continuous scale. A post hoc analysis using a Bonferroni adjustment was conducted. SE: Standard error, CI: confidence intervals.

Postnatal depression and worry

The STOMP model did not impact on the proportion of women scoring above the threshold for postnatal depression (12.5) using the EDPS. Women from NESB were more likely to score above the screening threshold. Twenty-six per cent of Arabic and twenty-two per cent of Chinese-speaking women scored above the threshold compared with twelve per cent of English-speaking women ($c^2(2)=15.6, p<.0001$).

There was no interaction between allocated group and language group on level of worry (*F(2,495)=0.44, p=0.6*). There were no differences between allocated groups on worry (*F(1,495)=1.8, p=0.2*) but there was a significant difference between language groups (*F(2,495)=8.4, p<0.0001*). Chinese-speaking women were significantly more worried than English-speaking women. Table 9.7 presents this post hoc analysis using a Bonferroni adjustment.

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Table 9.7: Postnatal worry by language group.

Language		Mean Diff	SE	p	95% CI
English-speaking vs	Chinese-speaking	-4.22	1.026	0.00	(-6.68, -1.76)
English-speaking vs	Arabic-speaking	-0.95	1.289	1.00	(-4.04, 2.15)
Chinese-speaking vs	Arabic-speaking	3.27	1.479	0.08	(-0.28, 6.83)

Postnatal worry was measured on a continuous scale. A post hoc analysis using a Bonferroni adjustment was conducted. SE: Standard error, CI: confidence intervals.

9.5.5 Infant feeding choices and experiences

The STOMP model of care did not impact on intention or initiation of breastfeeding, breastfeeding at discharge from hospital and breastfeeding at eight weeks (Table 9.6).

Table 9.8: Stated intention to breastfeed, initiation of breastfeeding, breastfeeding at discharge from hospital and breastfeeding at eight weeks by allocated group.

	STOMP group	Control group	p[a]
	Number (%)	Number (%)	
Intention to breastfeed	472 (94.0)	442 (92.9)	0.5
Initiation of breastfeeding	496 (90.2)	476 (88.9)	0.4
Breastfeeding on discharge from hospital	439 (79.8)	425 (78.8)	0.4
Breastfeeding at 8 weeks	190 (58.5)	172 (52.8)	0.3

[a]An independent sample t-test was used to examine differences between groups.

There were differences between language groups in intention, initiation and duration of breastfeeding (Fig 9.6). Chinese speaking women were less likely to express an intention to breastfeed at their first antenatal visit than English or Arabic-speaking women ($t(1)=24.1, p<0.0001$) and subsequently were less likely to initiate breastfeeding ($t(1)=26.1, p<0.0001$).

Figure 9.6: Breastfeeding status at four time points by language group.
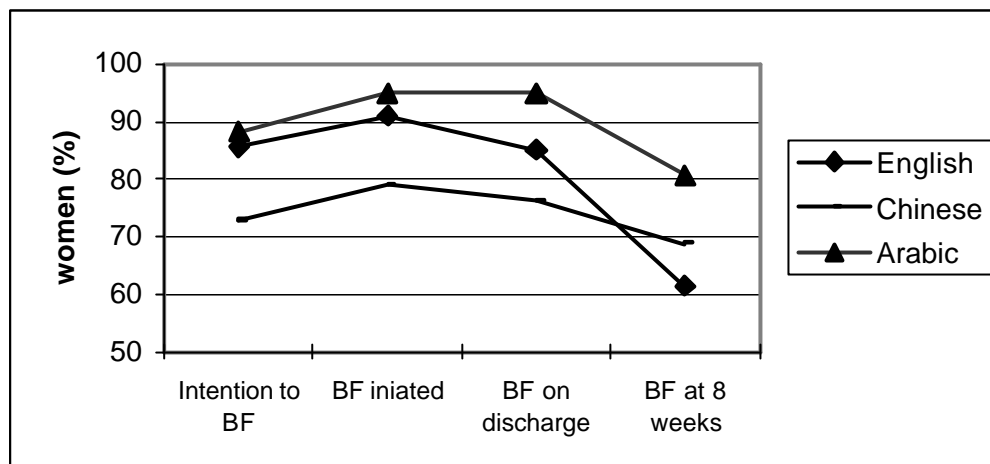
Proportion of women who: expressed an intention to breastfeed (BF) at their first antenatal visit; initiated BF; were BF on discharge from hospital; and, were still BF at eight weeks postpartum. All four variables were measured using dichotomous categorical responses. Statistical analyses were not conducted.

Breastfeeding to 8 weeks

Using a Kaplan-Meier procedure, a time-to-event graph was constructed for women who initiated breastfeeding (Figure 9.7). The duration of breastfeeding in the three language groups was described. Arabic-speaking women had significantly longer duration rates compared to both of the other groups with 77 per cent still breastfeeding at eight weeks. Seventy-three per cent of the Chinese-speaking women who initiated breastfeeding were still doing so at eight weeks. In comparison, 60 per cent of English-speaking women, who had initiated breastfeeding, were still doing so at eight weeks.

Figure 9.7: Proportion of women continuing to breastfeed during the first 8 weeks postpartum by language group.
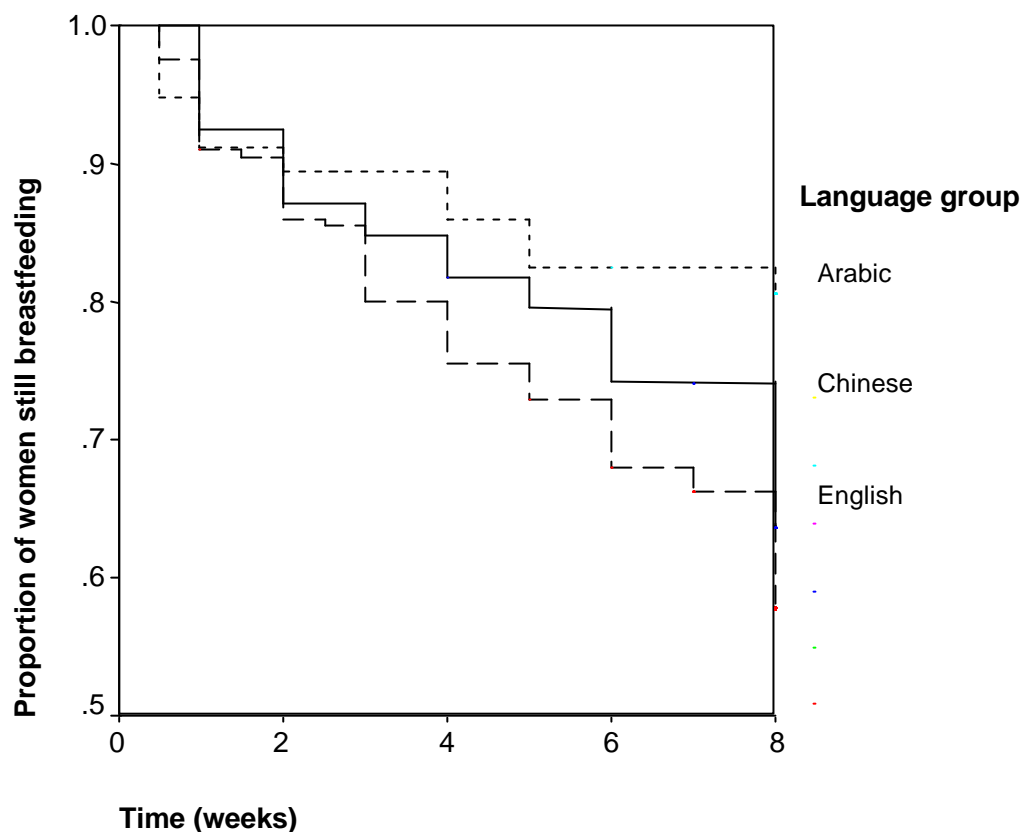
The 'time-to-event' graph illustrates breastfeeding duration over the first eight weeks. All women who initiated breastfeeding were included (English n=464; Chinese 147; Arabic 156). As women reported weaning their infants over the eight weeks, the proportion of women still breastfeeding decreased.

9.7 Discussion

The results from this secondary analysis suggest that Chinese and Arabic-speaking women have different experiences with maternity care compared with English-speaking women. The STOMP model seemed to improve the experience for women from NESB, particularly in the perceived quality of antenatal care and the amount of information provided about labour, birth and the postnatal period. It is evident, however that there are still problems in providing effective care for women from NESB, particularly, Chinese-speaking. Chinese-speaking women were more likely to report worry in the

postnatal period. Women from Arabic and Chinese-speaking groups were more likely to score above the threshold for postnatal depression than English-speaking women.

While this was a secondary analysis and insufficient data precluded some statistical analyses, the findings demonstrate interesting patterns and suggest that further research in this area is necessary.

9.7.1 Clinical outcomes

There were differences among the language groups in age, parity and gestation at hospital booking. Arabic speaking women were generally of higher parity and booked into hospital slightly later. Chinese-speaking women were older with fewer children. These findings are unsurprising and confirm what others have reported (de Costa 1988; Rice et al. 1999b). A greater proportion of Chinese-speaking women were diagnosed with gestational diabetes, an observation that has reported in an Australian sample (Beischer et al. 1991).

Interestingly, no Chinese-speaking and few Arabic-speaking women from the control group chose to attend the birth centre or the midwives' clinic for antenatal care. Arabic and Chinese-speaking women allocated to the STOMP group who refused the new model of care, chose to attend the antenatal clinic rather than the midwives' clinic or birth centre. An earlier evaluation of this birth centre found that few (0.8%) women were from a Chinese background (Homer et al 2000). The results suggest that either women did not receive, or were not given information about the various options, or that they felt more comfortable with the standard antenatal clinic. Chinese-speaking women were more likely to require an interpreter, which may have meant that the options of care were not sufficiently outlined. Rice et al (Rice et al 1999b) reported that traditionally, many women in non-westernised Asian countries have had their babies at home and on immigration to Australia would choose settings for birth that have a philosophy of low obstetric intervention. The findings from the sample in the STOMP study suggest that was not the case. Chinese-speaking women chose a conventional setting for labour and birth and that they had high rates of obstetric intervention as evidenced by the rates of elective caesarean section.

The differences between the language groups in rates of normal birth and caesarean section are of concern. As the frequencies were small, the differences may be due to chance, therefore the results should be interpreted with caution. Nonetheless, more

Chinese-speaking women had a caesarean section than all other women and Arabic-speaking women had the lowest rate of obstetric intervention. The STOMP model reduced the elective caesarean section rate in Chinese-speaking women but had little effect in Arabic and English-speaking women. STOMP reduced the emergency caesarean section rate in English and Chinese-speaking women with no effect in Arabic speaking women. While fewer Chinese-speaking women from the STOMP group had an elective caesarean section, more had an instrumental vaginal birth. Parity may an important predictor of some of these differences, as Arabic speaking women were more likely to be multiparous and Chinese-speaking women more likely to be primiparous. Nonetheless, it seems unlikely that parity alone can explain the differences, especially as this variable was evenly distributed between the allocated groups. Possibly the more positive experiences that STOMP women reported with antenatal care (for example, higher quality of antenatal care, less need for additional information and increased opportunities to discuss preferences for labour and birth) influenced Chinese-speaking women to attempt a labour rather than opt for an elective caesarean section. Continuity of care and carer by midwife and obstetrician in the antenatal period (discussed in Chapter 6 and 7) may have encouraged women to attempt normal labour. Another explanation may be the practice style of the obstetrician in the STOMP model. The rate of instrumental vaginal birth in Chinese-speaking women warrants ongoing investigation, as there is concern about the association between pelvic floor damage and operative vaginal birth and episiotomy (Sultan et al. 1996).

It is difficult to compare the birth outcomes of Chinese-speaking women with other research as there is little written about the obstetric outcomes of Chinese-speaking women in Australia. Rice's et al (Rice et al 1999b) study of Asian women in Victoria included Chinese-speaking women in the overall Asian sample. Chinese women were included in the Asian sample, along with Vietnamese and Cambodian women. This research did not find differences in the rate of elective caesarean section, however Asian-born women had a slightly higher rate of emergency caesarean rate compared to Australian-born women. Other research comparing the obstetric outcomes of Asian women with English women in Australia and the USA have only included Vietnamese and Cambodian women in the sample (Gann et al. 1989; Henry et al. 1992; Ward et al. 1981). These studies have reported similar, if not better, obstetric outcomes of women from an Asian background compared with their English-speaking counterparts. The

Chapter 9: Experiences of women from three diverse language groups

higher rate of caesarean section in Chinese-speaking women in the STOMP study may be because the number of cases within non-English speaking groups were too small (chance effect) or the population was fundamentally different from those reported elsewhere. Clearly more research about maternity services for Chinese-speaking women needs to be conducted to determine the cause of these differences. The rate of admission to the SCN in the control group also warrants further investigation.

9.7.2 Experience of care

Some of the differences in the experience of care, particularly for Chinese-speaking women, may be associated with age, parity and the need for interpreter services across the groups. Chinese-speaking women reported the greatest need for an interpreter and were more likely to have negative responses about their care. For example, they scored their quality of antenatal care lower and reported insufficient opportunities to discuss personal preferences and receive information and support. While interpreters were widely utilised in the antenatal period the results suggest that the service was inadequate or ineffectively used by midwives and doctors.

During the study the hospital had one Chinese-speaking ethnic liaison midwife who worked in the antenatal clinic and postnatal ward. The STOMP model did not include an ethnic obstetric liaison midwife. In the design and implementation of the model, it was proposed that Chinese-speaking women in the control group might have had a more positive experience, particularly in the antenatal period, than those in the STOMP group because of access to a bilingual midwife. This was not the case. One bilingual midwife was insufficient to meet the needs of the women from NESB in the control group. Continuity of care in a community-based setting seems to have improved the perceived quality of antenatal care and provided more information about labour, birth and the postnatal period across all language groups. Nonetheless, Chinese-speaking women still reported inferior experiences compared with other women regardless of the model of care. Clearly there is a need for further development of models of care so women from all language groups have quality of care.

9.7.3 Depression and worry

There were high levels of unhappiness and potential for depression reported from NESB women, antenatally and postnatally. In the antenatal period, Arabic-speaking

women scored well above other women on the threshold for depression using the EDPS. In the postnatal period, women from both NESBs scored above English-speaking women on the same scale. Chinese-speaking women were also more likely to report worry in the postnatal period. STOMP care did not impact on the proportion of women scoring above the threshold for depression.

The proportion of women scoring above the recommended threshold on the EDPS was within the wide range of prevalence estimates that have been reported. Estimates for the prevalence of postnatal depression range from three to thirty per cent (Pope et al 1999) and vary according to the method of measurement. Twelve studies that used the EDPS were included in this meta-analysis with a mean prevalence of 12 per cent (O'Hara & Swain 1996). The STOMP study used the EDPS although it was recognised that this was not the ideal instrument. A meta-analysis has suggested that self reporting instruments, such as the EDPS, invariably result in higher levels of postpartum depression than standardised diagnostic interview schedules (O'Hara & Swain 1996).

There is contention about cultural differences in postnatal depression. A recent systematic review of published literature on postnatal depression (Pope et al 1999) has suggested that there is no consistent support for the hypothesis of cultural differences in the prevalence of postnatal depression. The STOMP study suggests that the prevalence of postnatal depression, as measured by the EDPS screening tool, is higher in non-English speaking women than English-speaking. It is not clear whether the higher scores on the EDPS in women from NESB are an accurate reflection of high levels of depression, an artifact relating to interpretation or because the tool has a low sensitivity and specificity rate as a stand-alone instrument (Condon & Corkindale 1997). Research in Vietnamese, Arabic and English-speaking women in western Sydney examined postnatal depression on translated versions of the EDPS and found no significant differences among the three groups (Matthey et al. 1997). Matthey et al (Matthey et al 1997) reported that the final question in the EDPS (the thought of harming myself has occurred to me) was inappropriate for Arabic women and the four possible responses per question caused confusion in some women. This aspect of the instrument may explain the high rates of depression women from NESB.

Questions remain about the issues of depression and worry in women from NESB. Further research needs to be conducted to understand the experiences in these groups more thoroughly and to devise services that will support these women.

9.7.4 Infant feeding experiences

In this study, Chinese-speaking women were least likely to initiate breastfeeding or be breastfeeding on discharge from hospital. In contrast, Arabic-speaking women were most likely to initiate breastfeeding and be breastfeeding on discharge. These results are consistent with the findings of Scott et al (Scott et al. 1997a) who reported lower breastfeeding duration rates among Asian women and higher rates in Middle Eastern women.

Other research has indicated that women from NESB are less likely to breastfeed than women born in Australia (Lowe 1997; Williams & Carmichael 1983). Low breastfeeding rates amongst some migrant groups have been attributed to the transition from an extended to a nuclear family, an increased interest in Western mores, a need to work or study, and the availability of infant formula (James et al. 1994). Even where breastfeeding is considered normal in the country of birth, early weaning and artificial feeding is common following immigration to Australia (Manderson & Mathews 1981; Rossiter 1992). Other research has reported that a lower level of education and socio-economic background will affect breastfeeding rates more strongly than ethnicity alone (Manderson 1999; Williams & Carmichael 1983).

Differences between language groups in terms of intention and duration of breastfeeding were presented on the time to event graph (Figure 9.8). While fewer Chinese-speaking women stated an intention to breastfeed, those who did initiate were more likely to still be breastfeeding at eight weeks compared with English-speaking women. It is possible that Chinese-speaking women were more comfortable with registering a decision <u>not</u> to breastfeed than English-speaking women. Societal pressures may mean some English-speaking women who stated an intention to breastfeed, and subsequently did so, were somewhat ambivalent about this decision and had a lower threshold for weaning.

Research has suggested that the earlier the decision is made to breastfeed, the longer the duration (Jones et al. 1986; Lawson & Tulloch 1995; Scott & Binns 1999). Scott et al (Scott et al. 1997b) reported that women who had decided on their preferred feeding

method prior to pregnancy were more likely to initiate breastfeeding that those who chose during or after the pregnancy. Jones et al (Jones et al 1986) have suggested that an early decision might indicate a stronger desire and determination to breastfeed and these women would be more likely to persevere. The STOMP study was unable to determine whether the intention to breastfeed was decided prior to pregnancy. However as the question was asked at the booking visit, it was an early decision.

The STOMP model of care did not influence initiation or duration of breastfeeding. Research in new models of care have either not measured breastfeeding as an outcome at eight weeks (Kenny et al 1994; Rowley et al 1995) or have failed to show differences in breastfeeding duration (Waldenström & Nilsson 1994). While the model of maternity care may not make a difference, other research has shown that the provision of extra support by professionals with special skills in breastfeeding results in more mothers breastfeeding their infants until two months of age (Sikorski & Renfrew 2000). In future models of maternity care, postnatal support should be included. This is particularly true for women from NESB who may experience social isolation as a result of migration.

9.8 Summary

This chapter has discussed some of the issues for women from NESB in their use of maternity services. Women from diverse cultures have different needs and expectations of maternity care and this must be considered when designing and implementing services for women from NESB.

There has been little research into the obstetric characteristics, the antenatal, postnatal or breastfeeding experiences of women from NESB in Australia. This lack of research and understanding may contribute to the ongoing challenges that Australian maternity services have with the provision of care to these women. The small numbers of women in some of the groups and the low response rates (from Arabic-speaking women particularly) are acknowledged limitations of this study. For these reasons, and because it is a secondary analysis, the results must be interpreted with caution. Nonetheless, these findings add to the limited existing knowledge about the experiences of these women and will assist in the planning and development of maternity services that meet the needs of all women.

The final chapter presents a synthesis and summary of the main findings from each of the research questions and discusses the limitations of the study. Implications for maternity care in Australia are also discussed.

Chapter 10 An overview and discussion of the implications for maternity care

10.1 Introduction

This research suggests that a model of community-based continuity of maternity care, provided collaboratively by midwives and obstetricians, can be implemented within the current resources of a maternity unit, benefiting women and the organisation. The study recruited a diverse range of women, including those from NESB, and did not exclude women who developed complications in pregnancy. The results are generalisable to other public hospital systems in Australia.

The STOMP model has had a widespread impact across the maternity unit at George Hospital and is now a permanent and integrated option for the care of women. In 1999 the STOMP teams cared for 28 per cent of the women booked at the hospital and the model is currently being considered for more widespread adoption, including within a private hospital. This research has demonstrated that a randomised controlled trial can be used as part of a strategy to change the models of care provided within a health system. The design, choice of outcome measures and analysis means that the St George Hospital has sound quantitative data on which to base policy decisions about the sustainability of this model of care.

Chapter 10 presents a summary and general discussion of the results by returning to the questions posed in Chapter 1. The limitations of the study are discussed and the implications for maternity care in Australia and elsewhere are addressed.

10.2 Overview of the questions

The study asked six specific questions as outlined in Chapter 1.

10.2.1 Does the STOMP model result in comparable maternal and neonatal outcomes compared with standard care?

Chapter 5 presented the clinical outcomes of women and their neonates. The results demonstrate that the STOMP model of care produced satisfactory clinical outcomes. Fewer women from the STOMP group were admitted to hospital in the antenatal period,

although the numbers of complications were similar between the groups. STOMP women were less likely to have electronic fetal monitoring in labour or to have a caesarean section. This latter finding is in contrast to most other trials of continuity of maternity care (Waldenström & Turnbull 1998). The mechanism which resulted in the reduced caesarean section rate is unclear, although it is hypothesised that it may be related to continuity of care and carer, particularly in the antenatal period, which encouraged more women to attempt a trial of labour. The descriptive data presented in Chapter 9 suggest that the greatest impact on the STOMP model was in Chinese-speaking women. While the numbers of women who had elective and emergency caesarean section are small (particularly in the Chinese and Arabic-speaking groups) and statistical tests were not conducted, the disparity warrants further investigation.

Fewer STOMP neonates were admitted to the special care nursery (SCN), although this difference was not statistically significant. There were four perinatal deaths in each group although the study did not have sufficient power to detect significant differences of this outcome. One perinatal death in the STOMP group was judged to have been 'potentially avoidable'. In this case, clinical measurements implied that intrauterine growth was occurring even though the birth weight of the stillborn infant would have suggested otherwise. In view of the clinical observations, it seems unlikely that the course of the pregnancy would have been any different if this woman had received standard care.

10.2.2 Are community-based antenatal services, established as an outreach of a teaching hospital, associated with a better experience for women?

Chapter 6 presented the women's experience of community-based antenatal care compared with those in the control group, most of whom attended the hospital-based antenatal clinic. Women from the STOMP group reported more positive experiences than the control group. For example, they reported waiting less time for appointments, having better access to antenatal care and being less worried about their babies. STOMP women felt that their antenatal care was of a higher quality than control group women. Quality of care included being listened to, having adequate time to discuss concerns and problems, receiving enough information, advice and emotional support. These are all factors that have been identified as being determinates of satisfactory antenatal care (Brown & Lumley 1994; Green et al 1998a; Hirst et al 1998; McCourt et

al 1998; MORI (Market and Opinion Research International) 1993; Proctor 1998; Wilcock et al 1997).

