

**Does a change in the way early labour care is provided
reduce epidural rates?**

A pre-post intervention study

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Statement of Authorship and Sources

This thesis contains no material published elsewhere or extracted in whole or in part from a thesis by which I have qualified for or been awarded another degree or diploma. No other person's work has been used without due acknowledgement in the main text of the thesis. This thesis has not been submitted for the award of any degree or diploma in any other tertiary institution.

All research procedures reported on the thesis received the approval of the relevant Ethics/Safety Committees (where required).

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Signature of candidate

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Abstract

Background: Normal birth, by common definition, is achieved with minimal or no intervention and is widely regarded as the safest method of birth for healthy mothers and babies. There is evidence to support delaying women's admission to birthing suite until labour has established to avoid unnecessary interventions, such as epidurals and augmentation of labour.

Reflecting this evidence base a large metropolitan hospital (study site) introduced an early labour care model in September 2012, to improve the flow of work and provide better accommodation and an alternative care option for women and their support people during early labour. This involved creating a clinical framework consisting of clinical decision-making tools and pathways to increase the level of safety and quality care offered to those women not suitable for home or transfer to birth suite, and the creation of a dedicated early labour area separate to the hospital's assessment unit.

Aim: This study aimed to examine the birth outcomes of women presenting to the Pregnancy Assessment and Observation Unit (PAOU) in early labour to identify if a change in the way early labour care is provided has any influence on interventions used in labour, in particular epidural use. Additionally, whether there was an association with an increased occurrence of obstetric interventions with a longer length of time spent in the PAOU.

Research design: This study used a pre - post intervention design, and was conducted at a large tertiary referral hospital. Retrospective routinely collected data was analysed from eligible women who birthed during two time periods: May-September 2012 (Pre-Intervention Cohort) and October 2012- January 2014 (Post-Intervention Cohort), to make comparisons between the birth outcomes of women before and after an early labour care model (Intervention) was introduced by the hospital.

Intervention: All women in the study presented to the PAOU and were assessed for progress of labour. When not in active labour, women in the Pre-Intervention Cohort were encouraged to return home, those either not suitable for discharge or reluctant, either remained in the PAOU, or were transferred to the postnatal ward to await labour. This option did not include accommodation for support people. Women in the Post-Intervention Cohort were also encouraged to return home, if not suitable or met the criteria, they were transferred to the early labour area. The key differences of the two models of care were: own private room with ensuite (regardless of insurance status); support persons able to stay; easier to mobilise and outdoor courtyard and kitchenette available, in a quieter environment.

Participants and setting: Women who presented in spontaneous labour, with public or private insurance, who gave birth after 37 completed weeks of gestation, with a singleton pregnancy in a vertex presentation during (May 2012-January 2014) met the criteria for inclusion in the study. The total number of women represented in this study was 1388 (Pre-Intervention Cohort n= 625; Post-Intervention Cohort n= 763). Unexpectedly we found that the two cohorts were not matched samples. Differences were shown across several key indicators. The women in the Pre-Intervention Cohort were older, more likely to be multiparous, privately funded, Caucasian women who differed in their BMI status (more likely to be underweight or obese women) and educational attainment (more likely to have a tertiary degree). The Post-Intervention Cohort was made up of more publicly funded, first time mothers, of Asian and non-European ethnicity, with a normal weight range.

Outcome measures: The primary outcome of interest was the proportion of women who used an epidural in labour pre and post the implementation of an early labour care model. The secondary outcomes included the proportion of women undergoing augmentation of labour with oxytocin, or having an instrumental or caesarean birth, or with blood loss greater than 1500mls and the proportion of babies admitted to an intensive care nursery, and the length of stay to the PAOU.

Data Analysis: Descriptive statistics were used to describe the demographic profile of the women. Bi-variate analysis quantified associations between maternal characteristics and the primary and secondary outcome measures. Logistical regression analysis was used to address the research questions and control for potential confounders identified in the literature and through bi-variate analysis.