A move to community-based care demonstrates an important commitment to the ideals of primary health care. Despite numerous recommendations in Australian reports, the successful transfer of antenatal services from busy hospital clinics has been slow or has not occurred at all. The STOMP study demonstrates that it is possible to provide antenatal care in the community and that is associated with benefits for women. Other institutions may be able to replicate this aspect of the STOMP model to improve the experience of antenatal care for women.

10.2.3 Did the STOMP model improve women's experiences during labour, birth and the postnatal period?

Chapter 7 presented the experiences that women reported during labour, birth and in the postnatal period. Women in the STOMP group: felt more able to discuss their preferences for labour and birth with their caregivers; were better informed about various aspects of labour and birth; and, felt more in control during labour. The STOMP model of care did not impact on levels of worry, unhappiness or depression reported postpartum. Provision of postnatal care has been highlighted as the area in need of the greatest change and improvement from women in both groups. This is the subject of recent research in the maternity unit at St George Hospital (Cooke & Stacey 2000).

Continuity of carer in labour

The majority of STOMP women (79%) had continuity of <u>care</u> during labour and birth, that is a STOMP midwife from their respective team provided care, and almost two thirds of STOMP women reported continuity of <u>carer</u> during labour, that is, they had met the midwife previously. Most women liked the experience of continuity of carer in labour. Continuity of carer during labour was not a specific focus of the STOMP model. The rates are therefore encouraging considering the design of the model. For example, midwives were divided into smaller teams to increased continuity of carer during the antenatal period and it was acknowledged that this would impact on the probability of providing continuity of carer in labour.

A secondary analysis compared the experiences of women who received continuity of carer with those who did not. Women who received continuity of carer rated their

experience higher and reported a higher sense of control during labour. While this finding must be interpreted with caution, it suggests that continuity of carer can have benefits that can be quantitatively measured. Until now, most research that has identified benefits associated with continuity of carer during labour have been qualitative, with small, often purposive, samples (Morrison et al 1999); (Walsh 1999);(Coyle 1998; Farquhar et al 1994; McCourt et al 1998); (Murphy-Black 1993). It is possible that quantitative measures are insufficient to describe what it is about continuity of carer that is important to women (Page et al 2000). Green et al (Green et al 1998b) also suggest that routine questionnaires are unlikely to address the complex and often contradictory values around the importance of continuity of care and carer. More research needs to be conducted with models of care that have smaller groups of midwives (caseload models), so that the probability of having continuity of carer in labour is higher. This may unequivocally answer questions regarding the quantitative benefits of continuity of carer.

Most Australian women have not previously had an opportunity to receive continuity of midwifery carer in labour. Privately insured women usually have an obstetrician who reviews during labour and attends the birth. Women attending birth centres, or those who have private homebirth midwives, experience continuity of carer in labour but the number of women in these groups is small. It will be important to observe how women rate their maternity care in the future. If continuity of carer in labour becomes more common, there may be more demand for it. Despite this possibility, maternity care providers must not forget that what most women probably want is a midwife who is safe, competent, kind, supportive and able to facilitate a positive experience. Perhaps continuity of carer in labour is one strategy to develop midwives who are able to provide this standard of care.

10.2.4 From the perspective of the health system, did the STOMP model cost more or less to provide than the standard model?

Chapter 8 described the cost analysis used to evaluate the STOMP model and presented the results. The cost analysis demonstrates that there are cost savings associated with the STOMP model of care. This cost saving was maintained even when the largest single aspect of resource usage (SCN admission) was removed and when the models of care had equal rates of caesarean section.

The issue of cost is important and pivotal to the implementation of new models of maternity care, particularly in Australia. Previous models of maternity care in Australia have been established with additional funding, either from the federal government under such schemes as the Alternative Birthing Services Program (Hambly 1997) or by state governments, for example the NSW Women's Health Program (Kenny et al 1994). It has become almost expected that additional funding is required to establish new models. Anecdotal evidence suggests that some organisations have used this lack of additional funding as a reason for failing to implement recommendations from numerous reports, including the *Shearman Report* (NSW Health Department 1989) and *Options for Effective Care in Childbirth* (NHMRC 1996). The STOMP study has demonstrated that it is possible to implement a new model of care within an existing budget without additional funding (except for the small amount required to establish the community-based clinic). These findings may assist other maternity units in implementing a new model of care within their existing budget.

10.2.5 Did the STOMP model meet the needs of women from non-English speaking backgrounds?

Chapter 9 presented the results from the secondary analysis that examined the experiences of English, Chinese and Arabic-speaking women. The results suggest that there are differences in experiences and needs for these women. The levels of obstetric intervention and neonatal admission to the SCN were different between language and allocated groups. Statistical analyses were not conducted on many of these data so the results must be interpreted with caution. However, it appears that the STOMP model considerably reduced the caesarean section rate in Chinese-speaking women. This was particularly apparent in the rate of elective caesarean section. It is not clear why this occurred. It may be that the continuity of care and carer provided at the STOMP clinics meant that less elective caesareans were booked. It also may be related to the practice style of the obstetrician at the STOMP clinics, which meant Chinese-speaking women were encouraged to undergo a labour. We need to undertake more research in these areas to better understand the process that encourages woman to undergo a trial of labour and the long term effects (physical and psychological) of having an elective caesarean section as opposed to a vaginal birth.

The STOMP model of care seemed to improve the experiences for women from NESB. This was particularly true for the perceived quality of antenatal care and the amount of information about labour, birth and the postnatal period. It is evident that there are still problems in providing effective care for women from NESB, particularly for Chinese-speaking women.

Interpreter services were widely used at St George Hospital during the study and there were two bilingual midwives (ethnic obstetric liaison midwives) providing care in the antenatal clinic and postnatal ward. Nonetheless, it seems that these strategies were inadequate to meet the needs of women from NESB. Providing culturally appropriate and effective maternity care to women from NESB continues to be a challenge. Despite the difficulties we must continue to develop new ways of providing care so that the outcomes and experiences for these groups are improved.

10.2.6 Can a Zelen design be used to recruit a culturally and linguistically representative sample of women and strengthen the findings from research into maternity care?

The Zelen design (Zelen 1979) was selected firstly, to reduce disappointment bias in the conventional consent-randomisation process and secondly, to remove selection bias.

The presence of disappointment bias, and whether it was reduced, is difficult to establish. Women in the STOMP group reported more positive experiences with their care than those in the control group. Negative experiences reported by women in the control group were related to specific aspects of care, for example waiting times for appointments, difficulty accessing antenatal care and adequate knowledge. This suggests that the negative experiences were due to specific issues rather than disappointment with allocation. Control group women were still able to choose an alternative model of care, for example, birth centre or shared care. This may have meant less disappointment bias but the increased option of the control group may have diluted the contrasts between groups in some outcomes. Women in the STOMP group reported more positive experiences despite the level of choice available to control group women, making the results important in a 'real world' situation where women often have options for care.

Most women allocated to the STOMP group accepted the new model of care, as was the case in the 'Know Your Midwife' trial that also used a Zelen design (Flint et al 1989).

A proportion of women (12%) refused the offer of the STOMP model. This suggested that women did not feel coerced or obliged to give consent. As the analysis was by 'intention to treat' this may have affected the results, although it is likely that this effect would have been small.

The participants in the STOMP study did not appear to be compromised and were treated with respect. Consent was sought from all the participants, in particular ensuring that women in the control group were aware that they were part of a study. Control women were offered the standard of care that was consistent with normal practice at the St George Hospital.

The Zelen design reduced the impact of selection bias, as all women who were eligible were included prior to their first visit. This meant that a diverse and representative sample was obtained. Chapter 4 presented data that demonstrated that the STOMP sample was broadly representative of the overall population of women attending the hospital for maternity care. The Zelen design has ensured the study could provide information on the experiences and needs of women from NESB. An exclusively English-speaking sample would probably have resulted in different findings.

10.3 Limitations of the study

The study had a number of limitations, including: being unblinded; heterogeneity on an important outcome; different response rates between allocated and language groups; and, the multiplicity of standard care options for the control group. This section presents a summary of the limitations of the research and outlines some of the strategies that were utilised to minimise their impact on the study.

10.3.1 An 'unblinded' study

The STOMP study was unblinded. This occurs in many studies into changes to service delivery. Women who received the STOMP model were aware of the study as were the staff who provided their care. Women in the control group were also aware that they were in a study but their caregivers were not. These women did not have their medical records marked as 'research participants' and names of women in the control group were not accessible by the hospital staff. It was hoped that control group women would receive the usual standard of care and this would reduce any treatment effect associated with participation in the study. It was not possible to blind the data collectors

to the women's allocated group as medical records were clearly marked with the type of care they had received. For example, antenatal care was noted as being STOMP, birth centre, midwives clinic, GP shared care or antenatal clinic. The woman's allocated group was blinded from the reviewer of the eight perinatal deaths.

Bias related to the unblinded nature of some studies, particularly those in the areas of health service innovation and reform, is difficult to overcome. The very nature of the intervention and its delivery makes blinding impossible. A PROBE design (prospective, randomised, open, blinded endpoint) may be an alternative as data collectors would have been unaware of the women's allocation. However, in the STOMP study, women's records were clearly marked with their allocated group and model of care making this impossible. In the perinatal death review, the eight records were photocopied and evidence of allocated group was removed. This was not be performed for all 1 089 women.

Implementing a new model or innovation requires openness, honesty and requires and a high level enthusiasm from staff to become an entity that can be researched. These are strategies that are counterproductive to the notion of 'blinding'. It is possible that the positive results from the STOMP group were achieved because their caregivers were aware of the study and of the hypothesised outcomes, for example, a reduced caesarean section rate. The enthusiasm and commitment of the midwives and doctors may have contributed to the positive outcomes and experiences.

There is little that could have been done differently in the STOMP study. Ongoing quality control is an essential part of the STOMP model and continual monitoring may, in time, detect whether the effects of the STOMP model were due to the process of investigation or to the actual model.

10.3.2 Dilution of the effects of the model

The multiplicity of standard care options offered at St George Hospital during the study may have diluted some of the effects measured in the study. Control group women chose between standard hospital-based antenatal clinic, GP shared antenatal care, a midwives' clinic or a birth centre. The latter three options provided women with some form of continuity of care and carer throughout the antenatal period. The birth centre also provided continuity of care, and sometimes, continuity of carer during labour and birth. It would have been unethical to deny control group women the right to choose

their model of care as these four choices were standard options at the hospital. While almost three-quarters of women chose the standard antenatal clinic and delivery suite combination, 12 per cent of women attended the midwives clinic and 10 per cent the birth centre.

These choices meant that 21 per cent of women in the control group reported continuity of midwife carer during labour, a higher proportion than was expected. The intention to treat analysis meant all women allocated to the control group (regardless of their choice of care or whether they had continuity of carer in labour) were compared with all women allocated to the STOMP group. The higher than expected levels of continuity of carer in the control group may have diluted the impact this aspect of the study. If more women in the STOMP group and less women in the control group had continuity of midwife carer, the effect may have been greater. Equally, an increase in the effect of the STOMP model may be more evident in hospitals that do not have options that provide this continuity.

While the multiplicity of standard care options are a confounding factor and a limitation of the study, this situation also reflects the 'real world'. Women are increasingly demanding more options and choices in the provision of maternity care and many systems are attempting to provide these. It would be unreasonable and unethical to deny women the prospect of receiving continuity of care or carer in order to evaluate a new model of care with minimal confounding factors.

In the future, it may prove difficult to demonstrate statistically significant improvements in clinical and experiential outcomes as standard care options improve in accordance with what women want and what organisations realize that they can provide. This is because as care options improve, variances of a new model and standard models will increase. This should not diminish the importance systematically evaluating new models of care. Perhaps we should also look at using more exploratory methods to better understand the complex process of maternity care provision (Green et al 1998b; Page et al 1995).

10.3.3 Heterogeneity of the groups

The baseline characteristics of the two groups were similar in almost every way. The exception was that more control group women reported a previous caesarean section (8.2% versus 6.0%), although this was not statistically significant. Previous caesarean

section is one of the important predictors of a subsequent caesarean section. This problem, while addressed by controlling for previous caesarean section in the multivariate analysis, nonetheless remains a concern. It may be necessary to consider stratification for previous caesarean section in subsequent trials, although this may also make trials larger and more complicated.

10.3.4 Questionnaire distribution and response

There is controversy over the optimum time to distribute questionnaires assessing childbirth experiences. It has been suggested that there is a 'halo effect' following the birth of a healthy baby, with favourable responses readily reported and that a more realistic assessment of the experience is given seven to twelve months later (Erb et al. 1983). Postnatal questionnaires were mailed to women at eight weeks postpartum. While this is an acknowledged limitation of the study, it was thought that the response rate would be reduced with delayed assessment. The time frame in which the study was conducted also dictated the timing of questionnaire distribution. A delay in distribution of questionnaires would have meant the study was conducted over a longer period than was desirable.

Overall response rates to the questionnaires were acceptable and similar to that reported in other studies of this nature (Brown & Lumley 1994; Laslett et al 1997; Melia et al 1991; Rowley et al 1995; Zadoroznyi 1996). Women in the STOMP group were more likely to return antenatal questionnaires, which may have introduced a bias into the findings. It is possible that women who have negative experiences may have been less likely to return questionnaires. Responses from Arabic-speaking women were also particularly low. Arabic-speaking women were less likely to return completed questionnaires than English or Chinese-speaking women. Midwives caring for Arabic–speaking women believed that this occurred because these women perceived that childbearing was a normal component of life and unnecessary to formally evaluate. Perhaps Arabic-speaking women would have responded better to a telephone interview with a trained bilingual interviewer however this would have meant that data from English speaking and non-English speaking women were collected differently (Brown et al. 1994).

It was important to have similar response rates from Chinese and English-speaking women. Chinese-speaking women make up the largest group of women from NESB

attending the hospital. Their need for the interpreter service was also higher than the other groups. The strategies used to facilitate the involvement of women seemed largely successful in Chinese-speaking women, but less so in Arabic-speaking women. The characteristics of these groups were different. Chinese-speaking women were generally older, better educated and with fewer children than Arabic-speaking women. This may account for some of the variation in response rate. It is also possible (although not measured in the study) that the level of literacy was lower in Arabic-speaking group. It is also possible that some Arabic-speaking women do not read Arabic script. Despite these limitations, the study was an opportunity to report the experiences of a culturally diverse sample. The findings provide the maternity service with important information about the quality of care provided to women from minority groups.

Translations and ethnic obstetric liaison midwives were not available for women from language groups other than Arabic and Chinese. The response rate from the 'other' group was comparable with the English-speaking groups, suggesting that either the interpreter service was adequate or these women had higher levels of English than anticipated. The comparable response rate supports the decision to only translate consent forms, information sheets and questionnaires into Chinese and Arabic.

10.4 Implications for maternity care in Australia

The STOMP model was implemented as a strategy to improve clinical outcomes and women's experiences of care at no additional cost to the maternity unit of a NSW public hospital. While all aspects of the STOMP model may not be appropriate within all contexts, there may be components that can be adapted for particular settings. For example, community-based antenatal care may be possible in other hospitals. The results presented in this dissertation demonstrate that community-based antenatal care provided leads to improved experiences for women.

Maternity units can be reorganised and restructured to enable new models of care to be established within existing budgets. A commitment by the leaders of the service to the process of change is required. Strategies need to be developed to address the difficulties and barriers that will invariably arise. Models of care that are efficient and effective are more likely to be sustainable, that is, continue to exist in the long term.

10.4.1 Sustainability

The sustainability of new models of care is dependent on a number of factors, including the satisfaction of the staff who provide the care, and the cost of providing the service. Problems, including industrial award constraints and territorial disputes between obstetricians, GPs and midwives may contribute to reduced sustainability and a desire to revert to the status quo.

A sustainable model of care for midwives has been related to the avoidance of burnout and the provision of flexible woman-centred care (Sandall 1997). Sandall (Sandall 1997) found that having control over the organisation of work, social support at work and home and being able to develop meaningful relationships with women were important factors associated with the avoidance of burnout. A caseload model gives midwives more control over their workload and an opportunity to 'know' the women better, as there are fewer women to meet. For example, in a caseload model each midwife will be involved in the births of 70 women a year (Leap 1996). In a team model like STOMP, six midwives care for 300 women per year. A midwife in STOMP may provide care during labour for any one of these 300 women. Midwives are usually on-call more often in a caseload model, than in a team model. However, as they are on-call for proportionally fewer women they are less likely to be called (Leap 1996).

The STOMP model is by no means the 'ideal' model of maternity care, but it is one that has worked in our context at the St George Hospital. Additional elements could be included and may improve the experience for women. These might include an opportunity to have some antenatal visits in the home and the provision of first stage of labour care at home. Future expansion of the model may also include a home birth option. The inclusion of midwifery students into continuity of care models may educate midwives for whom this way of working is the norm rather than the exception. The 'way of working' refers not only to the system of being on-call for women in labour, but also a philosophy of women-centered practice. Additional elements would have to be planned and evaluated. The cost and the impact on the clinicians need to be considered in future development of new models of care.

We have found that each team of six midwives should 'book' 35 women per month with the aim of attending the labour and birth of 30 women per month in order to maximise efficiency and provide a manageable workload. This means that the teams can cater for

720 women a year, which is higher than our original estimations of 600 women a year. From anecdotes, this caseload means that the midwives are efficiently utilised. This caseload and activity level can take some time to achieve. There is an initial 'setting up' phase of nine to twelve months as the program is established, women are booked onto the team, midwives are recruited and any updating of midwifery skills occurs. During this period, considerable flexibility and adaptability of all staff is required.

Flexible systems mean that midwifery resources can be efficiently matched to actual need. For example, when there are no women in labour the staffing levels are low, conversely, when there are more women in labour, additional midwives are available.

Flexibility and a substantial caseload are important factors in ensuring long term sustainability of models of care. Flexibility is more difficult to achieve when models of care cater for a small proportion of the women at a particular hospital and the new model is not integrated into the wider unit (Audit Commission 1998). The STOMP model now caters for 28 per cent of the women at St George Hospital. The implementation and sustainability of two teams means that STOMP caters for a significant number of women. Implementing the model within existing resources also ensured that it was always part of the maternity service, rather than an 'add-on' model. We believe these factors will be important in assuring long-term sustainability and development.

10.4.2 Inter-disciplinary collaboration

Inter-disciplinary collaboration was an important factor in the STOMP model and may have contributed to the benefits. Collaboration is an essential part of contemporary maternity care however, there is little written on the topic. Celia Davies (Davies 2000) has written recently that collaboration in health care is "characterised by the recognition that it is not what people have in common, but their differences, that makes collaborative work powerful" (p. 1021). This observation is highly applicable in provision of maternity care, where both midwives and obstetricians have different but equally valid knowledge, expertise and resources and can combine these to provide a level of care that is highly effective. There are some women who need to see an obstetrician for medical reasons and others who choose to see one for reassurance, additional information or because this is their expectation of maternity care. Professional territorial disputes can impede a model of collaborative practice being implemented, often to the detriment of the women who want and need care from both professional groups.

Classifying women as 'low' or 'high' risk can contribute to these territorial disputes by creating additional barriers. The assumption can be that high risk women need doctors and low risk women need midwives. This supposition denies women choice and means that the inter-disciplinary collaboration is limited. A proportion of low risk women will want to see an obstetrician (if only for reassurance) and it is likely that many high-risk women benefit from midwifery as well as medical care.

The STOMP model provided care primarily from midwives with obstetric involvement when indicated (either due to medical reasons or personal choice). It appears that collaboration has been beneficial for women. For example, fewer women had an antenatal hospital admission, thus reducing the costs and the disruption for women. Other benefits, which have not been measured in this study, include those to the midwives and the obstetrician. Midwives have reported an increase in knowledge, skills and personal and professional confidence. Doctors have reported improved communication with midwives and a greater understanding of the role of the midwife. The doctors have also reported that from their perspective, the efficiency of care provided to women was high. For example, midwives ensured that pathology and ultrasound results were acted upon appropriately and efficiently. Results were always available at clinic visits. The level of responsibility and accountability towards the women also appeared to be high in the STOMP model. Both professions expressed the development of an increased level of trust and support which has improved their clinical practice. The qualitative study (known as SAMBA) conducted in conjunction with the STOMP study has followed midwives, doctors and managers over a two year period using focus groups and interviews. Analysis of these data will be conducted soon and will help explain the experience of this collaborative model of care from the perspective of the clinicians and managers.

10.4.3 Leadership and vision

Successful implementation of a new model of care requires strong inter-disciplinary leadership from within the organisation. Shifting the organisational culture to one where change is accepted and embraced also requires a clear vision of where the organisation is moving and what might be possible (Page et al 1995). This process requires creativity and imagination, a strong sense of how the vision may be translated into practice and a capacity to muster support, develop trust and collaborative effort

amongst staff. Changing the culture of an organisation is a slow process and one that requires leaders to be determined, savvy and demonstrate political skills. These skills include a capacity to listen to all sides of an argument, to negotiate, persuade and debate as necessary and to be discerning towards what is important to fight for and what can be left alone (Page et al 1995). Communication and information sharing about the change are also important components of change. It is of little value to drive an organisation towards a vision if no one knows what it is.

Ongoing support from management and inter-disciplinary collaboration are essential elements to ensure sustainability of the new model. It is important that this support is provided for midwives providing care in the new model as well as those who are 'core' midwives (Page et al 2000). Efforts should be made to include all staff in the design and implementation process. Strategies that were used in the STOMP study include: the distribution of a discussion paper to all staff; the establishment of a inter-disciplinary working party with regular meetings; formal and informal education sessions; and, constant feedback from senior staff to other staff in the unit. Newsletters, minutes of meetings and use of communication books are other practical measures that have been found to be helpful in the ensuring staff are informed and feel a sense of 'ownership' and inclusion in the process.

10.4.4 Further research and development

The STOMP model is only one way to provide maternity care and while there were benefits for women and the organisation, concerns still exist which require further research. The level of intervention in labour, the proportion of neonates admitted to the SCN, postnatal care in general and the level of information provided to women from NESB are all factors that have been identified as worthy of further research. A new model of care, which addresses the deficits identified in the provision of postnatal care, may need to be developed and evaluated. A caseload model, where groups of two to four midwives provide care to a smaller group of women may be the next step in the development of new models of maternity care in Australia. Any new model would require evaluation from the perspective of the women, the clinicians and the health care organisation.

The benefits of continuity of care and carer, particularly in labour, continue to be an important question and one that this study has not been able to fully answer. Qualitative

methodologies may the best way to understand continuity of carer in labour because of difficulties understanding the complex nature of values about continuity of carer in labour (Green et al 1998b; Page et al 2000). Qualitative research may lead to the development of a new questionnaire, which can evaluate the value of continuity of carer in labour more effectively.

The provision of continuity of care and carer will undoubtedly impact on the midwives and obstetricians who provide the care. The SAMBA study, which was conducted in tandem with this research, will help explain the experience of the health care providers. Other research to examine the impact of being 'on call' is important to understand the long-term effects of continuity of care models.

Many maternity units will not have access to ethnic obstetric liaison midwives or bilingual midwives. Despite this, it is still possible to include women from NESB in randomised controlled trials. Using interpreter services and translated materials and having a genuine commitment to participation of all women will contribute towards a diverse sample. As translation services are costly, identifying the most common language groups and targeting only these for translation will also facilitate recruitment and reduce costs.

10.5 Conclusion

The STOMP model of care is associated with benefits for women and for the health care system. Women report positive social and emotional experiences with a reduced caesarean section rate and reduced use of electronic fetal monitoring. The model is not more expensive for the health care system than standard care and was implemented within an existing budget and resource base.

Improvement in maternity care can be achieved. For change to occur, a strong commitment to improving services must com e from within the organisation and its staff. Support, collaboration and a clear vision of what is desirable and what might be possible all required to successfully implement a new model of care.

The STOMP model is one way to provide effective and efficient maternity care. It is a model that has been shown to be successful in a culturally diverse, teaching hospital. Other institutions may wish to implement similar models of care. They will need to

consider their own population, organisational structure and vision for the future. The STOMP model is a useful starting point.

References

Al-Mufti, R., McCarthy, A., Fisk, N. M. (1997). Survey of obstetricians' personal preference and discretionary practice. *European Journal of Obstetrics, Gynaecology & Reproductive Biology.* 73 (1), 1-4.

Alcorso, C., Schofield, T. (1991). *The National Non-English Speaking Background Women's Health Strategy.* Australian Government Publishing Service, Canberra.

Allen, J., Prvan, T., & Petocz, P. (1996). *Introductory Survey Research and Data Analysis Workshop.* University Statistical Consulting Service, University of Technology Sydney.

Allmark, P. (1999). Should Zelen pre-randomised consent designs be used in some neonatal trials? *Journal of Medical Ethics.* 25 (4), 325-329.

Anbar, D. (1983). The relative efficiency of Zelen's pre-randomisation design for clinical trials. *Biometrics.* 39 (3), 711-718.

Anderson, R. E., Anderson, D. A. (1999). The cost effectiveness of home birth. *Journal of Nurse-Midwifery.* 44 (1), 30-35.

Annibale, D. J., Hulsey, T. C., Wagner, C. L., Southgate, W. M. (1995). Comparative neonatal morbidity of abdominal and vaginal deliveries after uncomplicated pregnancies. *Archives of Pediatrics and Adolescent Medicine.* 149 (8), 862-867.

Anonymous (1995). Your baby is in a trial [editorial]. *Lancet.* 345, 805-806.

Anonymous (1996). Style matters: Ethnicity, race and culture: guidelines for research, audit and publication. *British Medical Journal.* 312 (7038), 1094.

Audit Commission (1998). *First Class Delivery: A National Survey of Women's Views of Maternity Care.* Department of Health, UK, London.

Australian Bureau of Statistics (1996). *Census of population and housing.* Australian Government Printing Service, Canberra.

Australian Bureau of Statistics (1997). *Australian Social Trends 1997.* Australian Government Publishing Service, Canberra.

Australian Council on Health Standards (1997). *Clinical Indicators – A Users Manual: Obstetrics and Gynaecology Indicators Version 2.* Australian Council on Health Standards, Sydney.

Ball, J. (1994). *Reactions to motherhood: the role of postnatal care.* Cambridge University Press, Cambridge.

Ball, J. A. (1989). Postnatal care and adjustment to motherhood. In *Midwives, Research and Childbirth, Volume 1.* S. Robinson & A. M. Thomson (eds). Chapman and Hall, London, pp. 154-175.

Barber, J. A., Thompson, S. G. (1998). Analysis and interpretation of cost data in randomised controlled trials: review of published trials. *British Medical Journal.* 317 (7167), 1195-1200.

Bartlett, M., Hecker, R., Jan, S., Capon, A., Conaty, S. (1998). *Evaluation of the Daruk Aboriginal Medical Service antenatal programs* The Public Health Association of Australian Inc. Annual Conference, Hobart, Tasmania.

Bartlett, R. H., Roloff, D. W., Cornell, R. G., Andrews, A. F., Dillon, O. W., Zwischenberger, S. B. (1985). Extracorporeal circulation in neonatal respiratory failure: a prospective randomised trial. *Pediatrics*. 76 (4), 479-487.

Beischer, N. A., Oats, J. N., Henry, O. A. (1991). Incidence and severity of gestational diabetes mellitus according to country of birth in women living in Australia. *Diabetes*. 40 (suppl 2), 35-38.

Belizán, J. M., Althabe, F., Barros, F. C., Alexander, S. (1999). Rates and implications of caesarean sections in Latin America: An ecological study. *British Medical Journal*. 319 (7222), 1397-1400.

Belizán, J. M., Farnot, U., Carroli, G., Al-Mazrou, Y. (1998). Antenatal care in developing countries. *Paediatric and Perinatal Epidemiology*. 12 (supp 2), 1-3.

Berg, J. A. (1999). Gaining access to under-researched populations in women's health research. *Health Care for Women International*. 20 (3), 237-243.

Bergsjo, P., Schmidt, E., Pusch, D. (1983). Differences in the reported frequencies of obstetrical interventions in Europe. *British Journal of Obstetrics and Gynaecology*. 90 (7), 628-632.

Biro, M. A., Lumley, J. (1991). The safety of team midwifery: the first decade of the Monash Birth Centre. *Medical Journal of Australia*. 155 (7), 478-480.

Blondel, B., Breart, G., Llado, J., Chartier, M. (1990). Evaluation of the home-visiting system for women with threatened preterm labor: results of a randomized controlled trial. *European Journal of Obstetrics, Gynaecology & Reproductive Biology*. 34 (1-2), 47-58.

Bobadilla, J. L., Walker, G. L. (1991). Early neonatal mortality and cesarean delivery in Mexico City. *American Journal of Obstetrics and Gynaecology*. 164 (1), 22-28.

Bottoms, S. F., Rosen, M. G., Sokol, R. J. (1980). The increase in caesarean birth rate. *New England Journal of Medicine*. 302 (10), 559-563.

Bowers, S. K., MacDonald, H. M., Shapiro, E. D. (1982). Prevention of iatrogenic neonatal respiratory distress syndrome: repeat cesarean section and spontaneous labour. *American Journal of Obstetrics and Gynaecology*. 143 (2), 186-191.

Boyce, P. M., Stubb, J., Todd, A. (1993). The Edinburgh postnatal depression scale: validation for an Australian sample. *Australian and New Zealand Journal of Psychiatry*. 27, 472-476.

Boyce, P. M., Todd, A. L. (1992). Increased risk of postnatal depression after emergency caesarean section. *Medical Journal of Australia* 157 (3), 172-174.

Bradley, C. (1993). Designing medical and educational studies. *Diabetes Care*. 16 (2), 509-518.

Brodie, P. (1994). Midwifery care for pregnant teenagers: primary health care in action. In *Promoting Health: The Primary Health Care Approach* A. Wass (ed). Harcourt Brace and Company, Sydney.

Brodie, P. (1996b). *Being with women: the experiences of Australian team midwives. Unpublished Masters by Research Thesis.* University of Technology Sydney, New South Wales.

Brodie, P. (1996a). *Report of a study tour to the United Kingdom on new models of midwifery care.* National Health and Medical Research Council, Canberra.

Brown, S., Dawson, W., Gunn, J., McNair, R. (1999). *Review of Shared Obstetric Care: Summary Report.* Centre for the Study of Mothers' and Children's Health, La Trobe University, Melbourne.

Brown, S., Lumley, J. (1994). Satisfaction with care in labour and birth: A survey of 790 Australian women. *Birth: Issues in Perinatal Care and Education.* 21 (1), 4-13.

Brown, S., Lumley, J. (1998). Changing childbirth: lessons from an Australian survey of 1336 women. *British Journal of Obstetrics and Gynaecology.* 105 (2), 143-155.

Brown, S., Lumley, J., Small, R., Astbury, J. (1994). *Missing Voices: The Experience of Motherhood.* Oxford University Press, Melbourne.

Brown, S. J. (1999). *Knowledge for Health Care Practice: A Guide to Using Research Evidence 1st ed.* WB Saunders Company, Philadelphia.

Brumfield, C. G. (1998). Early postpartum discharge. *Clinical Obstetrics and Gynaecology.* 41 (3), 611-625.

Butler, J., Abrams, B., Parker, J., Roberts, J. M., Laros, R. K. (1993). Supportive nurse-midwife care is associated with a reduced incidence of caesarean section. *American Journal of Obstetrics and Gynaecology.* 168 (3), 1407-1413.

Cai, W. W., Marks, J. S., Chen, C. H., Zhuang, Y. X., Morris, L., Harris, J. R. (1998). Increased cesarean section rates and emerging patterns of health insurance in Shanghai, China. *American Journal of Public Health.* 88 (5), 777-780.

Cape, K. (1993). *Birth in a New Country: The birthing needs of non-English speaking women in the west.* The Western Hospital and the Women's Health Service, Melbourne.

Cape, K. (1999). Birth in a new country. In *Asian Mothers, Western Birth, 2nd ed.* P. L. Rice (ed). AusMed Publications, Melbourne, pp. 101-116.

Cartwight, A. (1986). Some experiments with factors that might affect the responses of mothers to a postal questionnaire. *Statistics in Medicine.* 5 (6), 607-617.

Chalmers, I. (1989). Evaluating the effects of care during pregnancy and childbirth. In *Effective care in pregnancy and childbirth, Volume 1.* I. Chalmers, M. Enkin, & M. J. N. C. Keirse (eds). Oxford University Press, Oxford, pp. 3-29.

Chambliss, L. R., Daly, C., Medearis, A. L., Ames, M., Kayne, M., Paul, R. (1992). The role of selection bias in comparing caesarean section birth rates between physician and midwifery management. *Obstetrics and Gynecology.* 80 (2), 161-165.

Chang, R. W., Falconer, J., Stullberg, S. D., Arnold, W.J., Dyer, A. R. (1990). Pre-randomization: an alternative to classic randomisation. the effects on recruitment in a controlled trial of arthroscopy for osteoarthrosis of the knee. *Journal of Bone Joint Surgery.* 72A (10), 1451-1455.

Chapman, M. G., Jones, M., Springs, J. E., de Swiet, M., Chamberlain, G. V. P. (1986). The use of a birthroom: a randomised controlled trial comparing delivery with that delivery with that in the labour ward. *British Journal of Obstetrics and Gynaecology.* 93 (2), 182-187.

Clement, S., Candy, B., Sikorski, J., Wilson, J., Smeeton, N. (1999). Does reducing the frequency of routine antenatal visits have long term effects? Follow up of participants in a randomised controlled trial. *British Journal of Obstetrics and Gynaecology.* 106 (4), 367-370.

Coakes, S. J., Steed, L. G. (1999). *SPSS: Analysis without anguish.* John Wilet and Sons Australia Ltd, Brisbane.

Cogan, R., Spinnato, J. A. (1988). Social support during premature labour: effects on labour and the newborn. *Journal of Psychosomatic Obstetrics & Gynaecology.* 8, 209-216.

Cohen, M., Carson, B. S. (1985). Respiratory morbidity benefit of awaiting onset of labour after elective caesarean section. *Obstetrics and Gynecology.* 65 (6), 818-822.

Commonwealth Department of Health and Community Services. (1993). *Goals and targets of Australia's health in the year 2000 and beyond.* Australian Government Printing Service, Canberra.

Condon, J. T., Corkindale, C. J. (1997). The assessment of depression in the postnatal period: a comparison of four self-report questionnaires. *Australian and New Zealand Journal of Psychiatry.* 31 (3), 360-369.

Cooke, M., Barclay, L. (1999). Are we providing adequate postnatal services? *Australian and New Zealand Journal of Public Health.* 23 (2), 210-212.

Cooke, M., Stacey, T. (2000). Understanding postnatal care. *Midwifery Matters.* 14 (2), 25.

Coulter-Smith, S. D., Holohan, M., Darling, M. R. N. (1996). Previous caesarean section: a risk factor for major obstetric haemorrhage. *Journal of Obstetrics and Gynaecology.* 16, 349-352.

Cox, J. L., Holden, J. M., Sagovsky, R. (1987). Detection of postnatal depression. Development of the ten point Edinburgh Postnatal Depression Scale. *British Journal of Psychiatry.* 150, 172-176.

Coyle, K. (1998). *Women's perceptions of birth centre care: a qualitative approach. Unpublished thesis.* Edith Cowan University, Perth, Western Australia.

Cranley, M. S., Hedahl, K. J., Pegg, S. H. (1983). Women's perceptions of vaginal and cesarean deliveries. *Nursing Research.* 32 (1), 10-15.

Creasy, J. M. (1997). Women's experience of transfer from community-based to consultant-based maternity care. *Midwifery.* 13 (1), 32-39.

Creedy, D. (1999). *Birthing and the development of trauma symptoms: incidence and contributing factors. Unpublished doctoral dissertation.* Griffith University, Brisbane.

Davies, C. (2000). Getting health professionals to work together [Editorial]. *British Medical Journal.* 320 (7241), 1021-1022.

Day, P., Sullivan, E. A., Ford, J., Lancaster, P. (1999a). *Australia's mothers and babies 1997.* Australian Institute of Health and Welfare, National Perinatal Statistics Unit, Sydney.

Day, P., Sullivan, E. A., Lancaster, P. (1999b). *Australia's Mothers and Babies 1996.* Australian Institute of Health and Welfare, National Perinatal Statistics Unit, Sydney.

de Costa, C. M. (1988). Pregnancy outcomes in Lebanese-born women in western Sydney. *Medical Journal of Australia.* 149, 457-460.

Del Mar, C., Siskind, V., Acworth, J., Lutz, K., Wyatt, P. (1991). Shared antenatal care in Brisbane. *Australian and New Zealand Journal of Obstetrics and Gynaecology.* 31 (4), 305-306.

Dennis, M. (1997). Commentary: Why we didn't ask patients for their consent. *British Medical Journal.* 314, 1077.

Dennis, M., O'Rourke, S., Slattery, J., Staniforth, T., Warlow, C. (1997). Evaluation of a stroke family care worker: results of a randomised controlled trial. *British Medical Journal.* 314 (7087), 1071-1076.

Department of Health Expert Maternity Group (1993). *Changing Childbirth.* Department of Health HMSO, London.

Department of Health Western Australia (1990). *Ministerial task force to review obstetric, gynaecological and neonatal services in Western Australia.* Health Department of Western Australia, Perth.

DeSantis, L. (1990). Fieldwork with undocumented aliens and other populations at risk. *Western Journal of Nursing Research.* 12 (3), 359-372.

Dougall, A., Russell, A., Rubin, G., Ling, J. (2000). Rethinking patient satisfaction: patient experiences of an open access flexible sigmoidoscopy service. *Social Science and Medicine.* 50 (1), 53-62.

Dougherty, C. R. S., Jones, A. D. (1988). Obstetric management and outcome related to maternal characteristics. *American Journal of Obstetrics and Gynaecology.* 158 (3 Pt 1), 470-474.

Douglas, J. (1998). Meeting the health needs of women from black and minority ethnic communities. In *Women and health services: An agenda for change.* L. Doyal (ed). Open University Press, Buckingham.

Drummond, M. F., Stoddart, G. L. (1984). Economic analysis and clinical trials. *Controlled Clinical Trials.* 5 (2), 445-128.

Dye, T. D., Wojtowycz, M. A. (1999). Organisational variation, satisfaction and women's time investment in prenatal care. *Paediatric and Perinatal Epidemiology.* 13 (2), 158-169.

Efron, B., Tibshirani, R. J. (1993). *An Introduction to the Bootstrap.* Chapman & Hall, New York.

Ellenberg, S. S. (1984). Randomisation designs in comparative clinical trials. *New England Journal of Medicine.* 310 (21), 1404-1408.

Ellenberg, S. S. (1992). Randomized consent designs in comparative clinical trials: an update [letter]. *Statistics in Medicine.* 11 (1), 131-132.

Elliot, S. A., Anderson, M., Brough, D. I., Watson, J. P., Rugg, A. J. (1984). Relationship between obstetric outcome and psychological measures in pregnancy and the postnatal year. *Journal of Reproductive and Infant Psychology.* 2, 18-22.

Enkin, M., Keirse, M. J. N. C., Renfrew, M., Neilson, J. P. (1998). *Effective Care in Pregnancy and Childbirth, 2nd ed.* Oxford University Press, Oxford.

Erb, L., Hill, G., Houston, D. (1983). A survey of parents attitudes towards their caesarean births in Manitoba Hospitals. *Birth: Issues in Perinatal Care and Education.* 10 (2), 85-91.

Everitt, L., Barclay, L., Chapman, M., Hurst, R., Lupi, A., Wills, J. (1995). *St George Maternity Services Customer Satisfaction Research Project.* St George Hospital and Community Services, Sydney.

Farmer, E., Chipperfield, C. (1996). One-to-One midwifery: problems and solutions. *Modern Midwife.* 4, 19-21.

Farquhar, M., Camilleri-Ferrante, C., Todd, C. (1994). *An evaluation of midwifery teams in West Essex: executive summary.* Public Health Research Unit, Institute of Public Health, University of Cambridge, Cambridge.

Fellowes, D., Horsley, A., Rochefort, J. (1999). Changing practice: Is continuity of carer a top priority for all women? *Midwifery.* 7 (1), 36-40.

Fisher, B., Bauer, M., Margolese, R. (1985). Five year results of a randomised controlled trial comparing total mastectomy and segmental mastectomy with or without radiation in the treatment of breast cancer. *New England Journal of Medicine.* 321 (11), 665-673.

Fisher, J., Astbury, J., Smith, A. (1997). Adverse psychological impact of operative obstetric interventions: a prospective longitudinal study. *Australian and New Zealand Journal of Psychiatry.* 31 (5), 728-738.

Fitzpatrick, R. (1991a). Surveys of patient satisfaction: Designing a questionnaire and conducting a survey. *British Medical Journal.* 302 (6785), 1129-1132.

Fitzpatrick, R. (1991b). Surveys of patient's satisfaction: Important general considerations. *British Medical Journal.* 302 (6781), 887-889.

Fleissig, A. (1993). Are women given enough information by staff during labour and delivery? *Midwifery.* 90 (2), 70-75.

Fleissig, A., Kroll, D., McCarthy, M. (1996). Is community-led maternity care a feasible option for women assessed at low risk and those with complicated pregnancies? Results of a population based study in South Camden, London. *Midwifery.* 12, 191-197.

Fleissig, A., Kroll, D., McCarthy, M. (1997). General practitioners views on the implementation of community-led maternity care in south Camden, London. *British Journal of General Practice.* 47 (414), 45-46.

Flint, C. (1993). *Midwifery: Teams and Caseloads.* Butterworth-Heineman Ltd, Oxford.

Flint, C., Poulengeris, P., Grant, A. (1989). The "Know Your Midwife' scheme - a randomised trial of continuity of care by a team of midwives. *Midwifery.* 5 (1), 11-16.

Forbes, K. L., King, J. F. (1990). An investigation of the maternal antecedents of perinatal mortality in 2 large teaching hospitals. *Australian and New Zealand Journal of Obstetrics and Gynaecology.* 30 (3), 214-217.

Gann, P., Nghiem, L., Warner, S. (1989). Pregnancy characteristics and outcomes of Cambodian refugees. *American Journal of Public Health.* 79 (9), 1251-1257.

Garcia, J., Marchant, S. (1999). Care of the mother after birth. In *Community-based Maternity Care.* G. Marsh & M. Renfrew (eds). Oxford University Press, Oxford, pp. 398-407.

Giles, W., Collins, J., Ong, F., MacDonald, R. (1992). Antenatal care of low risk obstetric patients by midwives. *Medical Journal of Australia.* 157 (3), 158-161.

Gomez, O. L., Carrasquilla, G. (1999). Factors associated with unjustified caesarean sections in four hospitals in Cali, Colombia. *International Journal for Quality in Health Care.* 11 (5), 385-389.

Goyert, G. L., Bottoms, S. F., Treadwell, M. C., Nehra, P. C. (1989). The physician factor in cesarean birth rates. *New England Journal of Medicine.* 320 (11), 706-709.

Graham, W. J., Hundley, V. A., McCheyne, A. L., Hall, M. H., Gurney, E., Milne, J. (1999). An investigation of women's involvement in the decision to deliver by caesarean section. *British Journal of Obstetrics and Gynaecology.* 106 (3), 213-220.

Graveley, E. A., Littlefield, J. H. (1992). A cost-effectiveness analysis of three staffing models for the delivery o low-risk prenatal care. *American Journal of Public Health.* 82 (2), 180-184.

Green, J., Coupland, V. A., Kitzinger, J. V. (1990). Expectations, experiences, and psychological outcomes of childbirth: a prospective study of 825 women. *Birth: Issues in Perinatal Care and Education.* 17 (1), 15-24.

Green, J. M., Coupland, V. A., Kitzinger, J. V. (1988). *Great Expectations: A Prospective Study of Women's Expectations and Experiences.* Child Care and Development Group, University of Cambridge, Cambridge.

Green, J. M., Coupland, V. A., Kitzinger, J. V. (1998a). *Great Expectations: A prospective study of women's expectation and experiences of childbirth, 2nd ed.* Books for Midwives Press, Cheshire.

Green, J. M., Curtis, P., Price, H., Renfrew, M. J. (1998b). *Continuing to care: The organisation of midwifery services in the UK.* Books for Midwives Press, Hale.

Green, J. M., Stratham, H. F., Snowdon, C. M. (1993). *Pregnancy: A Testing Time.* Centre for Family Research, University of Cambridge, Cambridge.

Greene, R., Gardeil, F., Turner, M. J. (1997). Long-term implications of cesarean section. *American Journal of Obstetrics and Gynaecology.* 176 (1), 254-255.

Grullon, K. E., Grimes, D. A. (1997). The safety of early postpartum discharge: a review and critique. *Obstetrics and Gynecology.* 90 (5), 860-865.

Hambly, M. (1997). *Community Midwives Pilot Project Evaluation, Alternative Birthing Services in the Australian Capital Territory.* ACT Department of Health and Community Care, Canberra.

Harlow, B. L., Frigoletto, F. D., Cramer, D. W., Evans, J. K., Bain, R. P., Ewigman, B., McNellis, D., and the RADIUS Study Group (1995). Epidemiological predictors of cesarean section in nulliparous patients at low risk. *American Journal of Obstetrics and Gynaecology.* 172 (1 Pt 1), 156-162.

Harper, M. (1999). *Casemix Data: St George Hospital* St George Hospital, South Eastern Sydney Area Health Service, Sydney.