Findings: The final regression model did not identify Cohort or longer length of stay in the assessment unit as having a significant association with the rate of epidural use. Instead maternal characteristics such as nulliparity (OR: 1.507, $p=0.01$), Caucasian ethnicity (OR: 1.686, $p=0.008$), private insurance status (OR: 1.437, $p=0.037$) and whether a woman's labour was augmented with amniotomy (OR: 2.827, $p<0.001$) or syntocinon infusion (OR: 11.525, $p<0.001$) showed a positive association with a higher epidural rate. Therefore a change in the way early labour care was provided did not reduce the frequency of epidural use in labour or improve birth outcomes for this cohort of women.

Implications for practice:

Place of care was not a predictor for epidural use. Exploring environmental factors and facets of care delivery that may need to be modified to support normal birth is recommended.

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Abbreviations and Glossary

APH	Antepartum Haemorrhage
BMI	Body Mass Index
BS	Birthing Suite
COSMOS	Comparing Standard Maternity care with One-to-one midwifery support
CS	Caesarean Section
DoHWA	Department of Health, Western Australia
ELSA	Early Labour Support and Assessment trial
FMU	Freestanding Midwifery Unit
M@NGO	Midwives @ New Group practice Options
MCWP	Maternity Care Working Party
Medicare	Universal health insurance system available to all Australian residents and certain categories of visitors to Australia
MMH	Mater Mothers Hospital
M10E	Mothers level 10 East
MRU	Midwifery Research Unit
NHS	National Health Service
NZ	New Zealand
OU	Obstetric unit
PAOU	Pregnancy Assessment and Observation Unit
POP	Persistent Occiputo-Posterior
PPH	Postpartum haemorrhage
RCM	Royal College of Midwives
RCT	Randomised Control Trial
SROM	Spontaneous Rupture of Membranes
UK	United Kingdom
URN	Unique Record Number
VMO	Visiting Medical Officer
WHA	Women's Healthcare Australasia

WHO	World Health Organisation
Active labour	The period at which cervical dilatation progressively accelerates with regular painful contractions after 4-5cm dilated.
Amniotomy	Artificial rupture of membranes.
Augmentation	Accelerating the progress of labour by artificially rupturing the membranes with the use of an amnihook and/or by stimulating the uterus through the use of exogenous oxytocin.
Continuity of care	Maternity care by one or more known professionals throughout the women's pregnancy and birth.
Continuity of carer	Care is provided throughout the entire childbirth experience by one midwife with whom the woman has established a one-to-one relationship.
Early labour	Also known, as the "latent phase" is a period of time, not necessarily associated with painful contractions and some cervical change including effacement and cervical dilatation up to 4cm.
Eligible midwife	A midwife who has completed additional requirements, as legislated by the Commonwealth government, to receive a notation on their registration to enable them to provide Medicare rebatable services.
Epidural	An injection of a local anaesthetic into the space between the spinal column and the dural mater. Used to produce a loss of sensation especially in the abdomen and pelvic area during labour and birth.
High-risk pregnancy	A pregnancy that has identified risk factors that threaten the health and wellbeing of the mother and/or her fetus.
Induction of labour	The process of artificially initiating labour before its spontaneous onset.
Instrumental birth	A birth assisted by use of instrument (ventouse - "vacuum" or forcep).
Low risk pregnancy	No significant medical or obstetric risk factors identified pre-pregnancy, or during the antenatal and intrapartum period.
Midwife-led continuity	Also known as "caseload midwifery". Is a model of care where a woman is cared for by a known midwife or a small group of known midwives during her pregnancy, at birth and the postnatal period.
Models of care	How maternity care is organised and offered to women.
Multiparous	A woman who has previously given birth to one or more viable infants (> 20 weeks gestation or 400grams in Australia).
Normal birth	A vaginal birth that is achieved with minimal or no medical intervention, between 37-42 weeks gestation labouring spontaneously in a vertex position.

Nulliparous	A woman who is in her first pregnancy.
Private obstetric care	Antenatal care is provided in private consultation rooms by an obstetrician chosen by the woman. Her birth occurs in a private hospital where the obstetrician has visiting rights.
Public hospital care	Antenatal care as well as intrapartum care (care during labour & birth) is provided by employed midwives, resident, registrar and consultant obstetricians at public hospitals.
Shared maternity care	Where by a woman's maternity care is shared between different professionals. Can be between General practitioner (GP) and hospital care providers; or between.