Hartnoll, R. L., Mitcheson, M. C., Battersby, A., Brown, G., Ellis, M., Fleming, P. (1980). Evaluation of heroin maintenance in a controlled trial. *Archives of General Psychiatry.* 37 (8), 877-884.

Harvey, S., Jarrell, J., Brant, R., Stainton, C., Rach, D. (1996). A randomised, controlled trial of nurse-midwifery care. *Birth: Issues in Perinatal Care and Education.* 23 (3), 128-135.

Hemminki, E., Merilainen, J. (1996). Long-term effects of cesarean section: Ectopic pregnancies and placental problems. *American Journal of Obstetrics and Gynaecology.* 174 (5), 1569-1574.

Hemminki, E., Virta, A. L., Koponen, P., Malin, M., Kojo-Austin, H., Tuimala, R. (1990). A trial of continuous human support during labour: feasibility, interventions and mothers' satisfaction (Trial A - Pilot study with volunteer midwifery students). *Journal of Psychosomatic Obstetrics & Gynaecology.* 11, 239-250.

Henry, O. A., Guaran, R. L., Petterson, C. D., Walstab, J. E. (1992). Obstetric and birthweight differences between Vietnam-born and Australian-born women. *Medical Journal of Australia.* 156 (5), 321-324.

Hickey, K., Trompf, P., Reid, J. (1991). *Antenatal care for Muslim Lebanese women: a pilot study of utilisation, health beliefs and practices.* Cumberland Centre for Women's Health Studies, Cumberland College of Health Sciences, The University of Sydney, New South Wales.

Hillan, E. (1992b). Maternal-infant attachment following caesarean delivery. *Journal of Clinical Nursing.* 1 (1), 33-37.

Hillan, E. (1992a). Short term morbidity associated with cesarean delivery. *Birth: Issues in Perinatal Care and Education.* 19 (4), 490-194.

Hillan, E. (2000). The aftermath of caesarean delivery. *MIDIRS Midwifery Digest.* 10 (1), 70-72.

Hindle, D. (1993). *Product Costing: Education in Casemix Series, Module 2.* Centre for Health Service Development, University of Wollongong, New South Wales.

Hirst, J., Hewison, J., Dowswell, T., Baslington, H., Warrilow, J. (1998). Antenatal care: what do women want? In *Psychological perspectives on pregnancy and childbirth.* S. Clement (ed). Churchill Livingstone, Edinburgh.

Hodnett, E. D. (1999). Continuity of caregivers for care during pregnancy and childbirth (Cochrane Review). In *The Cochrane Library. Issue 4.* Update Software, Oxford.

Hodnett, E. D. (2000b). Caregiver support for women during childbirth (Cochrane Review). In *The Cochrane Library, Issue 4.* Update Software, Oxford.

Hodnett, E. D. (2000a). Support during pregnancy for women at increased risk (Cochrane Review). In *The Cochrane Library*, *Issue 4.* Update Software, Oxford.

Hofmeyr, G. J., Nikoderm, V. C., Wolman, W. L., Chalmers, B. E., Kramer, T. (1991). Companionship to modify the clinical birth environment: effects on progress and perceptions of labour, and breastfeeding. *British Journal of Obstetrics and Gynaecology*. 98 (8), 756-764.

Homer, C. S. E., Davis, G. K. (1999). Can elective induction of labour be women-centred? *British Journal of Midwifery*. 7 (11), 686-689.

Homer, C. S. E., Davis, G. K., Everitt, L. (1999). The introduction of a woman-held record into an antenatal clinic: a randomised controlled trial . *Australian and New Zealand Journal of Obstetrics and Gynaecology*. 39 (1), 54-57.

Homer, C. S. E., Davis, G. K., Petocz, P., Barclay, L., Matha, D., Chapman, M. G. (2000). The obstetric outcomes of low risk women: birth centre versus labour ward. *Australian Journal of Advanced Nursing* (in press).

Hosmer, D. W., Lemeshow, S. (1989). *Applied Logistic Regression.* Wiley, New York.

House of Commons (1992). *The Health Committee Second Report: Maternity Services Volume 1 (Chair: N. Winterton).* HMSO, London.

Hundley, V. A., Cruickshank, F. M. , Lang, G. D., Glazener, C. M. A., Milne, J. M., Blyth, D., Mollison, J., Donaldson, C. (1994). Midwife managed delivery unit: a randomised controlled comparison with consultant-led care. *British Medical Journal*. 309 (6966), 1400-1404.

Hundley, V. A., Donaldson, C., Lang, G. D., Cruickshank, F. M., Glazener, C. M. A., Milne, J. M., Mollison, J. (1995). Costs of intrapartum care in a midwife-managed delivery unit and a consultant-led labour ward. *Midwifery*. 11 (3), 103-109.

Hundley, V. A., Milne, J. M., Glazener, C. M. A., Mollison, J. (1997). Satisfaction and the three C's: continuity, choice and control. Women's views from a randomised controlled trial of midwife-led care. *British Journal of Obstetrics and Gynaecology*. 104 (11), 1273-1280.

Hunninghake, D. B. (1987). Summary conclusions. *Controlled Clinical Trials*. 8 (suppl.4), 1S-5S.

Hunninghake, D. B., Darby, C. A., Probstfield, J. L. (1987). Recruitment experience in clinical trials: Literature summary and annotated bibliography. *Controlled Clinical Trials*. 8 (suppl.4), 6S-30S.

Jacoby, A. (1987). Women's preferences for and satisfaction with current procedures in childbirth: findings from a national study. *Midwifery*. 3 (3), 117-124.

Jacoby, A., Cartwight, A. (1990). Finding out about the views and experiences of maternity-service users. In *The Politics of Maternity Care: Services for Childbearing Women in Twentieth-Century Britain*. J. Garcia, R. Kilpatrick, & M. Richards (eds). Clarendon Press, Oxford, pp. 238-256.

James, D. C., Jackson, R. T., Probart, C. K. (1994). Factors associated with breastfeeding prevalence and duration amongst international students. *Journal of the American Dietry Association*. 94 (2), 194-196.

Johnson, A., Johnson, P., Browne, E. (1991). Maternal care in a multicultural society. In *Health care and immigrants: a guide for the helping professions*. B. Fergusen & E. Browne (eds). MacLennan and Petty, Sydney, pp. 83-96.

Jolly, J., Walker, J., Bhabra, K. (1999). Subsequent obstetric performance related to primary mode of delivery. *British Journal of Obstetrics and Gynaecology.* 106 (3), 227-232.

Jones, D. A., West, R. R., Newcombe, R. G. (1986). Maternal characteristics associated with the duration of breastfeeding. *Midwifery.* 2 (3), 141-146.

Jones, L. (1999). Feasibility of collaboration? *25th Triennial Congress of the International Confederation of Midwives*, Manila, Philippines.

Keirse, M. J. N. C. (1994). Maternal mortality: stalemate or stagnant? *British Medical Journal.* 308 (6925), 354-355.

Kenny, P., Brodie, P., Eckermann, S., Hall, J. (1994). *Westmead Hospital Team Midwifery Project Evaluation: Final Report..* Westmead Hospital, Sydney, NSW.

Kenny, P., King, M. T., Cameron, S., Shiell, A. (1993). Satisfaction with postnatal care - the choice of home or hospital. *Midwifery.* 9 (3), 146-153.

King, J. F. (1993). Obstetric intervention and the economic imperative. *British Journal of Obstetrics and Gynaecology.* 100 (4), 303-306.

Kitzinger, S. (1998). The cesarean epidemic in Great Britain. *Birth: Issues in Perinatal Care and Education.* 25 (1), 56-58.

Klaus, M., Kennell, J. (1982). *Parent-infant bonding, 2nd edition.* Mosby, St Louis.

Lagercrantz, H. & Slotkin, T. A. (1986). The "stress" of being born. *Scientific American.* 254 (4), 100-107.

Lancet (1997). What is the right number of caesarean sections? *Lancet.* 349 (9055), 815.

Langer, A., Campero, L., Garcia, C., Reynosos, S. (1998). Effects of psychosocial support during labour and childbirth on breastfeeding, medical interventions, and mothers' wellbeing in a Mexican public hospital: a randomised clinical trial. *British Journal of Obstetrics and Gynaecology.* 105 (10), 1056-1063.

Laslett, A., Brown, S., Lumley, J. (1997). Women's views of different models of antenatal care in Victoria, Australia. *Birth: Issues in Perinatal Care and Education.* 24 (2), 81-89.

Lawson, K., Tulloch, M. I. (1995). Breastfeeding duration: prenatal intentions and postnatal practices. *Journal of Advanced Nursing.* 22 (5), 841-849.

Leap, N. (1996). Caseload practice: a recipe for burnout? *British Journal of Midwifery.* 4 (6), 329-330.

Leap, N., Cornwell, C. (1999). *Submission from the Australian College of Midwives Inc (SA Branch)* Senate Community Affairs Reference Committee, Canberra.

Lee, B. (2000). Too posh to push: The issue of caesarean section on demand. *RCM Midwives Journal.* 3 (2), 52-53.

Lee, G. (1994). A reassuring familiar face? Midwifery teams, continuity of carer. *Nursing Times.* 90 (17), 66-67.

Lee, G. (1997). The concept of 'continuity' - what does it mean? In *Reflections on Midwifery*. M. J. Kirkham & E. R. Perkins (eds). Bailliere Tindall, London, pp. 1-25.

Lee, L. A., Eagar, K. M., Smith, M. C. (1998). Subacute and non-acute casemix in Australia. *Medical Journal of Australia*. 169 (Suppl), S22-S25.

Leeder, S. R. (1999). *Healthy Medicine: Challenges facing Australia's health services.* Allen & Unwin, Sydney.

Lipson, J., Meleis, A. (1989). Methodological issues in research with immigrants. *Medical Anthropology*. 12 103-115.

Locke, M. (1985). Risk factors impinging on Vietnamese women of childbearing age in Australia. *Australian Family Physician*. 14 (12), 1332-1334.

Locker, D., Dunt, D. (1978). Theoretical and methodological issues in sociological studies of consumer satisfaction with medical care. *Social Science and Medicine*. 12 (4A), 283-292.

Lomas, J., Enkin, M. (1989). Variations in operative delivery rates. In *Effective Care in Pregnancy and childbirth*. I. Chalmers, M. Enkin, & M. J. N. C. Keirse (eds). Oxford University Press, Oxford.

Lowe, T. (1997). An optimistic study of breastfeeding rates in Victoria. In *NMAA Conference: Breastfeeding the Natural Advantage*, Nursing Mothers Association of Australia, Sydney, pp. 249-254.

Macfarlane, A., Chamberlain, G. (1993). What is happening to caesarean section rates? *Lancet*. 342 (8878), 1005-1006.

Mackenzie, I. Z. (1999). Should women who elect to have caesarean sections pay for them? [letter]. *British Medical Journal*. 318 (7190), 1070.

MacVicar, J., Dobbie, G., Owen-Johnstone, L., Jagger, C., Hopkins, M., Kennedy, J. (1993). Simulated home delivery in hospital: a randomised controlled trial. *British Journal of Obstetrics and Gynaecology*. 100 (4), 316-323.

Manderson, L. (1994). Pregnancy and birth in intercultural settings. In *Asian Mothers, Australian Birth*. P. L. Rice (ed). Ausmed Publications, Melbourne, pp. 3-15.

Manderson, L. (1999). Pregnancy and birth in intercultural settings. In *Asian Mothers, Western Birth*, *2nd ed.* P. L. Rice (ed). AusMed Publications, Melbourne, pp. 4-14.

Manderson, L., Mathews, M. (1981). Vietnamese attitudes towards maternal and infant health. *Medical Journal of Australia*. 1 (2), 69-72.

Marquis, B., Huston, C. (1994). *Management Decision Making for Nurses, 2nd ed.* Lippincott, New York.

Martel, M., Wacholder, S., Lippman, A., Brohan, J., Hamilton, E. (1987). Maternal age and primary cesarean section rates: A multivariate analysis. *American Journal of Obstetrics and Gynaecology*. 156 (2), 305-308.

Martins, J. M., Greenwell, J., Linder-Pelz, S., Webster, M. A. (1987). *Evaluation of outcomes: deliveries at the birth centre and traditional setting at the Royal Hospital for Women, Sydney* NSW Department of Health, Sydney.

Mason, S. (1997). Obtaining informed consent for neonatal randomised controlled trials - "an elaborate ritual"? *Archives of Diseases in Childhood.* 76 (3), F143-F145.

Maternity Services Advisory Committee (1999). *The NSW Framework for Maternity Services* NSW Health, Sydney.

Matthey, S., Barnett, B. E., Elliott, A. (1997). Vietnamese and Arabic women's responses to the Diagnostic Interview Schedule (depression) and self-report questionnaires: cause for concern. *Australian and New Zealand Journal of Psychiatry.* 31 (3), 360-369.

Matts, J., McHugh, R. (1987). Randomization and efficiency in Zelen's single-consent design. *Biometrics.* 43 (4), 885-894.

McCourt, C., Page, L. (1996). *Report on the Evaluation of One-to-One Midwifery.* The Hammersmith Hospitals NHS Trust and Thames Valley University, London.

McCourt, C., Page, L., Hewison, J. (1998). Evaluation of One-to-One Midwifery: Women's responses to care. *Birth: Issues in Perinatal Care and Education.* 25 (2), 73-80.

McCourt, C., Percival, P. (1999). Social support in childbirth. In *The New Midwifery*, L. A. Page (ed). Churchill Livingstone, Edinburgh, pp. 245-266.

McGinley, M., Turnbull, D., Fyvie, H., Johnstone, I., MacLennan, B. (1995). Midwifery development unit at Glasgow Royal Maternity Hospital. *British Journal of Midwifery.* 3 (7), 362-371.

McLean, S. (1997). Commentary: No consent means not treating the patient with respect. *British Medical Journal.* 314, 1076-1077.

Melia, M., Morgan, M., Wolfe, C. D. A., Swan, A. V. (1991). Consumers' views of the maternity services: implications for change and quality assurance. *Journal of Public Health Medicine.* 13 (2), 120-126.

Meren, J. G. (1995). Ethics of consent for babies in randomised clinical trials [letter]. *Lancet.* 345, 1370.

Middlemiss, C., Dawson, A., Gough, N., Jones, M., Coles, E. (1989). A randomised study of a domiciliary antenatal care scheme: maternal psychological effects. *Midwifery.* 5 (2), 69-74.

Milburn, N., Gary, L., Booth, J., Brown, D. (1992). Conducting epidemiological research in a minority community: methodological considerations. *Journal of Community Psychology.* 19 (1), 3-12.

Moertel, C. G., Childs, D. S., O'Fallon, J. R. (1984). Combined 5-fluoroouracil and radiation therapy as a surgical adjuvant for poor prognosis gastric carcinoma. *Journal of Clinical Oncology.* 2 (11), 1247-1254.

Molloy, D., Richardson, P. (1994). Caesarean section - public versus private. Why the differential? A reply to 'Obstetric intervention and the economic imperative'. *British Journal of Obstetrics and Gynaecology.* 101 (1), 88-90.

Morgan, M., Fenwick, N., McKenzie, C., Wolfe, C. D. A. (1998). Quality of midwifery led care: assessing the effects of different models of continuity for women's satisfaction. *Quality in Health Care*. 7 (2), 77-82.

Market and Opinion Research International (1993). *The Maternity Services Research Study conducted for the Department of Health (UK).* MORI, London.

Morrison, J. J., Rennie, J. M., Milton, P. J. (1995). Neonatal respiratory morbidity and mode of delivery at term: influence of timing of elective caesarean section. *British Journal of Obstetrics and Gynaecology*. 102 (2), 101-106.

Morrison, S., Percival, P., Haucky, Y., McMurray, A. (1999). Birthing at home the resolution of expectations. *Midwifery*. 15 (1), 32-39.

Murphy-Black, T. (1993). *Identifying the key features of continuity of care in midwifery* Nursing Research Unit, University of Edinburgh, Edinburgh.

Nahas, V. L., Hillege, S., Amasheh, N. (1999). Postpartum depressions: the lived experiences of Middle Eastern migrant women in Australia. *Journal of Nurse-Midwifery*. 44 (1), 65-74.

Newell, D. J. (1992). Intention-to-Treat Analysis: Implications for quantitative and qualitative research. *International Journal of Epidemiology*. 21 (5), 837-841.

National Health and Medical Research Council (1996). *Options for Effective Care in Childbirth* Australian Government Printing Service, Canberra.

Nivison-Smith, I. (1998). *South Eastern Sydney Area Health Service Social and demographic characteristics. Summary Report* South Eastern Sydney Multicultural Health Unit, Sydney.

Notzon, F. C., Cnattinguis, S., Bergsjo, P., Cole, S., Taffel, S., Irgens, L., Daltveit, A. K. (1994). Cesarean Section Delivery in the 1980s: International Comparison by Indication. *American Journal of Obstetrics and Gynaecology*. 170 (2), 495-504.

NSW Health (2000). *New South Wales Mothers and Babies 1998* NSW Health Department, Sydney.

NSW Health Department (1989). *Final Report of the Ministerial Task Force on Obstetric Services in NSW: The Shearman Report*. NSW Department of Health, Sydney.

NSW Health Department (1996). *NSW Midwifery Taskforce Report*. NSW Department of Health, Sydney.

NSW Health Department (1998a). *New South Wales Mothers and Babies 1997.* NSW Health Department, Sydney.

NSW Health Department (1998b). *New South Wales Mothers and Babies 1996.* NSW Department of Health, Sydney.

NSW Health Department (1998c). *New South Wales Multicultural Health Communication Service: Health Columns Project, 2 February 1998.* NSW Health Department, Sydney.

NSW Health Department. (1999). South Eastern Sydney Area Health Service Profile. *http://internal.health.nsw.gov.au/areas/sesahs/profile.htm* . Accessed June 1999.

O'Driscoll, K., Foley, M. (1983). Correlation of decrease in perinatal mortality and increase in caesarean section rate. *Obstetrics and Gynecology.* 61 (1), 1-5.

O'Hara, M. W., Swain, A. M. (1996). Rates and risks of postpartum depression - a meta analysis. *International Review of Psychiatry.* 8, 37-54.

O'Rourke, P. P., Crone, R. K., Vacanti, J. P. (1989). Extracorporeal membrane oxygenation and conventional medical therapy in neonates with persistent pulmonary hypertension of the newborn: a prospective randomised study. *Pediatrics.* 84 (6), 957-963.

Oakley, A., Hickey, D., Rajan, L., Rigby, A. (1996). Social support in pregnancy: does it have long term effects? *Journal of Reproductive Health and Infant Psychology.* 14, 7-22.

Oakley, A., Rajan, L., Grant, A. (1990). Social support and pregnancy outcome. *British Journal of Obstetrics and Gynaecology.* 97 (2), 155-162.

Owens, D. J., Bachelor, C. (1996). Patient satisfaction and the elderly. *Social Science and Medicine.* 42 (11), 1483-1491.

Paediatric Mental Health Service (1995). *Review of services for women with postnatal distress and depression.* South Western Sydney Area Health Service, Sydney.

Page, L. A., Bentley, R. K., Jones, B., Marlow, D. (1995). Transforming the organisation. In *Effective Group Practice in Midwifery: Working with Women.* L. A. Page (ed). Blackwell Science, Oxford, pp. 77-95.

Page, L. A., Cooke, P., Percival, P. (2000). Providing one-to-one care and enjoying it. In *The New Midwifery: Science and Sensitivity in Practice.* L. A. Page (ed). Churchill Livingstone, Edinburgh, pp. 123-140.

Paterson-Brown, S. (1999). Should doctors perform an elective caesarean on request? *British Medical Journal.* 317 (7156), 462.

Paterson-Brown, S., Fisk, N. M. (1997). Caesarean section: every women's right to choose? *Current Opinion in Obstetrics and Gynaecology.* 9 (6), 351-355.

Perkins, E. R., Unell, J. (1997). Continuity and choice in practice: a study of a community-based team midwifery scheme. In *Reflections on midwifery*, M. J. Kirkham & E. R. Perkins, eds., Bailliere Tindall, London, pp. 26-46.

Phelan, P. D., Tate, R., Webster, F., Marshall, R. P. (1998). DRG cost weights - getting it right. *Medical Journal of Australia.* 169 (Suppl.), S36-S38.

Phoenix, A. (1990). Black women and the maternity services. In *The Politics of Maternity Care: Services for Childbearing Women in 20th Century Britain.* J. Garcia, R. Kilpatrick, & M. Richards, (eds). Clarendon Press, Oxford, pp. 274-299.

Pope, S., Watts, J., Evans, S., McDonald, S. (1999). *Postnatal Depression: A Systematic Review of the Literature 1980-1999.* Women's and Children's Research Foundation, Perth.

Proctor, S. (1998). What determines quality in maternity care? Comparing the perceptions of childbearing women and midwives. *Birth: Issues in Perinatal Care and Education.* 25 (2), 85-93.

Quinlivan, J. A., Petersen, R. W., Nichols, C. N. (1999). Patient preference the leading indication for elective caesarean section in public patients - Results of a 2-year prospective audit in a teaching hospital. *Australian and New Zealand Journal of Obstetrics and Gynaecology.* 39 (2), 207-214.

Ramsay, K. (1996). *Evaluation of the Community Midwifery Service.* Mater Misericordiae Mothers Hospital Brisbane, Queensland, Brisbane.

Ratcliffe, J., Ryan, M., Tucker, J. S. (1996). The costs of alternative types of routine antenatal care for low-risk women: shared care vs care by general practitioners and community midwives. *Journal of Health Services and Research Policy.* 1 (3), 135-140.

Rice, P. L. (1994). *Asian Mothers, Australian Birth.* Ausmed Publications, Melbourne.

Rice, P. L., Naksook, C., Watson, L. E. (1999a). The experiences of postpartum hospital stay and returning home among Thai mothers in Australia. *Midwifery.* 15 (1), 47-57.

Rice, P. L., Watson, L., Lumley, J. (1999b). Women born in Asia: their obstetric profiles. A Victorian study. In *Asian Mothers, Western Birth, 2nd ed.* P. L. Rice (ed). Ausmed Publications, Melbourne, pp. 15-30.

Rigby, K., Clark, R. B., Runciman, W. B. (1999). Adverse events in health care: setting priorities based on economic evaluation. *Journal of Quality in Clinical Practice.* 19 (1), 7-12.

Rissel, C. (1997). The development and application of a scale of acculturation. *Australian and New Zealand Journal of Public Health.* 21 (6), 606-613.

Roberts, C. L., Tracey, S., Peat, B. (2000). Rates for obstetric intervention among private and public patients in Australia: population based descriptive study. *British Medical Journal.* 321 (7254), 137-141.

Robinson, R. (1993). Costs and cost-minimisation analysis. *British Medical Journal.* 307 (6906), 726-728.

Rossiter, J. C. (1992). Attitudes of Vietnamese women to baby feeding practices before and after immigration to Sydney, Australia. *Midwifery.* 8 (3), 103-112.

Rowley, M. J., Hensley, M. J., Brinsmead, M. W., Wlodarczyk, J. H. (1995). Continuity of care by a midwife team versus routine care during pregnancy and birth: a randomised trial. *Medical Journal of Australia.* 163 (6), 289-193.

Ryan, M. (1999). *Do clinical outcomes differ between a birth centre and a labour ward? (Abstract)* Biennial Conference of the Australian College of Midwives, Inc., Hobart, Tasmania.

Sandall, J. (1997). Midwives' burnout and continuity of care. *British Journal of Midwifery.* 5 (2), 106-111.

Schellings, R., Kessels, A. G. H., van Riet, G., Sturmans, F. (1999). The Zelen design may be the best choice for a heroin-provision experiment. *Journal of Clinical Epidemiology.* 52 (6), 503-507.

Scott, A. (1994). A cost analysis of early discharge and domiciliary visits versus standard hospital care for low-risk obstetric clients. *Australian and New Zealand Journal of Public Health.* 18 (1), 96-100.

Scott, J. A., Binns, C. W. (1999). Factors associated with the initiation and duration of breastfeeding: a review of the literature. *Breastfeeding Review.* 7 (1), 5-16.

Scott, J. A., Binns, C. W., Aroni, R. A. (1997a). *Report 2: Factors associated with the duration of breastfeeding and women's breastfeeding experiences* Curtin University of Technology and La Trobe University, Melbourne.

Scott, J. A., Binns, C. W., Aroni, R. A. (1997b). The influence of reported paternal attitudes on the decision to breastfe ed. *Journal of Paediatric and Child Health.* 33 (4), 305-307.

Seguin, L., Therrien, R., Champagne, F., Larouche, D. (1989). The components of women's satisfaction with maternity care. *Birth: Issues in Perinatal Care and Education.* 16 (3), 109-113.

Senate Community Affairs References Committee (1999). *Rocking the Cradle: A Report into Childbirth Procedures* Commonwealth of Australia, Canberra.

Senate Community Affairs References Committee (2000). *First Report: Public Hospital Funding and Options for Reform* Commonwealth of Australia, Canberra.

Shearer, E. (1993). Cesarean section: medical benefits and costs. *Social Science and Medicine.* 37 (10), 1223-1231.

Shields, N., Holmes, A., Cheyne, H., McGinley, M., Young, D., Gilmour, W. H., Turnbull, D., Reid, M. (1999). Knowing your midwife during labour. *British Journal of Midwifery.* 7 (8), 504-510.

Shorten, A. (1995). Obstetric early discharge versus traditional hospital stay. *Australian Health Review.* 18 (2), 19-39.

Shorten, A., Lewis, D. E., Shorten, B. (1998). Trial of labour versus elective repeat caesarean section: a cost effectiveness analysis. *Australian Health Review.* 21 (1), 8-28.

Showalter, E., Griffin, A. (1999). All women should have a choice [commentary]. *British Medical Journal.* 319, 1401.

Sikorski, J., Clement, S., Wilson, J., Das, S., Smeeton, N. (1995). A survey of health professionals' views on possible changes in the provision and organisation of antenatal care. *Midwifery.* 11 (4), 61-68.

Sikorski, J., Renfrew, M. J. (2000). Support for breastfeeding mothers (Cochrane Review). In *The Cochrane Library, Issue 2,* Update Software, Oxford.

Sikorski, J., Wilson, J., Clement, S., Das, S., Smeeton, N. (1996). A randomised controlled trial comparing two schedules of antenatal visits: the antenatal care project. *British Medical Journal.* 312 (7030), 546 -553.

Slome, C., Wetherbee, H., Daly, M., Christensen, K., Meglen, M., Thiede, H. (1976). Effectiveness of certified nurse-midwives. A prospective evaluation study. *American Journal of Obstetrics and Gynaecology.* 124 (2), 177-182.

Small, R., Yelland, J., Lumley, J., Rice, P. L. (1999). Cross cultural research: trying to do it better. 1. Issues in study design. *Australian and New Zealand Journal of Public Health.* 23 (4), 385-389.

Smulders, B. (1999). *The place of birth: Its impact on midwives and women* ACE Graphics, Sydney.

Snowden, C., Elbourne, D., Garcia, J. (1998). Zelen randomisation: Attitudes of parents participating in a neonatal clinical trial. *Controlled Clinical Trials.* 20, 149-171.

Snowden, C., Garcia, J., Elbourne, D. (1997). Making sense of randomization; responses of parents of critically ill babies to random allocation of treatment in a clinical trial. *Social Science and Medicine.* 45 (9), 1337-1355.

Stacey, T. (2000). *Describing postnatal care: a qualitative analysis.* Unpublished Masters of Public Health treatise, University of New South Wales, Sydney.

Stamp, G., Crowther, C. A. (1994). Women's views of their postnatal care by midwives at an Adelaide women's hospital. *Midwifery*. 10 (3), 148-156.

Stimson, G., Webb, B. (1975). *On Going to See the Doctor.* Routledge and Kegan Paul, London.

Stirrat, G. M., Farndon, J., Farrow, S. C., Dwyer, N. (1992). The challenge of evaluating surgical procedures. *Annals of the Royal College of Surgeons England.* 74 (80), 84.

Stock, J., Wraight, A. (1993). *Developing continuity of care in maternity services: the implications for midwives.* Institute of Manpower Studies, University of Sussex, Falmer.

Stratham, H., Green, J., Kafetsios, K. (1997). Who worries that something might be wrong with the baby? A prospective study of 1072 pregnant women. *Birth: Issues in Perinatal Care and Education.* 24 (4), 223-233.

Sultan, A. H., Monga, AK., Stanton, S. L. (1996). The pelvic floor sequelae of childbirth. *British Journal of Hospital Medicine.* 55 (9), 575-579.

Summers, A., McKeown, K., Lord, J., Walton, L. (1997). Different women, different views. *British Journal of Midwifery.* 5 (1), 46-50.

Taffell, S. M., Placek, P. L., Moien, M., Kosary, C. L. (1991). 1989 U.S. cesarean section rate steadies. *Birth: Issues in Perinatal Care and Education.* 18 (2), 73-77.

Taylor, J. (1999). Life chances: Issues of childbearing and poverty among Asian immigrants. In *Asian Mothers, Western Birth, 2nd ed.* P. L. Rice (ed). AusMed Publications, Melbourne, pp. 191-214.

Tew, M. (1990). *Safer Childbirth? A Critical History of Maternity Care.* Chapman and Hall, London.

Thacker, S. B., Stroub, D. F. (2000). Continuous electronic heart rate monitoring versus intermittent auscultation for assessment during labour (Cochrane Review). *Cochrane Library. Issue 2.* Update Software, Oxford.

Therapeutic Goods Administration (1991). *Guidelines for Good Clinical Research Practice (GCRP) in Australia* Commonwealth of Australia, Canberra .

Thiele, B., Thorogood, C. (1997). *Community Based Midwifery Program in Fremantle, Western Australia.* Centre for Research for Women (WA) and the Fremantle Community Midwives, Fremantle.

Thomas, L. H., McColl, E., Priest, J., Bond, S. (1996). Open-ended questions: do they add anything to a quantitative patient satisfaction scale? *Social Sciences and Health* 2, 23-35.

Thong, Y. H., Harth, S. C. (1991). The social filter of informed consent in clinical research. *Pediatrics*. 87, 568-569.

Tinkler, A., Quinney, D. (1998). Team midwifery: the influence of the midwife-woman relationship on women's experiences and perceptions of maternity care. *Journal of Advanced Nursing*. 28 (1), 30-35.

Tobias, J. S., Souhami, R. L. (1993). Fully informed consent can be needlessly cruel. *British Medical Journal*. 307, 1199-1201.

Torgerson, D. J., Roland, M. (1998). What is Zelen's design? *British Medical Journal*. 316 (6913), 606.

Traynor, J. D., Peaceman, A. M. (1998). Maternal hospital charges associated with trial of labour versus elective repeat cesarean section. *Birth: Issues in Perinatal Care and Education*. 25 (2), 81-84.

Turcot, L., Marcoux, S., William, F. (1997). Multivariate analysis of risk factors for operative delivery in nulliparous women. *American Journal of Obstetrics and Gynaecology*. 176 (2), 395-402.

Turnbull, D., Holmes, A., Shields, N., Cheyne, H., Twaddle, S., Gilmour, W. H., McGinley, M., Reid, M., Johnstone, I., Geer, I., McIlwaine, G., Lunan, C. B. (1996). Randomised, controlled trial of efficacy of midwife-managed care. *Lancet*. 348 (9022), 213-218.

Twaddle, S., Young, D. (1998). The economics of maternity care. In *Community-based Maternity Care*. In *Community-based Maternity Care*. G. Marsh & M. Renfrew (eds). Oxford University Press, Oxford, pp. 119-136.

UK Collaborative Trial Group (1996). UK collaborative randomised trial of neonatal extra-corporal membrane oxygenation. *Lancet*. 348 75-82.

US Department of Health and Human Services (1991). *Healthy people 2000: National health promotion and disease prevention objectives* DHHS (PHS 91-50212), Washington DC.

van Roosmalen, J. (1989). Perinatal mortality in rural Tanzania. *British Journal of Obstetrics and Gynaecology*. 96 (7), 827-834.

van Roosmalen, J. (1999). Unnecessary caesarean should be avoided [letter]. *British Medical Journal*. 318 (7176), 121.

van Roosmalen, J., van der Does, C. D. (1995). Caesarean birth rates worldwide. *Tropical and Geographical Medicine*. 47 (1), 19-22.

Victorian Department of Health (1990). *Having a Baby in Victoria: Ministerial Review of Birthing Services in Victoria* Victorian Department of Health, Melbourne.

Wagner, M. (1994b). *Pursuing the Birth Machine: the Search for Appropriate Birth Technology*. ACE Graphics, Sydney.

Wagner, M. (1994a). The Australian Birth Machine. *Future Birth Conference*. ACE Graphics, Sydney.

Waldenström, U. (1987). Early discharge with domiciliary visits and hospital care: parent's experience of two modes of postpartum care. *Scandinavian Journal of Caring Science*. (2), 51-58.

Waldenström, U. (1998). Continuity of carer and satisfaction. *Midwifery*. 14 (4), 207-213.

Waldenström, U., Lawson, J. (1997). *Birth centre practices in Australia.* Unpublished report: Royal Women's Hospital, Melbourne.

Waldenström, U., Nilsson, C. A. (1993). Women's satisfaction with Birth Centre care: A randomised controlled trial. *Birth: Issues in Perinatal Care and Education*. 21 (1), 3-13.

Waldenström, U., Nilsson, C. A. (1994). No effect on birth centre care on either duration or experience of breastfeeding, but more complications: findings from a randomised controlled trial. *Midwifery*. 10 (1), 8-17.

Waldenström, U., Nilsson, C. A. (1997). A randomised controlled study of birth centre care versus standard maternity care: Effects on women's health. *Birth: Issues in Perinatal Care and Education*. 24 (1), 17-26.

Waldenström, U., Nilsson, C. A., Winbladh, B. (1997). The Stockholm birth centre trial: maternal and infant outcome. *British Journal of Obstetrics and Gynaecology*. 104 (4), 410-418.

Waldenström, U., Turnbull, D. (1998). A systematic review comparing continuity of midwifery care with standard maternity services. *British Journal of Obstetrics and Gynaecology*. 105 (11), 1160-1170.

Walker, P. H., Stone, P. W. (1996). Exploring cost and quality: community-based versus traditional hospital delivery systems. *Journal of Health Care Finance*. 23 (1), 23-47.

Walsh, D. (1999). An ethnographic study of women's experience of partnership caseload midwifery practice. *Midwifery*. 15 (3), 165-176.

Ward, G., Pridmore, B. R., Cox, C. W. (1981). Vietnamese refugees in Adelaide: an obstetric analysis. *Medical Journal of Australia*. 1, 72-75.

Weiner, C. P. (1994). Fetal growth deficiency and its evaluation. In *High Risk Pregnancy*. D. K. James et al (eds). WB Saunders, London, pp. 760.

Westbrook, J. (1993). Patient satisfaction: methodological issues and research findings. *Australian Health Review*. 16, 75-88.

Whitfield, C. R., Smith, N. C., Cockburn, F., Gibson, A. A. M. (1986). Perinatally related wastage - a proposed classification of primary obstetric factors. *British Journal of Obstetrics and Gynaecology*. 93 (7), 694-703.

Wilcock, A., Kobayashi, L., Murray, I. (1997). Twenty-five years of obstetric patient satisfaction in North America: a review of the literature . *Journal of Perinatal and Neonatal Nursing*. 10 (4), 36-47.

Wilkinson, C., McIlwaine, G., Boulton -Jones, C., Cole, S. (1998). Is a rising caesarean section rate inevitable? *British Journal of Obstetrics and Gynaecology*. 105 (1), 45-52.

Williams, B., Coyle, J., Healy, D. (1998). The meaning of patient satisfaction: an explanation of high reported levels. *Social Science and Medicine*. 47 (9), 1351-1359.

Williams, H. E., Carmichael, A. (1983). Nutrition in the first year of life in a multi-ethnic poor socio-economic municipality in Melbourne. *Australian Paediatric Journal*. 19 (2), 73-77.

Williams, S., Dickson, D., Forbes, J., McIlwaine, G., Rosenberg, K. (1989). An evaluation of community antenatal care. *Midwifery*. 5 (2), 63-68.

Williamson, S., Thomson, A. M. (1996). Women's satisfaction with antenatal care in a changing maternity service. *Midwifery*. 12 (4), 198-204.

Wilson, H. S. (1989). *Research in Nursing, 2nd ed.* Addison Wesley, California.

World Health Organisation (1978). *Primary Health Care: A report from the International Conference on Primary Health Care.* WHO, Geneva.

World Health Organisation (1985). Appropriate technology for birth. *Lancet*. (ii), 436-437.

Wraight, A., Ball, J., Seccombe, I., Stock, J. (1993). *Mapping Team Midwifery. IMS Report 242 to the Department of Health*. Institute of Manpower Studies, Brighton.

Wright, R. E. (1997). Logistic regression. In *Reading and Understanding Multivariate Statistics*. L. G. Grimm & P. R. Yarnold (eds). American Psychological Association, Washington, DC, pp. 217-244.

Yelland, J., Small, R., Lumley, J., Liamputtong Rice, P., Cotronei, V., Warren, R. (1998). Support, sensitivity, satisfaction: Filipino, Turkish and Vietnamese women's experiences of postnatal hospital stay. *Midwifery*. 14 (3), 144-154.

Yelland, J., Small, R., Lumley, J., Rice, P. L. (1997). Choice or constraint? Infant feeding Amongst Vietnamese, Turkish and Filipino women. In *NMAA Conference Proceedings: The Natural Advantage*. Nursing Mothers Association of Australia, Sydney, pp. 249-254.

Young, D., Lees, A., Twaddle, S. (1997). Professional issues: The costs to the NHS of maternity care: midwife managed vs shared. *British Journal of Midwifery*. 5 (8), 465-472.

Young, D., Shields, N., Holmes, A., Turnbull, D., Twaddle, S. (1997). Aspects of antenatal care. A new style of midwife-managed antenatal care: costs and satisfaction. *British Journal of Midwifery*. 5 (9), 540-545.

Zadoroznyi, M. (1996). Women's satisfaction with antenatal and postnatal care: an analysis of individual and organisational factors. *Australian and New Zealand Journal of Public Health*. 20 (6), 594-602.

Zelen, M. (1979). A new design for randomized controlled trials. *New England Journal of Medicine*. 33 (22), 1242-1245.

Zelen, M. (1990). Strategy and alternative designs for clinical trials: an update. *Statistics in Medicine*. 9 (6), 645-656.

Zelen, M. (1992). Randomised controlled trials [letter]. *Lancet*. 340 (8815), 375.

Appendix 1: A comparison of the characteristics of the seven continuity of midwifery care models of care previously evaluated as randomised controlled trials.

	Flint et al (Flint et al 1989)	MacVicar et al (MacVicar et al 1993)	Kenny et al (Kenny et al 1994)	Rowley et al (1995)	Turnbull et al (1996)	Harvey et al (1996)	Waldenström et al (1997)	Homer (2000)[a]
Country	England	England	Australia	Australia	Scotland	Canada	Sweden	Australia
Randomisation	Zelen	Zelen	Conventional	Conventional	Conventional	Conventional	Conventional	Zelen
Participants (n)	1001	3510	446	814	1299	218	1860	1089
Risk status	Low	Low	Low and High	Low and high	Low	Low	Low	Low and high
Routine medical visits	yes	yes	yes	yes	As necessary	yes	As necessary	As necessary
Antenatal transfer	No	yes	no	no	yes	yes	yes	no
Antenatal care	Hospital	Hospital	Hospital	Hospital	Hospital	Hospital	Birth centre	Community
Number of midwives	4	10	8	6	20	7	10	6
Number of teams	One	One	One	One	One	One	One	Two
Postnatal home visits	yes	no	yes	no	yes	yes	yes	yes

The trials were identified in the systematic review conducted by Waldenström and Turnbull (1998). [a]The STOMP model is included.

Appendix 2: A description of the organisational process undertaken by the maternity unit at St George Hospital to establish the two STOMP teams.

Establishment of STOMP teams

Each STOMP team consists of seven full time equivalent (FTE) midwives. This gives a working roster of six midwives per team plus one FTE to cover the annual leave requirements for the team. Adequate uptake of annual leave entitlements is an essential component of the STOMP model to ensure that the midwives do not become exhausted and 'burnt out'. Under the current NSW Nurses Award, midwives who work rotating rosters are entitled to six to seven weeks annual leave. This means that there is always one of the seven midwives on annual leave. Midwives negotiate this amongst themselves to ensure minimal disruption to team numbers and continuity for women.

The two teams were established by re-organising the staffing levels within each clinical area in the maternity unit. In each area, an estimation was made of the midwifery time required to cater for 300 women per year per team. This equates to an annual caseload of 50 women per FTE midwife per year and, based on our experience is the maximum number to ensure feasibility. This caseload may not be suitable in all settings. Factors such as skill mix, travel time and the type of women need to be considered before a decision is made on the eventual caseload.

The annual caseload has guided the re-organisation of the staff to create the teams. For example, to staff the community-based antenatal clinic, it was estimated that two midwives would be required for a minimum of four hours twice a week. In the Delivery Suite however, a midwife was required 24 hours per day. In the early stages of development it was suggested that care in labour may be provided in eight hour shifts, which meant three shifts were required per day. Postnatal care, either provided in the community or in the hospital, would be provided by one midwife on a day shift in the postnatal ward. These estimations enabled the calculation of the number of FTE positions required from each area in order to establish a team. The FTE calculations are displayed in Table 1.

Table 1: The proportion of FTE positions required from each area in the maternity unit to establish one STOMP team

Clinical area	Amount of time required	FTE
Antenatal clinic	16 hrs per week	0.42
Delivery Suite/Birth Centre	8hrs x 3 shifts x 7 days per week	4.42
Postnatal ward	8hrs per day	1.47
TOTAL		**6.31**

In order to establish the teams, positions were reassigned from the antenatal clinic, Delivery Suite/Birth Centre and the postnatal/domicillary service to the STOMP team. For example, the equivalent of 4.42 FTE positions in the Delivery Suite became STOMP positions for one team. This meant that no additional funding was required to create the staffing levels for two teams of midwives. In total 12.6 FTE's were needed to establish two teams.

During the first four months after the establishment of each team, women were recruited at their booking visit. This meant that on-call for labour and birth did not start until the first cohort of women were around 36 weeks (that is, approximately 4 months from when recruitment commenced). During these first four months, the team midwives remained in their respective clinical areas and were released to provide the antenatal clinic service. At all other times they continued to work usual rosters within maternity unit. Flexibility and support from all staff was required in order to make this a reality.

Recruitment of midwives

Midwives for the STOMP teams were recruited from the existing staff of midwives within the Division of Women's and Children's Health at St George Hospital. In November 1996, an 'Expression of Interest' for the first team was posted in all maternity areas, following a series of formal and informal sessions, where the STOMP model and the role of the STOMP midwives was described and discussed. Six midwives responded to this advertisement and all were subsequently appointed. The second team was recruited in May 1997. The majority of these midwives had come to St George Hospital with the intention of joining a continuity of care team.

Both teams were made up of midwives with a diversity of experience, skills and philosophy (Table 2).

Table 2: Profile of midwives initially recruited to the STOMP teams

[a]	Recruited from[b]:	Years of midwifery experience	Years of midwifery at SGH	Recruited from:	Years of midwifery experience	Years at of midwifery at SGH
	Rockdale STOMP (recruited Dec 1996)			**Hurstville STOMP (recruited May 1997)**		
1	Delivery suite	8	6	Birth centre	2	0.6
2	Birth centre	2	1.5	Birth centre	4	0.25
3	Birth centre	5	5	Delivery suite	0.75	0.75
4	Postnatal ward	1	1	Birth centre	4	0.2
5	Delivery suite	2	2	Birth centre	15	4
6	Delivery suite	2	1	Delivery suite	4	0.25
	Mean in yrs	3.3	2.75	Mean in yrs	4.5	1.0

[a] Six midwives were initially recruited to each team. [b]They came from a variety of clinical areas at the St George Hospital.

'Up-skilling' the team midwives

The initial four months was important to identify the additional skills that working as a team midwife necessitated. For example, one of the midwives in the first team had worked in the Delivery Suite for more than 5 years with no recent experience in antenatal or postnatal care. This midwife was rotated to these areas in the first 4 months so that she could receive the additional experience that was needed.

Midwives entering the STOMP teams were required to complete a 'Skills Inventory' which was a self-assessment process aimed at identifying skills that needed 'updating'. Identifying areas of skill deficit gave midwives an opportunity to address these areas prior to commencing on the team and/or during the early days of STOMP. This tool was adapted with permission from research in the Midwifery Development Unit in Scotland (McGinley et al 1995) and consisted of a series of skills that midwives rated using a four

point scale from "I don't have these skills yet" to "I am fully updated". Figure 1 presents an example of the antenatal section of the Skills inventory.

Figure 1: An example of the antenatal section in the *Skills Inventory*.

Antenatal skills	I don't have these skills yet	I require a lot of updating	I require some updating	I am fully updated
Record a booking history	1	2	3	4
Conduct subsequent antenatal visits	1	2	3	4
Plan and pre-book interpreters	1	2	3	4
Use parenting education resources	1	2	3	4
Advise re appropriate screening tests	1	2	3	4
Take necessary action with test results	1	2	3	4

Midwives entering the STOMP teams were required to complete the inventory (by circling the appropriate number). This assisted them to identify their strengths and deficits. This process ensured that the orientation program met specific needs.

Data from this tool was used to plan a clinical program to meet the needs of each midwife prior to the commencement of on-call cover.