Prologue

The very meaning of a midwife shapes midwifery philosophy; women are part of our story and part of our journey. For me, being a midwife is as much a part of who I am as being a loving mother, wife and friend. I feel extremely privilege to be “with woman” during this life event, and have great respect for the culture of birth and the different ways of supporting women and their families. I have a strong commitment to our profession and a belief birth is a normal physiological process that needs to be protected. However, my clinical experience reminds me never to be complacent. My practice as a nurse and midwife has until recently been restricted to the same tertiary referral hospital, with higher than average rates of intervention and obstetric emergencies. It would be easy to be primed to think birth is dangerous and something to be managed working in this environment. However, I constantly keep myself in check not to lose sight of what is normal, and continue to practice the same philosophy I began this journey with 11 years ago.

I often refer to myself as being ‘institutionalised’ to this way of practise, accustomed to having the most up to date equipment and specialists on hand, among the most highly respected. Further reflection gives me a greater appreciation of this experience and the way in which it has shaped my practice. I am fortunate to work within a collaborative, multidisciplinary diverse and experienced team, learning every day from colleagues who have skills from different cultures and models of care.

My role at the Mater Mothers Hospital (MMH), has entailed working in the Pregnancy Assessment and Observation Unit (PAOU), a triage area, providing clinical management and support to women and their families on their presentation to hospital as well as working within the birthing suites and theatre where I provide ongoing intra-partum care and support. As my career has progressed so has my interest in improving my own practice, and that of others I work with and for, through postgraduate studies, self-reflection, and quality improvement.

Working in the PAOU since its beginnings in 2008, I was concerned by the number of women who were presenting to the hospital in the early stage of labour, as well as the inconsistencies in which we as individual practitioners, and as a health service generally managed these women. I witnessed varying staff attitudes towards this stage of labour, and varying practices dependent upon model of care (private, public or midwifery group practice). Women reluctant to go home if not yet deemed to be in labour either remained in the assessment area, or were given a bed on the postnatal floor separated from their support people. This management resulted in issues of bed blockages across

both departments, an increase in staff workload and, I believe, led to unnecessary monitoring of mother and baby, and augmentation of labour. The senior management was at the time not offering any solution but recognised these variances in care as problematic, hence I found myself as an active member of a working party searching for ways to improve service delivery.

This research project commenced as a quality improvement program initially for the health facility. I constructed a preliminary questionnaire (Appendix 1) for staff working within birthing services (included PAOU and birth suite (BS) staff) as a starting point. The questionnaire aimed to look at ways to improve the flow of work through these areas, as well as staff satisfaction and attitudes towards early labour and current staffing levels. The analysed questionnaire identified issues that were constructive (some of which were already under review) and I reported back to staff (Appendix 2). Following this initial questionnaire, I developed a staff satisfaction survey (Appendix 3) as a quality assurance activity for the working party and distributed to all maternity care providers within the MMH to identify the staff's level of satisfaction with the way we as an organisation managed women in early labour. The results identified dissatisfaction with the practices and management of women and their families who sought early labour support. Written responses for suggested improvements showed 40% of staff recommended an early labour area within the hospital as a top priority. This survey provided feedback to management, and an opportunity for staff to feel their opinions were valued.

My enquiry led to a desire to influence a better understanding of the early stage of labour for both the women and the staff, and how the care we provide may influence birth outcomes and a woman's perception of her overall childbirth experience. In my clinical role I commenced auditing birth outcomes of women presenting during the early stage of labour to PAOU and the length of admission before transfer to BS. I theorised that the longer they remained in the assessment area (due to reluctance to go home or lack of space on the postnatal floor to accommodate them as they established labour), the more likely they were to transfer through to BS requiring further pain relief or augmentation. As a member of the quality working party, I enlisted the help of the hospital statistician to analyse the data for quality assurance purposes. My initial results suggested a correlation between length of time spent in the PAOU and epidural use. I presented the audit findings and recommendations to my manager and other interested parties, including a presentation at a medical education meeting. I was given constructive feedback on areas of limitation and bias, and a suggestion to pursue this as a Masters project.