Setting up the antenatal clinics

A small amount of additional equipment was purchased in order to set up the community-based antenatal services. This included two portable examination tables, four hand-held fetal doppler machines, two automated urinalysis device, four sphygmomanometers and stethoscopes.

Working systems for the team midwives

The team midwives are rostered to cover the antenatal clinics, the postnatal ward and domicillary visits and to provide on-call for labour care. The midwives are responsible for writing their own rosters and within the rostering process they negotiate the spread of on-call to ensure that it is equitable. Midwives are not on-call on their days off or on their additional day off (ADO). The midwives operate a tally sheet system to accommodate their on call shifts. The tally sheet system is permissible under the current NSW Nurses' Award.

Midwives are on-call for 12 hour periods. They are paid for 8 hours regardless of whether they come in to work. If they are not called in, then they owe 8 hours on their 'tally sheet'. If they are called in for 12 hours, then the additional 4 hours is taken off their tally sheet. They do not get paid overtime but are paid an on-call allowance ($13.08 per shift). The midwives write their own rosters, which means individual requests can be readily incorporated. They work four weeks of day shifts (including, two 'on call' shifts) followed by two weeks of night duty (eight 'on-call' shifts).

Our experience has shown that team midwives usually owe the organisation 20-30 hours at any one time and it is felt that this is an advantageous situation. Morale seems to be higher when midwives owe hours rather than the reverse. In addition, in times of necessity, for example, sick leave that cannot be filled or when there is a lack of experienced midwives on any one shift, the team midwives can be asked to work an extra shift in order to repay some of their hours.

Efficiency and sustainability

In order to maximise efficiency, we have found that each team of six midwives should 'book' 35 women per month with the aim of attending the labour and birth of 30 women per month. This means that the teams can cater for 720 women a year, which is higher than our original estimations of 600 a year. Our experience is that this level of activity means that the midwives are well utilised. This level of activity however can take some time to achieve. There is an initial 'setting up' phase of 9 to 12 months as the program is established, women are booked on the team, midwives are recruited and any upgrading of midwifery skills occurs. During the period, considerable flexibility and adaptability of all staff is required.

There are times within any maternity unit and delivery suite where there are deficits with the combination of experienced and less experienced midwives on any one shift. One advantage of having a singe midwifery manager for all birthing services (Delivery Suite, Birth Centre and the STOMP teams) is that any staffing problems can be identified early and alternative strategies put in place. These strategies might include utilising experienced team midwives (especially those who owe significant hours to the organisation). Again, this requires, however a high degree of flexibility and trust between management, team midwives and 'core' midwifery staff. The keys to success of a new model of care also include a capacity to think laterally when problem-solving

and to monitor the progress of the teams, including hours owing, annual leave requirements and general morale.

Appendix 3: A comparison of the reporting of cultural diversity in the sample and population in 12 randomised controlled trials of models of midwifery care.

	Authors	Model[a]	Sample (n)	Study design	Cultural diversity reported in sample	Cultural diversity reported in population
1	(Slome et al. 1976)	A, B & C	438	No consent	Yes	No
2	(Chapman et al. 1986)	B only	148	Conventional	No	No
3	(Flint et al 1989)	A, B & C	1001	Zelen	Yes	No
4	(Chambliss et al. 1992)	B only	492	No consent	No	No
5	(Giles et al 1992)	A only	89	Conventional	English-speaking only	No
6	(MacVicar et al 1993)	A & B	3510	Zelen	No	No
7	(Hundley et al 1994)	B only	2844	Conventional	No	No
8	(Kenny et al 1994)	A, B & C	446	Conventional	Yes	Yes
9	(Rowley et al 1995)	A & B	814	Conventional	Yes	No
10	(Turnbull et al 1996)	A, B & C	1299	Conventional	No	No
11	(Harvey et al 1996)	A, B & C	218	Conventional	Yes	No
12	(Waldenström et al 1997)	A, B & C	1860	Conventional	Yes	No

[a]Model of care: A = antenatal, B = intrapartum, C = postnatal. These trials were identified as trials of models of midwifery care by Waldenström and Turnbull (1998). Only 7 of the 12 trials examine continuity of midwifery care through the antenatal, intrapartum and postpartum periods (Appendix 1).

Appendix 4a: Consent form for the STOMP group (available in Chinese and Arabic).

St George Outreach Maternity Care Project

Why have I been invited to participate?

You have been invited to participate in a study that is examining how best maternity services can be delivered in this hospital.

You have been invited because you are attending an antenatal clinic at St George Hospital, you are less than 24 weeks pregnant, your name was randomly chosen from a list of all pregnant women coming to this hospital, and you live in the Rockdale catchment area.

What is the purpose of this study?

We hope to learn whether a different way of providing maternity care is beneficial to you and to the hospital. The different type of maternity service we are studying is called continuity of care.

Studies at the John Hunter Hospital in Newcastle and at Westmead Hospital in Sydney, have suggested that women like continuity of care and that it is as safe and effective as the standard maternity service. However, these studies were quite small, and further research is needed to determine if this type of service can be instituted throughout NSW maternity hospitals.

What does the study involve?

If you agree to be part of this study you will be cared for throughout your pregnancy, childbirth and postnatal period by a group ɗ 6 midwives. **This is called continuity of care**. This same group of midwives will provide all midwifery antenatal care, care during labour and delivery and postnatal care. Consultation will occur with doctors as necessary **at any time** if a complication develops.

Antenatal care will be provided from a community based clinic in Rockdale. This clinic will run two days a week and will be staffed by two midwives and a specialist obstetrician at all times.

You will be able to go home early if you wish on an early discharge program, and the continuity of care midwives will visit you at home.

You will be asked to complete a questionnaire during your pregnancy and one 6 weeks after the birth. The questionnaires will take between 10 and 30 minutes to complete.

Are there any risks?

All women will receive all necessary care. This means that if any complications arise during the pregnancy, you will be referred to the appropriate doctors.

The questionnaires will not contain your name. This is to protect your identity and allow you to answer the questions anonymously.

If you need to know more information, the continuity of care coordinator, Pat Brodie, can be contacted to answer your questions on 9350 1111 page 212.

How will the information be used?

The results of this study will be published in a report. You will receive a copy of this report once it has been published. Any information obtained in connection with the study which can identify you will remain confidential and will only be disclosed with your permission. By signing this form you consent to the disclosure of information that will not identify you.

What happens if I don't wish to participate or I withdraw my consent?

Your decision whether or not to participate will not affect your relationship with the South Eastern Sydney Area Health Service (SESAHS). If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time. Any such withdrawal will not affect any future treatment, or your relationship with the SESAHS or any persons treating you. The SESAHS has produced a 'Customer Charter' which is available from PO Box 430, Kogarah, 2217.

Who can I contact if I have any questions?

Ms Jo Wills (the senior midwifery manager in the Department of Obstetrics and Gynaecology) is one of the Chief investigators on this study. She can be contacted on 9350 3101 if you have any questions. You will be given a copy of this form to keep.

I, _____ have read this consent form and understand the purpose and risks of the study and I agree to participate.

_____   _____

Signature of Participant   Signature of Witness

Date _____   Date _____

_____   Date _____

Signature of Interpreter (if applicable)

Revised 8 May 97

Appendix 4a

Appendix 4b: Consent form for the control group (available in Chinese and Arabic).

Satisfaction with maternity care at St George Hospital

Why have I been invited to participate?

You have been invited to participate in a study which is examining how you feel about the maternity services at this hospital.

You have been invited because you are attending an antenatal clinic at St George Hospital, you are less than 24 weeks pregnant and your name was randomly chosen from a list of all pregnant women coming to this hospital.

What is the purpose of this study?

We hope to learn whether the hospital is providing a satisfactory maternity service. We also hope to learn about the experiences and physical outcomes of women and babies at this hospital.

A project examining customer satisfaction with maternity services was conducted two years ago at this hospital. Some of the recommendations of this project have been implemented. We hope to learn whether the changes have been beneficial and to discover what other changes might be good for women and their families.

What does the study involve?

If you agree to be part of this study you will be asked to complete a questionnaire during your pregnancy and one 6 weeks after the birth. The questionnaires will take between 10 and 30 minutes to complete.

When you have had your baby, a research midwife will collect some information from your medical records. The information is related to physical outcomes, for example, the type of pregnancy, labour and birth you had, the weight of your baby, and any complications you or your baby experienced. The information collected will not contain your name. You will be allocated a number which will appear on this information and on the questionnaires.

Are there any risks?

The questionnaires and the information from your records will not contain your name. This is to protect your identity and allow you to answer the questions anonymously.

If you need to know more information, Pat Brodie, one of the senior midwives at St George Hospital, can be contacted to answer your questions on 9350 1111 page 212.

How will the information be used?

The results of this study will be published in a report. Any information obtained in connection with the study and that can identify you will remain confidential and will only be disclosed with your permission. By signing this form you consent to the disclosure of information that will not identify you.

Appendix 4b

What happens if I don't wish to participate or I withdraw my consent?

Your decision whether or not to participate will not affect your relationship with the South Eastern Sydney Area Health Service (SESAHS). If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time. Any such withdrawal will not affect any future treatment, or your relationship with the SESAHS or any persons treating you. The SESAHS has produced a 'Customer Charter' which is available from PO Box 430, Kogarah, 2217.

Who can I contact if I have any questions?

Ms Jo Wills (the senior midwifery manager in the Department of Obstetrics and Gynaecology) is one of the Chief investigators on this study. She can be contacted on 9350 3101 if you have any questions.

You will be given a copy of this form to keep.

I, _____ have read this consent form and understand the purpose and risks of the study and I agree to participate.

_____   _____

Signature of Participant   Signature of Witness

Date _____   Date _____

_____

Signature of Interpreter (if applicable)

Date _____   Page 2 of 2

Revised 8 May 97

Appendix 4b

Appendix 5: Data collection form for medical records audit

Q1. Study Number   _____

Q2. Gestation at Booking   _____wks

Q3. Consent   Yes [ ] No [ ]

Q4a. Randomised Group   1. Team   [ ]

                             2. Control   [ ]

Q4b. Group   1. RD   [ ]

                             2. HUR   [ ]

Q4c: Did the woman receive the randomised option for the whole study

                      Yes [ ] No [ ]

Q4d: If no, state why: ……………………………………

Q5. MRN: _____

Q6. Confinement DRG   _____

Q7. Age: _____

Q8. Country of Birth   _____

Q9. Primary Language   _____

Q.10. Interpreter required   Yes [ ] No [ ]

Q.11. Parity   1. Nulliparous; 2. Multiparous

Q.12. Number of previous viable births [}

Q.13. Height_____Q.14. Weight_____

Q.15a. Drugs of Addiction Yes [ ]   No [ ]   Q.15b specify_____

Medical History

Q.16   Asymptomatic Cardiac Disease   Yes [ ] No [ ]

Q.17   Grand Multiparity   Yes [ ] No [ ]

Q.18   Significant post-partum haemorrhage in past   Yes [ ] No [ ]

Q.19   Previous Caesarean Section   Yes [ ] No [ ]

Q.20   Epilepsy   Yes [ ] No [ ]

Q.21   Antepartum Haem orrhage   Yes [ ] No [ ]

Q.22   Pre Eclampsia   Yes [ ] No [ ]

Q.23   Gest. Diabetes   Yes [ ] No [ ]

Q.24   Preterm Labour   Yes [ ] No [ ]

Q.25a   Other   Yes [ ] No [ ]   Q25bSpecify_____

Q.26 Was the last birth a caesarean section   1. Yes [ ] 2. No [ ] 3.N/A [ ]

Q.27 Marital Status   1. M or Def [ ]; 2. Single. [ ]; 3. Sep [ ]

Q.28 Currently working   1. Yes [ ]   2. No [ ]

Q.29a Occupation _____Q.29b Code_____

Q.30 Education Level   [ ] 1. None; 2. Primary; 3. Secondary; 4. Tertiary; 5. Unk

Antenatal Outcomes:

Q.31 Primary Antenatal Care   [ ]

     1. STOMP; 2. ANC; 3. Birth Centre; 4. MWC; 5. GP Shared Care

Q.32 Adjunct Antenatal Care   [ ]

     1. No Adjunct Care; 2. ANC; 3. GP Shared Care; 4. RAP

Q.33 Did this person attend DAU   1. Yes [ ]   2. No [ ]

Q.33b. Number of visits   _____

Q.34 Intention to breastfeed   [ ]   1. Yes   2. No   3. Not recorded

Q.35 Number of antenatal visits   _____

Q.36 Number of different midwife carers   _____

Q.37 Number of different medical carers   _____

Q.38 Number of antenatal CTG's   _____

Q.39 Number of Ultrasounds   _____

Q.40 Number of presentations to delivery Suite   _____

Q.41 Admission to 1 West   [ ]   1. Yes   2. No

Q.42 Total length of stay in 1West   _____

Q.43 1DRG   _____

Q.44 2DRG   _____

Complications of this pregnancy:

Q.45. Antepartum Haemorrhage   Yes [ ] No [ ]

Q. 46. Pre Eclampsia   Yes [ ] No [ ]

Q. 47. Gestational Diabetes   Yes [ ] No [ ]

Q.48 Preterm R.O.M.   Yes [ ] No [ ]

Q.49 . Threatened Prem Labour   Yes [ ] No [ ]

Q.50a. Other   Yes [ ] No [ ]

Q.50b. Specify   _____

Intrapartum Outcomes:

Q.51 Gestation at delivery   _____wks

Q.52 Onset of labour [ ]

     1. Spontaneous 2.Induction   3. No Labour

Type of induction of labour

Q.53 Prostin   1. Yes [ ]   2. No [ ]

Q.54 Syntocinon   1. Yes [ ]   2. No [ ]

Q.55 ARM   1. Yes [ ]   2. No [ ]

Q.56a Reason for induction of labour (primary reason)_____

1 Diabetes, **2** PROM at Term, **3** hypertensive disorders, **4** IUGR, **5** isoimmunisation, **6** fetal distress, **7** fetal demise, **8** chorioamnionitis, **9** prolonged pregnancy, **10** other, **11** No Induction of Labour

Q.56b Specify (**10)** other   _____

Q.57 Was this Labour Augmented   [   ]   **1**. Yes   **2**. No   **3**. NA

Q.58 Type of Augmentation   [ ]   **1**. ARM ; **2**. Syntocinon;

3. ARM & Syntocinon; **4.** N/A

Fetal Monitoring in Labour

       Q.59 1. Admission CTG   1. Yes [ ]   2. No [ ]

       Q.60 EFM in labour   1. Yes [ ]   2. No [ ]

Length of Labour Q.61 1st stage   _____mins

                Q.62 2nd stage   _____mins

                Q.63 3rd stage   _____mins

Q.64 Length of Rupture of Membranes   _____mins

Q.65 Presentation: [ ]

     1. Cephalic; 2. Breech; 3. Other; 4. Not Recorded

Q.66 Type of delivery   [ ]

1. NVD; 2. Elective CS; 3. Emergency CS; 4. Vaginal Breech; 5. Forceps; 6. Vacuum Extraction

Q.67 Reason for Operative Delivery   [ ]

     1. No Operative delivery; 2. CPD; 3. Previous uterine surgery (other than CS); 4. Delay 2nd stage; 5. Hypertension; 6. Maternal Exhaustion; 7. Malpresentation / Malposition; 8. Antepartum haemorrhage; 9. Fetal distress; 10. Failure to Progress <3cms dilated; 11. Failure to progress >3cms dilated; 12. Other

Q67b. Specify other   _____

Q.68a Accoucher   [ ]

     1. Certified Midwife; 2. Team Midwife; 3. Student Midwife; 4. Registrar; 5. RMO; 6. Obstetrician; 7.Medical Student

Q.68b. If the woman was a team woman, was a TM in attendance at the birth

1. Yes [ ]; 2. No[; 3. Not applicable [ ]

Q.69a Did a midwife previously known to the woman, provide <u>labour</u> care?

     1. Yes [ ]   2. No[ ]

Q.69b Did a midwife previously known to the woman, provide <u>delivery</u> care?

     1. Yes [ ]   2. No[ ]

Q69c) If yes, to question 69a), how many times? _____

Q69d) If yes, to question 69b), how many times? _____

Q.70 Perineum   [ ]   1. Intact; 2. Graze; 3. Episiotomy

                                       4. Laceration; 5. 3rd degree Laceration; 6. N/A

Q. 71 Sutured.   [ ]   1. Yes; 2. No; 3. N/A

Q.72 Meconium Stained Liquor   1. Yes [ ]   2. No [ ]

Q.73 Grade_____

Pain Relief in labour and delivery :

Q.74. Nitrous Oxide   Yes [ ]   No [ ]

Q.75. Pethidine   Yes [ ]   No [ ]

Q.76. Epidural / Spinal   Yes [ ]   No [ ]

Q.77. Puedendal Block   Yes [ ]   No [ ]

Q.78. General Anaes   Yes [ ]   No [ ]

Complications during labour and delivery:

Q.79 Pyrexia   Yes [ ]   No [ ]

Q.80 Intrapartum haem.   Yes [ ]   No [ ]

Q.81 Hypertension   Yes [ ]   No [ ]

Q.82 Shoulder dystocia   Yes [ ]   No [ ]

Q.83 PPH   Yes [ ]   No [ ]

Q.84 Fetal Distress   Yes [ ]   No [ ]

Q.85 Retained Placenta   Yes [ ]   No [ ]

Q.86a. Other   Yes [ ]   No [ ]   Q86b. specify _____

Timing:

Q.87 Time in Delivery Suite: Admission to Birth   _____mins

Q.88 Total number of different midwife carers in Delivery Suite   _____

Q.89 Number of different medical carers in Delivery Suite   _____

Neonatal Outcomes:

Q.90 Date of Birth_____

Q.91 Plurality: 1. Singleton, 2. Multiple pregnancy   [ ]

Q.92 Baby's MRN_____

Q.93 This baby: 1. Singleton, 2. Twin One, 3. Twin Two   [ ]

Q.94 Sex   1. Male [ ]   2. Female [ ]

Q.95 Status: 1. Live birth [ ]   2. Stillborn [ ]

Q.96 Reason for stillbirth   [ ]

       1. No Stillbirth; 2. Fetal Anomaly; 3. Hypoxia; 4. Cord accident; 5. Unknown; 6. Other

Q.97 Birthweight _____g

Resuscitation

Q.98 Suction   Yes [ ]   No [ ]

Q.99 Oxygen   Yes [ ]   No [ ]

Q.100 Direct Laryngoscopy   Yes [ ]   No [ ]

Q.101 Tracheal Aspiration   Yes [ ]   No [ ]

Q. 102 Intubation   Yes [ ]   No [ ]

Q.103 Insufflation   Yes [ ]   No [ ]

Q.104 Apgar score at 1min_____Q.105 Apgar score at 5 mins_____

Q.106 Paediatric Doctor at birth   1. Yes [ ]   2. No [ ]

Q.107 Was infant admitted to SCN   1. Yes [ ]   2. No [ ]

Q.108 Age at admission to SCN   [ ]

1. Not Admitted; 2. Immediately; 3. Within 6hrs; 4. 7-12hrs; 5. 13-24hrs; 6. Greater than 24hrs

Q.109a Primary Reason for Admission to SCN   [ ]

     1. Not admitted; 2. Resp Distress; 3. Prematurity; 4. Hypoglycaemia; 5. Hypothermia; 6. Birth Trauma; 7. Infection; 8. Phototherapy; 9. Congenital Abnormality; 10. Low Birth Weight / SGA; 11. Other

Q109b. Specify_____

Q.110a Did the baby go to SCN for < 4hrs (ie for observation but not admission)

                           1. Yes [ ]   2. No [ ]

Q.110b. Length of stay in SCN   [_____days]

Q.111a Congenital Abnormalities   1. Yes [ ]   2. No [ ]

Q. 111b. Please specify _____

Q.112 Was this infant transferred to a NICU   Yes [ ] No [ ]

Q.113a Primary Reason for transfer to NICU   [ ]

     1. Not Transferred; 2. Hypoxia; 3. Fetal Anomaly; 4. Prematurity; 5. Other

Q113b. Specify_____

Q.114 NND   1.Yes [ ] 2. No [ ]

Q.115 Age at NND _____days

Q.116 Reason_____

Q.117 Neonatal DRG   _____

Post-Partum Outcomes:

Q.118 Length of hospital stay   _____days

Q.119 Did this woman have domiciliary visits?   1. Yes[ ] 2. No [ ]

Q.120 How many domiciliary visits occurred   _____

Q.121 How many domiciliary phone calls occurred? _____

Q.122 Number of days on domiciliary care   _____

Q.123 Total length of post-natal care _____days

Q.124 Did a midwife previously known to the woman, provide any postnatal care?

1. Yes[ ] 2. No [ ]

Q.125 Was breastfeeding initiated   1. Yes [ ]   2. No [ ]

Q.126 What type of infant feeding on discharge from postnatal care? [ ]

     1. Fully breastfeeding; 2. Partially breastfeeding; 3. Artificially feeding

Complications of puerperium:

Q.127 Wound Infection   1. Yes [ ]   2. No [ ]

Q.128 Secondary PPH   1. Yes [ ]   2. No [ ]

Q.129 Mastitis   1. Yes [ ]   2. No [ ]

Q.130 Retained products of conception   1. Yes [ ]   2. No [ ]

Q.131a Other   1. Yes [ ]   2. No [ ]

Q.131b please specify _____

Q.132 Readmission within 6 weeks   1. Yes [ ]   2. No [ ]

Q.133 Weeks postnatal at readmission _____weeks

Q.134 Reason_____

Q.135 Post-Partum Readmission DRG   [ ]

1. Not Applicable; 2. 678; 3. 679; 4. other

Q. 136. Specify other readmission DRG   _____

Appendix 6: Clinical definitions used in the medical record audit.

Data sheet variable	SPPS variable	Description/definition
1. Study Number	STUDY1	
2. Gestation at Booking	GESTAT2	Gestation in weeks at 1st visit to the ANC (pink folder)
3. Consent	CONSENT3	Did the woman consent to being in the study?
4a. Allocated Group	GROUP4A	1= Team 2= Control
4b. Site	GROUP4B	1=ROCKDALE 2=HURSTVILLE
4c. Did the woman receive the allocated option for the whole study	GROUP4C	1= Yes 2= No
4d. If no, state why	GROUP4D	For women who transferred from STOMP to ANC or RAP
5. MRN	MRN5	Medical Records Number
6. DRG	DRG6	Confinement DRG should be on the front sheet.
DEMOGRAPHICS		
7. Age	AGE7	Age at delivery in years (find on front sheet)
8. Country of birth	COB8	See attached appendix NSW Health Department Code
9. Primary Language	PRIMLAN9	See attached appendix (eg English = 10, Arabic = 42)
10. Interpreter required	INTRPT10	According to antenatal card Yes (1) (2) No
11. Parity	PARITY11	1= Nulliparous 2= multiparous (previous birth >20 weeks)
12. Number of previous viable births	PARITY12	Births where gestation was greater than 20 wks
13. Height	HEIGHT13	As per AN folder in cm
14. Weight	WEIGHT14	As per AN folder in kilograms
15a. Drugs of Addiction	DRUG15A	Other than Alcohol or Cigarettes (1) Yes (2) No
15b. Specify drugs of addiction	SPEC15B	
ANTENATAL HISTORY		
16. Asymptomatic Cardiac Disease	QUEST16	Yes/No: Eg. cardiac murmurs
17. Grand Multiparity	QUEST17	Yes/No: Para 5 or greater
18. Significant past PPH	QUEST18	Yes/No: PPH >600mls on history
19. Previous CS	QUEST19	Yes/No: Any pregnancy that has been terminated by CS as recorded on AN card
20. Epilepsy	QUEST20	Yes/No: As recorded on AN card
21. APH	QUEST21	Yes/No: As recorded on booking

22. Pre-Eclampsia	QUEST22	Yes/No: Recorded as hypertension/PE in pregnancy
23. Gestational Diabetes	QUEST23	Yes/No: Recorded as Gestational diabetes
24. Preterm Labour	QUEST24	Yes/No: Labour at <37 weeks gestation
25a. Other	QUEST25A	Yes/No: Any other history which may be significant and relevant to this pregnancy-eg pre existing IDDM
25b. specify other	QUEST25B	String variable
26. Was the last birth a CS?	LSTBIR26	Was the birth directly previous to this pregnancy a CS? Yes/No
27. Marital Status	QUEST27	1=married or defacto, 2=single, 3=separated
28. Currently Working	WORK28	Yes/No: According to Antenatal folder
29a. Occupation	OCCPTN	String variable: According to Antenatal folder
29b. Occupation Code	OCCUP29b	Coded variable using scores from *Power, Privilege and Prestige: Occupations in Australia* (Daniel, 1983).
30. Education Level	EDUC30	According to Antenatal folder 1=none, 2=primary, 3=secondary, 4=tertiary, 5=not recorded (NB: TAFE = tertiary)
ANTENATAL PERIOD		
31. Primary ANC	PRIM31	STOMP: should have green/yellow dot on notes Antenatal Clinic: often not explicitly recorded,. May have red dot on notes Birth Centre: Should have a stamp in the AN record Midwives Clinic: may or may not be recorded (runs on Thursday nights) Often continuity of care by midwives only may denote Midwives Clinic. GP Shared Care: Usually will have "wants shared care" written at the 1st visit. SC women will usually not have many visits, booking, 28weeks, 36 weeks, 41 weeks
32. Adjunct AN care	ADJ32	No adjunct care: only received one of the above forms of antenatal care ANC: as above GP Shared Care: this will usually be for STOMP women who also choose SC. This should be documented on the AN folder

		RAP: Orange RAP sticker on notes
33. Did she attend the DAU?	DAU33A	Yes/No
33b. Number of visits	DAU33B	DAU visits will be documented in the continuation notes. There should also be front sheets for each occasion of service. The DRG for a DAU visit for hypertension is 686.
34. Intention to breastfeed	INTBF34	Yes/No or not recorded: As recorded in the antenatal folder
35. Number of antenatal visits	QUEST35	As indicated by dates in antenatal folder
36. Number of different midwife carers	NUMMW36	As recorded on the antenatal folder: determined by number of different signatures. Only routine antenatal care is included. If women are admitted to the ward these additional midwives are not included in the count.
37. Number of different medical carers	NUMMED37	As recorded on the antenatal folder: determined by number of different signatures. Only routine antenatal care is included. If women are admitted to the ward these additional doctors are not included in the count.
38. Number of antenatal CTG's	ANCTGS38	Recorded in notes/ traces/ dates. IOL pre and post-prostin CTGs are not included. Admission CTG in labour is not included.
39. Number of Ultrasound's	ULTRA39	Reports will usually be in the antenatal folder or commented on in the notes or at the visits
40. Number of presentations to DS	QUEST40	As recorded in notes. Each different time a women presents to Delivery Suite is recorded. The presentation to DS that results in her being admitted to DS in labour is not counted as a 'presentation'.
41. Antenatal Admission to 1W	QUEST41	As recorded in notes 1= yes 2= no
42. Length of stay on 1W	WEST42	No of days: after 12 midnight is counted as one day (ie midnight to midnight) Add all antenatal visits together
43. Antenatal DRG	ANDRG43	These will be recorded on the front medical records sheet with antenatal notes Will be marked as NA if not applicable. NB: If the woman is admitted and stays in hospital until after confinement (is not discharged) then she will only have a confinement DRG. She will not have a separate antenatal DRG. DRG1 is the 1st Antenatal adm
44. 2nd Antenatal admission	ANDRG44	DRG2 is the 2nd Antenatal adm

COMPLICATIONS OF THIS PREGNANCY

45. APH	HAEM45	Yes/No: Vaginal bleeding after 20 weeks gestation
46. Pre-Eclampsia	QUEST46	Yes/No: Should be defined in the notes but may be alerted to by one or all of the following: Admission to DAU with average BP of >= 140/90, admission to 1W with overnight BP >= 140/90, Proteinuria with protein/ creatinine ratio >30. or Acute BP>= 170/110
47. Gestational Diabetes	DIAB47	Yes/No: 2 hour 75GTT > 7.8mmol
48. Preterm ROM	ROM48	Yes/No: Ruptured membranes at <37 weeks gestation
49. Threatened Prem Labour	TPL49	Yes/No: Labour at <37 weeks gestation
50A. Other	OTHER50A	Yes/No: Any others which may be significant or relevant
50B. Specify any other	SPECI50B	String variable.

INTRAPARTUM OUTCOMES

51. Gestation at delivery	GEST51	Pregnancy in weeks to be calculated. The final EDC will be written at the top of the antenatal visit sheet of the AN folder
52. Onset of labour	LABOUR52	Documented in MR10b 1=spontaneous, 2=IOL, 3=no labour IOL– when labour (e the presence of painful rythmical contractions and dilatation of the cervix) has not occurred.
Type of Induction 53. Prostin 54. Syntocinon 55. ARM	PROST53 SYNTOC54 ARM55	Yes/No: Prostin will be found on the medication sheets in the notes Yes/No: IV syntocinon and ARM are documented on the MR10b form.
56a. Reason for induction 56b Specify	IOL56	Reasons from ACHS indicators: 1 Diabetes, 2 PROM at term , 3 hypertensive disorders, 4 IUGR, 5 isoimmunisation, 6 fetal distress, 7 fetal demise, 8 chorioamnionitis, 9 prolonged pregnancy, 10 other, 11 no induction of labour Specify Other for option 10
57. Was this labour augmented	AUG57	Yes/No: Where labour has commenced and these options ie prostin syntocinon and ARM have been used this then becomes an augmentation. Augmentation will be indicated in notes/ MR10b

Appendix 6

58. Type of Augmentation	AUG58	Documented on 10b or in notes
		1=ARM, 2=syntocinon, 3=both
Fetal Monitoring in Labour:		
59. Admission CTG	ADMCTG59	Yes/No: Short trace on admission only: CTG was placed on the woman when she arrived in labour and removed once it was reactive.
60. EFM in Labour	EFMLAB60	Yes/No: If any further electronic monitoring is commenced through the labour then it is considered a monitored labour.
Length of Labour:		As per MR10b in minutes
61. 1st Stage	LABOUR61	
62. 2nd Stage	LABOUR62	
63. 3rd Stage	LABOUR63	
64. Length of ruptured membranes	ROM64	Time from when membranes ruptured to end of 2nd stage (this will be documented on MR10b)
65. Presentation	PRES65	1. Cephalic
		2. Breech
		3. Other
		4. Not Recorded
66. Type of Delivery	DEL66	Documented MR10b
67. Reason for Operative Delivery	OPDEL67A	Will find in the notes, on the MR10b or the operation sheet
		1. No Operative Delivery
		2. CPD
		3. Previous Uterine Surgery (other than CS)
		4. Delay 2nd Stage
		5. Hypertension
		6. Maternal Exhaustion
		7. Malpresentation / Malposition
		8. Antepartum Haemorrhage
		9. Fetal Distress
		10. Failure to Progress <3cms
		11. Failure to progress >3cms
		12. Other (specify in next question)
67b. Specify other reason	SPEC67B	String variable

68. Accoucher	QUEST68	As per MR 10b/operation sheet
		1. Certified Midwife
		2. Team Midwife
		3. Student Midwife
		4. Registrar
		5. RMO
		6. Obstetrician
		7. Medical Student
69a. Did a midwife previously known to the woman, provide care during labour?	MID69a	Yes/No.
		Check signatures to identify if the midwives during <u>labour</u> had previously given antenatal care.
		If a 'known' midwife provided any care during the labour this is counted as a 'yes'. This includes giving prostin
69b. Did a midwife previously known to the woman, provide care during <u>delivery</u>?	MID69b	Yes/No.
		Check signatures to identify if the midwives during <u>delivery</u> had previously given antenatal care.
		If a 'known' midwife provided any care during the delivery this is counted as a 'yes'.
69c). If yes, to either previous questions, how many times was care provided	MID69c	If yes to Q69a or 69b, how many times had that MW given antenatal care? Check signatures to see how many times the midwives during labour and delivery had previously given antenatal care.
70. Perineum	PERI70	As per MR10b I
		1= Intact, 2= Graze, 3=Episiotomy, 4=Laceration, 5= 3rd Degree Laceration, 6=NA (ie CS)
71. Sutured	SUTUR71	Yes/No: As per MR10b
72. Meconium stained liquor		1=yes 2=no
73. MSL Grades	MECGR73	Good volume of amniotic fluid lightly stained with meconium.
		Reasonable amount of fluid with heavy suspension of meconium.
		Thick meconium - undiluted

Pain Relief in Labour and Delivery		Yes/No responses to each
74. Nitrous Oxide	N2O74	
75. Pethdine	PETH75	
76. Epidural / Spinal	EPID76	
77. Puedendal Block	PUDEND77	
78. General Anaesthetic	GA78	
Complications During Labour:		Yes/No responses to each.
79. Pyrexia	PYREX79	Where temperature is elevated and treatment for same implemented.
80. Antepartum/Intrapartum Haemorrhage	HAEM80	Any bleeding from or into the genital tract from the 20th week of pregnancy up to the birth of the baby
81. Hypertension requiring treatment	HYPERT81	BP>= 170/ and or /110
82. Shoulder Dystocia	SHOULD82	Impaction of the shoulders at the brim after delivery of the head
83. PPH	PPH83	600 mls - As per the NSW midwives data collection
84. Fetal Distress	FETAL84	As documented
85. Retained Placenta	PLACEN85	As documented
86a. Other	OTHER86A	Any other complications noted on the Delivery suite record requiring treatment
86b. Specify other	SPEC86B	String variable
87. Length of Time in Delivery Suite	TIMEDS87	Admission to Birth in minutes (excludes giving prostin) Therefore refers to the time when woman is transferred back to DS for labour and delivery.
88. Total Number of different midwife carers in DS	MID88	Need to look through the notes: number of different midwives who have written in the notes in Delivery Suite or during the birth. Elective CS still applicable
89. Number of different medical carers in Delivery Suite	DOC89	Need to look through the notes: total number of different doctors who have written in the notes while the woman was in delivery suite. Elective CS still applicable
NEONATAL DETAILS		
90. Baby's date of birth	DOB90	dd/mm/yy
91. Plurality	PLURAL91	Was the pregnancy singleton (1) or multiple (2)?
92. Baby's MRN	MRN92	Baby's Medical Record Number
93. Identifying baby	BABY93	Is this baby a singleton (1) or Twin One (2) or Twin Two (3)?

94. Sex	SEX94	1= male, 2=female
95. Status	STATU95	1. Live Birth, 2. Stillbirth
96. Reason for Stillbirth	QUEST96	Needs to be documented in the neonate's notes: on clinical or PM grounds
97. Birthweight	BIRTH97	grams
Resuscitation	SUCT98 OXY99 LARYN100 TRACH101 INTUB102 INSUF103	1=Suction; 2=Oxygen; 3=Direct Laryngoscopy, 4=Tracheal Aspiration, 5=Intubation; 6=Insufflation Documented on MR10b form. To welling and warmth is presumed for all infants so this data is not collected. Infants may have more than one method of resuscitation used. Yes/No responses
Apgar Scores 104. Apgar Score at 1 min 105. Apgar Score at 5 mins	 APGAR104 APGAR105	As documented on MR10b form.
106. Paed at the birth?	PAED106	Was a paed present at the delivery? This may be documented on the MR10b form (at the bottom). Also may be found in the baby's notes.
107. Admission to SCN	SCN107	Often this will be on the MR10b form but may also only be gathered by reading the mother's notes. An admission to SCN is defined as >4hr stay.
108. Age at admission to SCN	QUEST108	1. Not admitted, 2. Immediately (ie within 1 hour), 3. Within 6hrs, 4. 7-12hrs, 5. 13-24hrs, 6. Greater than 24
109a. Primary Reason for admission to SCN	QUES109A	This will be taken primarily from the baby's front sheet but if this is inadequate the notes or discharge summary should provide the information. Only one reason will be entered. 1. Not admitted, 2 Respiratory Distress, 3. Prematurity, 4. Hypoglycaemia, 5. Hypothermia, 6. Birth Trauma, 7. Infection 8. Phototherapy, 9. Congenital Abnormality, 10 LBW/SGA, 11 Other
109b. Specify any other	QUES109B	String variable
110a. SCN observation	SCN110A	Did the baby go to SCN for less than 4hours, ie, just for brief observation but was not admitted – Yes/No response

110b. SCN length of stay	SCN110B	Length of stay in full days. NB: greater than 4 hours but less than 24 hours is still considered one day. (Past midnight denotes a day)
111a. Congenital abnormalities	ABN111A	Yes/no and specify. Found either on front sheet, discharge summary or notes.
111b. Specify abnormality	SPEC111B	String variable
112. Transfer to NICU	NICU112	Was this infant transferred to a Level 3 NICU? Yes/No
113a. Reason for TF to NICU	QUES113A	Primary reason: 1. Not transferred 2. Hypoxia, 3. Anomaly, 4. Prematurity, 5. Other
113b. Specify other reason for TF	SPEC113B	String variable
114. Neonatal Death	NND114	Yes/No. The death of a live born infant within 28 days of birth.
115. Age at NND	AGE115	Age in days when death occurred
116. Reason	NND116	Document reason if known. String variable
117. Neonatal DRG	DRG117	DRG if applicable
POSTNATAL DETAILS		
118. Length of hospital stay	LOS118	After 12 midnight becomes one day then from midnight to midnight
119. Did this woman have domiciliary visits	VISIT119	Yes/No Did a domiciliary midwife visit the woman at home. If so, she will have an MEDP section in her notes with the visits documented.
120. How many domiciliary visits	NUM120	How many visits occurred?
121. How many domiciliary phone calls were made	PHONE121	How many times did the midwives ring the woman at home? This should also be documented in the MEDP section.
122. Number of days with domiciliary care	DAYS122	Total number of days receiving domiciliary care, either visits or phone calls.
124. Did a midwife previously known to the woman, provide any postnatal care?	MID124	Need to look at the signatures of the midwives who provided postnatal care, and check if any provided antenatal or intrapartum care.
125. Was breastfeeding initiated	BF125	Did the mother commence breastfeeding / Did mother offer the infant the breast at all following birth
126. Infant feeding	FEED126	What method of feeding was being used when the baby was discharged from postnatal care (ie from hospital or domiciliary care: which ever occurs latest) Will be found on MDC, in the notes or the MEDP section. 1= Fully BF, 2=Partially BF,3=AF.
Complications of the puerperium 127. Wound infection 128. Secondary PPH 129. Mastitis 130. Retained products of conception 131a. Other	WOUND127 PPH128 MAST129 RPOC130 OTH131A	Will hopefully be on the front sheet but may also be in the notes, usually the medical summaries. This includes all complications that are documented in the notes up to 6 weeks postpartum. Need to check outpatient notes as well as some women may come to the OPD or Emergency department.
131b. Specify other	SPEC131B	String variable

132. Readmission within 6 weeks	READM132	Yes/No: Is there any evidence in the notes that the woman was readmitted during the puerperium? If so, there should be a separate admission with a front sheet, DRG and notes. This will include SGH only
133. Weeks postnatal at readmission	QUEST133	How many weeks since the birth? To the nearest week
134. Reason	QUEST134	Should get this from the front sheet. String variable
135. Postpartum readmission DRG	DRG135	This will be on the front sheet.

Appendix 7: Antenatal questionnaire. This was also available in Chinese and Arabic.

St George Hospital Maternity Services Study

Antenatal Questionnaire

Study number: _____

Thank you for continuing to be part of the maternity services study at St George Hospital. This questionnaire is to obtain some information about the antenatal care you have received. This questionnaire will take about 20 minutes to complete.

Please tick the ONE BOX that best suits your answer.

Your answers are confidential and will in no way affect the care and service you are given.

1. How many weeks pregnant are you today _____

2. What type of antenatal care are you currently having?
   ⇒ Hospital antenatal clinic (visits at St George Hospital) ❏
   ⇒ Shared care with St George Hospital clinic and GP ❏
   ⇒ Community Clinic (eg Rockdale or Hurstville) ❏
   ⇒ Shared care with Community Clinic and GP ❏
   ⇒ Midwives Clinic (Thurs evening) at St George Hospital ❏

3. How long do you usually have to wait before being seen at your clinic appointments?

   ⇒ Less than 15 minutes ❏
   ⇒ 15 to 30 minutes ❏
   ⇒ 30 to 45 minutes ❏
   ⇒ 45 minutes to 1 hour ❏
   ⇒ More than 1 hour ❏

4. Is the waiting time acceptable to you?

   ❏ ❏ ❏ ❏
   Always   Mostly   Occasionally   Never

5. Do the antenatal clinic days and times suit you?

   ⇒ all the days and times of the clinics suit me ❏
   ⇒ most of the days and times suit me ❏
   ⇒ none of the days and times suit me ❏

6. If the times and days of the clinics are not convenient or do not suit you, what would you prefer? Please comment in the space below:

7. How do you usually get to your antenatal visits?

⇒ By public transport (train and /or bus) ❑
⇒ Walk all the way ❑
⇒ Private car ❑

8. Is this journey usually ……. ?

⇒ very easy ❑
⇒ fairly easy ❑
⇒ fairly difficult ❑
⇒ very difficult ❑

9. If you drive to your antenatal visits, do you usually ….?

⇒ Manage to find a car park easily ❑
⇒ Have some difficulty finding a car park ❑
⇒ Have great difficulty finding a car park ❑

10. Do you usually have other children with you when you go for your antenatal visits?

⇒ No, I don't have other children, this is my first pregnancy ❑
⇒ No, I usually leave them behind ❑
⇒ Yes, I usually bring them to the clinic ❑

11. During your pregnancy, how many <u>different</u> <u>midwives</u> have you seen so far at your antenatal check-ups? If you are not sure please give an estimate or a guess.

PLEASE FILL IN A NUMBER   _____

12. During your pregnancy, how many <u>different</u> <u>doctors</u> (either GP or hospital doctors) have you seen so far at your antenatal check-ups? If you are not sure please give an estimate or a guess.

PLEASE FILL IN A NUMBER   _____

13. Is it important for you to see the same person/people for most of your visits?

❑   ❑   ❑

	Yes	No	Does not matter

14. Would you like to have had more time talking to the doctors or midwives during your check-ups?

❑	❑	❑
Yes definitely	Yes, possibly	No, not really

15. Do you feel the midwives listen to what you have to say?

❑	❑	❑	❑	❑
Always	Mostly	Occasionally	Never	I haven't seen a midwife

16. Do you feel the doctors listen to what you have to say?

❑	❑	❑	❑	❑
Always	Mostly	Occasionally	Never	I haven't seen a doctor

17. So far, would you like to have had more time to talk to a doctor or midwife about….

Please tick one box on each line

	Yes definitely	Yes possibly	No, not really
a) medical advice about pregnancy and childbirth,	❑	❑	❑
b) general advice and reassurance about what happens during pregnancy and childbirth,	❑	❑	❑
c) or just for emotional support	❑	❑	❑

18. Have you received any conflicting advice or information from different doctors or midwives you have seen through this pregnancy?

Yes, often	❑
Yes, occasionally	❑
No.	❑

19. When you have your antenatal check-ups, is there someone (a doctor or a midwife) who:

PLEASE TICK ONE BOX ON EACH LINE

	Yes at most check-ups	Yes but only at some	No, not really
a) encourages you to ask all the questions you want to?	❑	❑	❑
b) will explain things so that you can understand	❑	❑	❑
c) has got to know you, remembers you and your progress from one visit to the next?	❑	❑	❑
d) will sit back and listen if you wanted to talk about the pregnancy and how you are feeling	❑	❑	❑

Would you like to write anything or make a comment about your answer to this question here?

20. Below is a list of words which women have used to describe the way they feel about being pregnant and towards the baby. Please read through the list and circle the number which best describes the way you feel <u>now</u> about **BEING PREGNANT**.

Please circle one number on each line

	Not a all							*Very much*
a) fulfilled	0	1	2	3	4	5	6	7
b) stressed	0	1	2	3	4	5	6	7
c) pleased	0	1	2	3	4	5	6	7
d) optimistic	0	1	2	3	4	5	6	7
e) worried	0	1	2	3	4	5	6	7
f) uncertain	0	1	2	3	4	5	6	7
g) depressed	0	1	2	3	4	5	6	7
h) excited	0	1	2	3	4	5	6	7
i) in control	0	1	2	3	4	5	6	7
j) vulnerable	0	1	2	3	4	5	6	7
k) special	0	1	2	3	4	5	6	7

21. Please read through this list and circle the number that best describes how you feel <u>now</u> about **THE BABY.**   PLEASE CIRCLE ONE NUM BER ON EACH LINE

	Not a all							*Very much*
l) attached	0	1	2	3	4	5	6	7
m) loving	0	1	2	3	4	5	6	7
n) uncertain	0	1	2	3	4	5	6	7
o) maternal	0	1	2	3	4	5	6	7
p) concerned	0	1	2	3	4	5	6	7
q) detached	0	1	2	3	4	5	6	7
r) confident	0	1	2	3	4	5	6	7
s) anxious	0	1	2	3	4	5	6	7

Appendix 7

Please look at the list below and tell us what, if any, are your worries at the moment, that is **today**. The list is not meant to give you more things to worry about!

22. Please circle a number for each one to show how much of a worry it is to you, from 0 if it is not a worry, to 5 if it is something which you are extremely worried about.

Please circle one number on each line

		Not a worry				A major worry	
a)	the position of the baby	0	1	2	3	4	5
b)	whether the baby might be too big	0	1	2	3	4	5
c)	how much your baby is moving	0	1	2	3	4	5
d)	whether your baby is growing well at the moment	0	1	2	3	4	5
e)	the possibility of your baby having a disability or an abnormality	0	1	2	3	4	5
f)	whether your baby is too small	0	1	2	3	4	5
g)	your own health during the pregnancy	0	1	2	3	4	5
h)	your sex life	0	1	2	3	4	5

23. Please continue circling the numbers to show how much of a worry these things are to you from 0 if it is not a worry, to 5 if it is something which you are extremely worried about.