So began this journey of higher degree research. Quickly I learnt of ethical considerations and procedures, and the lengthy steps required to meet the standards to use data for research purposes rather than quality assurance. It was through the many challenges I encountered along the way that I realised my passion for this area of maternity care was impacting positively on my own individual practice and that of my colleagues. Hospital executives and management have viewed my passion and enquiry into early labour positively, I am grateful to have been given the opportunity to be involved in the development of service and practice change to improve outcomes for labouring women.

Whilst writing this thesis, my awareness grew for the benefits of working in partnership with women and their choice of care provider. I have since furthered my career prospects and collaborative relationships by obtaining Medicare eligibility. Becoming an eligible midwife allows me to provide Medicare rebatable services to women, order diagnostic investigations and an endorsement to prescribe scheduled medicines for midwifery practice. At present I am working towards credentialing to gain visiting access into the MMH as a privately practising midwife in collaboration with seven private obstetricians to increase women's access to both midwifery and medical models with a focus on continuity of carer. Midwives are the experts in normal and provide compassion, empathy, education, guidance and experience to know when to refer on. I am going to take the advantage of the knowledge and expertise I have acquired over the past decade, and through completion of this master's, and apply these to different ways of being with women and contributing to the options of care available.

Chapter One: Introduction to the thesis

1.1 Overview

This chapter provides a definition of early labour; describes the research setting and presents a justification for the research project. The research aims as well as the thesis overview are outlined.

1.2 Background

Clinically, early labour, also known as the latent phase of labour, is hard to define (Neal et al., 2010; Reuwer, Bruinse, & Franx, 2009). The onset of labour is determined by care providers retrospectively, and can vary greatly as it relies on the women's subjective opinions and perceptions of clinical symptoms (Gross et al., 2009). The Queensland Maternity and Neonatal Guidelines for normal birth, definition of early labour is used for the purposes of this study, and is described as "a period of time, not necessarily continuous, that is associated with painful contractions and some cervical change including effacement and cervical dilatation up to 4cm" (Queensland Health, 2012, p. 25).

Women in early labour often seek reassurance and confirmation from professionals that labour has started. For some women, it is the uncertainty and anxiety about labour events that leads them to present to hospital during the early stage of labour (A. Miller & Shriver, 2012). This initial admission has been identified as a time of disruption to a woman's coping strategies (E. Hodnett, Downe, Edwards, & Walsh, 2005), leading to a reported 10-30% increase in birth suite admissions in the past decade of women not in active labour (see glossary) (Queensland Health, 2012). Early admission to birth suites has been associated with an increase in the use of interventions during labour, the evidence of which will be discussed in the next chapter; contributing to poor clinical and psychological outcomes for women, as well as increased costs associated with childbirth (Spiby, Green, Hucknall, Foster, & Andrews, 2007). An increased rate of epidural use has been associated with women presenting in early labour. Although portrayed by some as the most effective form of pain relief, epidural analgesia has been associated with adverse maternal and neonatal perinatal outcomes (Anim-Somuah, Smyth, & Jones, 2011; Jones et al., 2012).

Birth is considered 'normal' when it is achieved with minimal or no medical intervention, and should be considered desirable for all low risk women between 37-42 weeks gestation labouring spontaneously in a vertex position (Maternity Care Working Party, 2007). Key government policy documents recognise the possibilities that appropriate labour care will reduce unnecessary interventions, such as epidural and instrumental use and increase the chance of normal birth (The Australian Health Ministers' Conference, 2010).

In Australia, maternity care facilities range from those intended to provide low risk care, through to tertiary level referral centres such as the setting for this study, the Mater Mothers Hospital (MMH), delivering care to women with low to complex needs. The MMH, South Brisbane aims to provide high quality maternity services for both publicly funded and privately funded women before, during and after birth (Mater Misericordiae Health Services, n.d.). While services and accommodation differ between health insurance statuses, what is shared for all women is the location for labour triage and assessment. This area is known as the Pregnancy Assessment and Observation Unit (PAOU) and is located on the entry level (level five) of the MMH and adjoins the birthing suites. Triage areas, such as the PAOU, have been identified as one approach to managing the increasing number of women attending labour wards that are found not to be in labour (Mahlmeister & Van Mullem, 2000). Additionally, triage areas have been demonstrated to improve the identification of obstetric emergencies, assist in managing the workload in busy clinical areas and are efficient resource use (Mahlmeister & Van Mullem, 2000).