PLEASE CIRCLE ONE NUMBER ON EACH LINE

		Not a worry				A major worry	
i)	your weight	0	1	2	3	4	5
j)	labour and giving birth	0	1	2	3	4	5
k)	feeding your baby after he or she is born	0	1	2	3	4	5
l)	coping with your baby	0	1	2	3	4	5
m)	your relationship with your partner	0	1	2	3	4	5
n)	your housing	0	1	2	3	4	5
o)	money problems	0	1	2	3	4	5
p)	employment problems	0	1	2	3	4	5

Appendix 7

Thank you for continuing to fill out this questionnaire. Your opinions, comments and suggestions are very important to us.

These questions are about your feelings and moods in pregnancy. Please tick the answer which comes closest to how you have felt <u>in the last week</u>, not just how you feel today.

24. In the past week I have been able to laugh and see the funny side of things.

> As much as I could ❏
> Not quite so much now ❏
> Definitely, not so much now ❏
> Not at all ❏

25. In the past week I have looked forward with enjoyment to things.

> As much as I ever did ❏
> Rather less than I used to ❏
> Definitely, less than I used to ❏
> Hardly at all ❏

26. In the past week I have blamed myself unnecessarily when things went wrong.

> Yes, most of the time ❏
> Yes, some of the time ❏
> Not very often ❏
> No, never ❏

27. In the past week I have been anxious or worried for no good reason.

> No, not at all ❏
> Hardly ever ❏
> Yes, sometimes ❏
> Yes, very often ❏

28. In the past week I have felt scared or panicky for no very good reason.

> Yes, quite a bit ❏
> Yes, sometimes ❏
> No, not much ❏
> No, not at all ❏

29. In the past week things have been getting on top of me.

       Yes, most of the time I haven't been able to cope at all ❑

       Yes, sometimes I haven't been coping as well as usual ❑

       No, most of the time I have coped quite well ❑

       No, I have been coping as well as ever ❑

30. In the past week I have been so unhappy that I have had difficulty sleeping.

       Yes, most of the time ❑

       Yes sometimes ❑

       Not very often ❑

       No, not at all ❑

31. In the past week I have been so sad or miserable that I have been crying.

       Yes, most of the time ❑

       Yes, quite often ❑

       Not very often ❑

       Not at all ❑

32. In the past week I have been so unhappy.

       Yes, most of the time ❑

       Yes, quite often ❑

       Not very often ❑

       Not at all ❑

33. In the past week the thought of harming myself has occurred to me.

       Yes, quite often ❑

       Sometimes ❑

       Hardly ever ❑

       Never ❑

Only one page to go! Thank you for continuing to fill out this questionnaire.

These last questions are about your antenatal care.

34. During your last pregnancy, who provided your antenatal care?

⇒ This is my first pregnancy ❑

⇒ Hospital clinic with doctors ❑

⇒ Hospital clinic with midwives ❑

⇒ Hospital clinic with midwives and doctors ❑

⇒ Private doctor ❑

⇒ Private midwife ❑

⇒ Other, please say what: _____ ❑

35. If you were to have another pregnancy, where would you wish to have your antenatal care?

⇒ No further pregnancy planned ❑

⇒ Hospital clinic with doctors ❑

⇒ Hospital clinic with midwives ❑

⇒ Private doctor ❑

⇒ Shared care with family doctor/GP ❑

⇒ Clinic in a health centre like Rockdale or Hurstville ❑

⇒ Private midwife ❑

36. This space is for to say anything (good or bad) about your antenatal care or anything else you would like us to know.

Pregnancy can be a stressful, as well as an exciting and happy time. If any of these questions have made you feel low or depressed or worried, please talk to your midwife or your doctor. They will be happy to help you talk about your concerns or may be able to help in other ways.

Please fill in today's date. _____/_____/_____

THANK YOU VERY MUCH FOR COMPLETING THIS QUESTIONNAIRE

When you have finished, please place the form in the envelope provided, seal it and place it in the questionnaire boxes in the waiting room or the reception desk.

Appendix 8: Postnatal questionnaire. This was also available in Chinese and Arabic.

St George Hospital Maternity Services Study

Postnatal questionnaire

Study number: _____

Thank you for being part of the Maternity Services Study at St George Hospital. This questionnaire will take about 20 minutes to complete. Your answers are confidential and will in no way affect future care and services you receive.

1. How many weeks old is your baby today?

_____
Please write in the number of weeks

2. Before you had your baby, did you talk to your midwives and doctors about what you wanted to happen during labour and delivery? (For example, preferences about pain relief, being attached to a monitor, having an episiotomy, whether to be awake or asleep for a caesarean section).

Yes, I had talked quite a lot about what I wanted to happen	❏
Yes, I had talked about what I wanted briefly	❏
No, I had preferences but did not talk about them	❏
No, I had no particular preferences	❏

3. Looking back now, would you have liked to have talked more to your doctors and midwives about your preferences?

Yes, definitely	❏
Yes, possibly	❏
No, not really	❏

4. Looking back now, do you think you knew enough about the things listed below before you had your baby, or would you have liked to know more about:

		I knew enough	I would have liked to know more
a)	The different pain relief methods available	❏	❏
b)	Complications in labour and things that might happen if something goes wrong	❏	❏
c)	What is involved in an induction of labour, and when it might be necessary	❏	❏
d)	What is involved in having a caesarean and when it might be necessary	❏	❏
e)	What might happen immediately after the baby is born	❏	❏
f)	How you would feel the first few days after the birth	❏	❏
g)	Feeding the baby, and all that this involves	❏	❏
h)	How to look after a new baby	❏	❏

Appendix 8

5. Did you know the midwife who cared for you during your labour beforehand?

No ☐

Yes, I had met her <u>only once</u> before during my antenatal care ☐

Yes, I had met her <u>more than once</u> before during my antenatal care ☐

Only answer question 6 if you answered NO to the last question. Otherwise leave it blank.

6. Would you have liked to have been looked after during your labour, by a midwife you had got to know during your pregnancy?

No, not really ☐

Yes, possibly ☐

Yes, definitely ☐

I don't know ☐

Only answer question 7 if you answered YES to Question 5. Otherwise leave it blank.

7. Did you like being looked after by a midwife you had met before?

No, not really ☐

Yes, possibly ☐

Yes, definitely ☐

I don't think it made a difference ☐

8. What was the experience of childbirth like for you?

Please let us know how the experience of childbirth (vaginal birth or caesarean section) was for you by giving it a mark out of ten. Ten out of ten would mean an absolutely wonderful experience that could not have been better, zero out of ten would mean a thoroughly unsatisfactory experience with nothing good to be said for it.

Marks out of ten _____ *PLEASE FILL IN A NUMBER*

9. How well do you think you managed during the labour and birth?

Please circle a number

Did not cope at all well					Coped extremely well
0	1	2	3	4	5

10. In general, did you feel in control of what was being done for you by the staff during labour and birth?

Yes, always ☐

Yes, most of the time ☐

Only some of the time ☐

No, hardly at all ☐

I did not want to feel in control ☐

11. Did you feel in control of the way you managed yourself during labour and birth?

Yes, always	❏
Yes, most of the time	❏
Only some of the time	❏
No, hardly at all	❏
I did not want to feel in control	❏

12. Thinking about your health and recovery since the birth of your baby, do you feel you are back to normal now?

Yes, completely	❏
Yes, mostly	❏
No, not yet	❏

13. At the moment how well, are you managing with:

Please circle a number

		Not managing well at all				Managing extremely well	
a)	Feeding your baby	0	1	2	3	4	5
a)	Looking after your baby	0	1	2	3	4	5

14. Did you breast feed your baby at all (or give any of your expressed milk).

No, not at all (Go to Question 17)	❏
Yes, but now I have stopped completely (Go to Question 15 and 16)	❏
Yes, and I am still breast feeding (Go to Question 17)	❏

15. If you have stopped breast feeding completely, for how many weeks did you feed?

Please write in the number of weeks: _____

16. If you have stopped breast feeding completely, why did you stop? Please write in the space below.

Appendix 8

17. A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to indicate how you feel right now, that is, at this moment.

AT THE PRESENT TIME:

		Not at all	Somewhat	Moderately so	Very much so
1.	**I feel calm**	1	2	3	4
2.	**I feel secure**	1	2	3	4
3.	**I am tense**	1	2	3	4
4.	**I am regretful**	1	2	3	4
5.	**I feel at ease**	1	2	3	4
6.	**I feel upset**	1	2	3	4
7.	**I am presently worrying over possible misfortunes**	1	2	3	4
8.	**I feel rested**	1	2	3	4
9.	**I feel anxious**	1	2	3	4
10.	**I feel comfortable**	1	2	3	4
11.	**I feel self-confident**	1	2	3	4
12.	**I feel nervous**	1	2	3	4
13.	**I am jittery**	1	2	3	4
14.	**I feel 'highly-strung'**	1	2	3	4
15.	**I am relaxed**	1	2	3	4
16.	**I feel content**	1	2	3	4
17.	**I am worried**	1	2	3	4
18.	**I feel over excited**	1	2	3	4
19.	**I feel joyful**	1	2	3	4
20.	**I feel pleasant**	1	2	3	4

18. Please indicate the extent to which the following statements describe the way you GENERALLY feel.

Please circle an appropriate number for each question.

		Almost never	Some-times	Often	Almost always
1.	**I feel pleasant**	1	2	3	4
2.	**I tire easily**	1	2	3	4
3.	**I feel like crying**	1	2	3	4
4.	**I wish I could be as happy as others seem to be**	1	2	3	4
5.	**I am losing out on things because I can't make up my mind soon enough**	1	2	3	4
6.	**I feel rested**	1	2	3	4
7.	**I am calm, cool and collected**	1	2	3	4
8.	**I feel that difficulties are piling up so that I cannot overcome them**	1	2	3	4
9.	**I worry too much over something that really doesn't matter**	1	2	3	4
10.	**I am happy**	1	2	3	4
11.	**I am inclined to take things hard**	1	2	3	4
12.	**I lack self-confidence**	1	2	3	4
13.	**I feel secure**	1	2	3	4
14.	**I try to avoid facing a crisis or difficulty**	1	2	3	4
15.	**I feel blue**	1	2	3	4
16.	**I am content**	1	2	3	4
17.	**Some unimportant thoughts run through my mind and bother me**	1	2	3	4
18.	**I take disappointments so keenly that I can't put them out of my mind**	1	2	3	4
19.	**I am a steady person**	1	2	3	4
20.	**I get in a state of tension or turmoil as I think over my present concerns and interests**	1	2	3	4

Appendix 8

19. Please look at the list below and tell us what, if any, are your worries at the moment. The list is not meant to give you more things to worry about!

Please circle a number for each one to show how much of a worry it is to you, from 0 if it is not a worry, to 5 if it is something which you are extremely worried about.

Please circle one number on each line

	Not a worry					A major worry
a) your baby's health now	0	1	2	3	4	5
b) your baby's long term health	0	1	2	3	4	5
c) coping with your baby	0	1	2	3	4	5
d) feeding your baby	0	1	2	3	4	5
e) your own health and recovery since the birth	0	1	2	3	4	5
a) your sex life	0	1	2	3	4	5
b) your relationship with your partner	0	1	2	3	4	5
c) your housing	0	1	2	3	4	5
d) money problems	0	1	2	3	4	5
e) employment problems	0	1	2	3	4	5

The next questions are about your feelings and moods since the baby has been born. Thank you for continuing to fill out the questionnaire, only a few pages to go.

Please tick the answer which comes closest to how you have felt <u>in the last week</u>, not just how you feel today.

20. In the past week I have been able to laugh and see the funny side of things.

     As much as I could   ❑

     Not quite so much now   ❑

     Definitely, not so much now   ❑

     Not at all   ❑

21. In the past week I have looked forward with enjoyment to things.

     As much as I ever did   ❑

     Rather less than I used to   ❑

     Definitely, less than I used to   ❑

     Hardly at all   ❑

22. In the past week I have blamed myself unnecessarily when things went wrong.

     Yes, most of the time   ❑

     Yes, some of the time   ❑

     Not very often   ❑

     No, never   ❑

Appendix 8

23. In the past week I have been anxious or worried for no good reason.

      No, not at all ❑
      Hardly ever ❑
      Yes, sometimes ❑
      Yes, very often ❑

24. In the past week I have felt scared or panicky for no very good reason.

      Yes, quite a bit ❑
      Yes, sometimes ❑
      No, not much ❑
      No, not at all ❑

25. In the past week things have been getting on top of me.

      Yes, most of the time I haven't been able to cope at all ❑
      Yes, sometimes I haven't been coping as well as usual ❑
      No, most of the time I have coped quite well ❑
      No, I have been coping as well as ever ❑

26. In the past week I have been so unhappy that I have had difficulty sleeping.

      Yes, most of the time ❑
      Yes sometimes ❑
      Not very often ❑
      No, not at all ❑

27. In the past week I have been so sad or miserable that I have been crying.

      Yes, most of the time ❑
      Yes, quite often ❑
      Not very often ❑
      Not at all ❑

28. In the past week I have been so unhappy

      Yes, most of the time ❑
      Yes, quite often ❑
      Not very often ❑
      Not at all ❑

29. In the past week the thought of harming myself has occurred to me.

Yes, quite often	❑
Sometimes	❑
Hardly ever	❑
Never	❑

30. Could you circle all the words below that describe your baby?

Placid	alert	demanding	unresponsive
Responsive	stubborn	cuddly	draining
Grizzly	fascinating	exhausting	determined
Talkative	angry	fretful	contented

New parenthood can be a stressful time as well as a rewarding time. If any of these questions has made you feel low or depressed or worried, please talk to your early childhood nurse or your doctor. They will be happy to help you talk about your concerns or may be able to help in other ways.

If you prefer, we can arrange for someone from the hospital or your nearest early childhood centre to contact you. This will be completely confidential. Would you like someone to contact you?

❑   ❑

YES   NO

If so, please give
us your phone
number

_____

31. This space is if you want to make any comments (good or bad) about your maternity care, your childbirth experiences or anything else.

This last question is to do with the Early Childhood Centre

32.   a) Have you been to an Early Childhood Centre with your new baby yet?

❑   ❑
YES   NO

If YES

b) Which centre have you attended?

_____

c) How many weeks old was your baby when you first went?

_____

d) How many times have you been since with this baby?

_____

Please fill in today's date. _____/_____/_____

THANK YOU VERY MUCH FOR COMPLETING THIS QUESTIONNAIRE. WE REALLY APPRECIATE YOUR VALUABLE TIME.

When you have finished, please return it in the stamped addressed envelope provided.

Appendix 9: Case descriptions of the eight perinatal deaths

Case 1 was a 32 year multiparous woman with two previous uneventful pregnancies that resulted in normal vaginal births at term and normal birth weights. Her first antenatal visit was at 12 weeks gestation. All pathology investigations were unremarkable. Her estimated date of confinement was 8 October which was equivalent to an obstetric ultrasound performed at 18 weeks. She received antenatal care at the STOMP clinic, attending at 15, 16, 23, 28, 31 and 34 weeks. Her fundal height at 28 weeks gestation was recorded at 27cm, at 31 weeks recorded at 31 cm and at 34 weeks recorded at 33cm. These last three recordings were by the same midwife. Fetal heart sounds were heard at all these visits and fetal movements reported by the woman. Her blood pressure was normal throughout the pregnancy. She presented to the delivery suite at 36 weeks with no fetal movements for two days. Fundal height at this point was measured at 28 cm. A fetal death in utero was diagnosed and an induction of labour was performed two days later. The women requested the two day delay. A stillborn girl (birth weight 1395g) was born. The autopsy reported an infant with moderate skin maceration and blistering and with weight and measurements equivalent to 31 weeks. The infant had no dysmorphic features but the placenta showed extensive infarction. All maternal pathology investigations were normal.

Report from reviewer:
> Intrauterine growth restriction, Category 2.2 placental pathology. Potentially avoidable (probably small at 31-34 weeks but undetected).

Case 2 was a 21 year old multiparous woman in her second pregnancy. Her first baby was born normally after an uneventful pregnancy. Her first visit was at 16 weeks gestation and she elected to receive antenatal care through the STOMP clinic, attending at 19, 25 and 29 weeks. Her pathology results at booking were normal. An obstetric ultrasound at 18 weeks revealed a single live intrauterine fetus with no structural abnormalities. At 31 weeks she was presented with decreased fetal movements and an ultrasound revealed hydrops fetalis with marked fetal ascites and oligohydramnios of undetermined cause. She was transferred to a level 3 hospital for ongoing assessment and care, where she underwent an aspiration of paracentesis with subsequent demise of the fetus. An induction of labour was performed. The infant weighed 2.6kg and was reported to be oedematous. No postmortem was attended.

Report from reviewer:

> Non-immune hydrops, Category 9.2 fetal abnormality cardiovascular system. Unrelated to the model of care received.

Case 3 was a 34 year old woman in her eighth pregnancy. Her past obstetric history included two elective terminations and one spontaneous miscarriage at 16 weeks. Her other four pregnancies have resulted in live healthy infants, the last born by emergency caesarean section for fetal distress. She attended her first antenatal visit at 22 weeks gestation and her pathology results were normal. She received care at the STOMP clinic (attending at 29, 36 and 37 weeks) with alternative visits conducted with her GP. Her pregnancy was normal with an obstetric ultrasound at 24 weeks reporting a morphologically normal fetus. She presented to the delivery suite at 38 weeks complaining of decreased fetal movements and was diagnosed with a fetal death in utero. She underwent an induction of labour, which resulted in a normal vaginal delivery of a stillborn male. A postmortem was not performed. Vaginal swab culture revealed growth of Group B streptococcus, however, placental pathology reported no evidence of villitis, chorioamnionitis or funisitis.

Report from reviewer:

> Unexplained, Category 3. Unrelated to the model of care received.

Case 4 was a 34 year old multipara. Her first baby was born normally after which she experienced a postpartum haemorrhage. Her first antenatal visit was at 21 weeks gestation. She was offered STOMP care, which she declined, choosing instead to come to the hospital antenatal clinic (standard care). At 36 weeks she was involved in a low impact motor vehicle accident and was admitted to the antenatal ward overnight. At 38 weeks she was diagnosed with a breech presentation and underwent an external cephalic version which was unsuccessful. Pelvimetry was undertaken which reported an adequate pelvis. An obstetric ultrasound estimated the fetal weight to be 3.6kgs. She presented five days later in early labour with an unstable lie. A cephalic presentation was confirmed and, as the woman was keen to have a vaginal birth, an induction of labour was commenced. The membranes were ruptured artificially revealing thick meconium stained liquor and a sustained fetal heart rate decelleration to 80 beats per minute. An emergency caesarean section was performed. The infant was born without

heart rate or signs of breathing. Despite aggressive resuscitation the infant was not revived.

Report from reviewer:

Intrapartum asphyxia, Category 5.1. Unrelated to the model of care received.

Case 5 was a 16 year old primiparous woman. She attended her first antenatal visit at 17 weeks gestation with normal pathology results and a normal ultrasound. She received care in the antenatal clinic and attended regularly. Her pregnancy progressed normally except for a mild increase in blood pressure at 30 weeks, which resolved spontaneously. She had an obstetric ultrasound at 35 weeks due to a discrepancy in fundal height measurement. The ultrasound demonstrated satisfactory growth and normal doppler measurements. She presented in early labour at 39 weeks and a fetal death in utero was diagnosed. She progressed to a normal vaginal birth of a stillborn male infant. A postmortem was not performed. All pathology investigations performed as a result of the perinatal death were normal.

Report from reviewer:

Unexplained, Category 3. Unrelated to the model of care received.

Case 6 was a 28 year old primiparous woman who attended her first antenatal visit at 15 weeks gestation. She presented at 23 weeks with ruptured membranes and cervical dilatation of 2cm. The parents decided against transfer to a level 3 hospital, electing conservative management. Twenty-four hours later she commenced contractions and progressed to a normal birth of a male infant (birth weight 625g) with an irregular heart rate and mild respiratory effort. The infant continued to have a heart rate and 'Cheyne-Stoke' breathing for 12 hours. A postmortem was not performed. Pathology results revealed a normal karyotype with no obvious signs of infection. Blood tests for lupus anticoagulant were negative. A hysterosalpingram was performed one month later, which showed no evidence of cervical incompetence.

Report from reviewer:

Preterm labour (?cervical incompetence), Category 14.5. Unrelated to the model of care received.

Case 7 was a 33 year old multiparous woman with a previous obstetric history of a forceps birth for fetal distress. She attended her first antenatal visit at 12 weeks

gestation with normal pathology investigations and a normal obstetric ultrasound at 18 weeks. She received care at the antenatal clinic attending only once, at 19 weeks. At 21 weeks gestation she presented with a 24 hours history of vaginal bleeding and abdominal pain. On speculum examination a bruised foot was seen in the introitus. She proceeded to a footling breech birth of a stillborn male infant (birth weight 340g). The autopsy reported normal male infant with no evidence of infection in the placenta.

Report from reviewer:

Antepartum haemorrhage, Category 8.1 (abruption). Unrelated to the model of care received.

Case 8 was a 28 year old primiparous woman who attended her first antenatal visit at 12 weeks gestation with no significant past history. She chose to receive GP shared antenatal care, attending the hospital antenatal clinic at 29, 36, 40 and 41 weeks. Her pregnancy was normal. At 41 weeks and 4 days gestation she was admitted for induction of labour for prolonged pregnancy. Vaginal misoprostol was used to induce labour. She progressed slowly despite augmentation and after 13 hours underwent an emergency caesarean section for failure to progress. Late in the course of the labour she became febrile (39^0C) and was treated with intravenous penicillin. The membranes had been ruptured for 12 hours prior to the infants birth and meconium stained liquor was noted during the labour. The baby was born in good condition (Apgar scores of 9 at 1 minute and 9 at 5 minutes) with a birth weight of 3.7kgs. The infant was transferred to the special care nursery at two hours of age because of respiratory distress and placed in headbox oxygen. The baby progressively deteriorated during the day with apnoeic episodes necessitating intubation, bilateral pulmonary haemorrhages and pneumothoraces and progressive metabolic and respiratory acidosis. Despite aggressive and sustained management by the paediatric team and the neonatal emergency transfer team the baby died aged 12 hours. The autopsy report attributed the death to E coli septicaemia, probably pneumonia.

Report from reviewer:

Acute chorioamnionitis and E coli pneumonia, Category 12.2. Unrelated to the model of care received. "The condition of congenital pneumonia is probably preventable by identification of carriers and maternal intrapartum antibiotics. Intrapartum antibiotics should have been penicillin and gentamicin, but I doubt this would have been soon enough to affect the outcome of this baby".

Appendix 9