Recent government reforms in Australia aimed at protecting and promoting normal birth make recommendations for service providers to improve service provisions to be woman-centred and accessible to all. A review of birthing services at the MMH in 2011, led to the establishment of a collaborative working party consisting of executive staff, managers, administrative staff, private obstetricians, public consultants, registrars, and clinical midwives working in the PAOU. The aim of this working party was to identify areas for service improvement within the PAOU and to actively implement changes in order of priority. Sub-groups were formed to concentrate on different areas of need (telephone triage, patient flow, documentation, early labour management, confidentiality and equipment). Of importance for this study, was the identification there was a lack of model of care for women seeking early labour support in terms of meeting clinical, environmental or the women's needs (Figure 1).

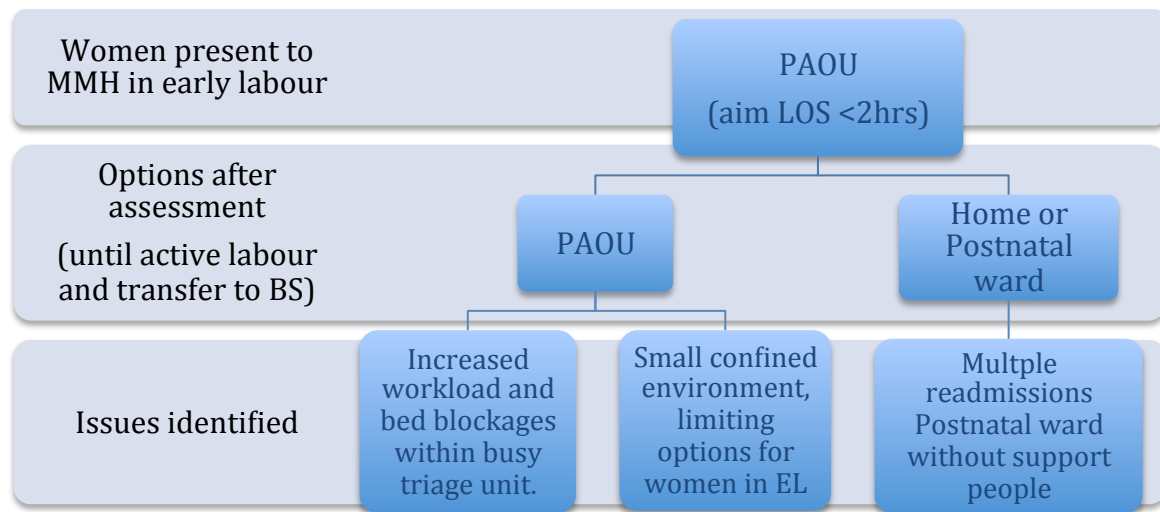


Figure 1. Pre-Intervention Cohort: model of care for early labour (May – September 2012).

The PAOU provided labour assessment to approximately 8,000 women in 2012, but also provided other services for acute, booked and emergency presentations for women who are twenty weeks gestation to six weeks postpartum. This unit is staffed with 2-3 midwives, and in addition to triaging women, receives all the phone calls of women seeking support or advice for pregnancy or postpartum related concerns. As a result, it is a busy unit with the deliberate aim to keep women for less than two hours. The increasing number of women presenting to the PAOU in early labour (and for some, their reluctance to return home) was causing issues with bed blockages and increased staff workloads. The two-hour timeframe and lack of appropriate space, impacted on the quality of care provided to women seeking early labour support. As a clinical midwife working within this unit, I theorised the longer women in early labour remained in the PAOU, the more likely they were to be transferred to birth suite for augmentation or requests for pain relief.

Therefore, on the 25th September 2012 management implemented a new early labour care model, in response to the collaborative working party. This new early labour care model included a clinical framework and the creation of an early labour area on the eastern side of Level 10 of the MMH (M10E) (Figure 2).

The aim of the new early labour care model was to:

- Improve the work flow through PAOU by reducing the length of stay (LOS) after triage
- Provide better accommodation and an alternative care option for women and their support people, during early labour
- Increase the level of privacy offered to women during early labour and
- Provide an increased level of safety and quality care for those women not suitable for discharge home or transfer into birth suite.

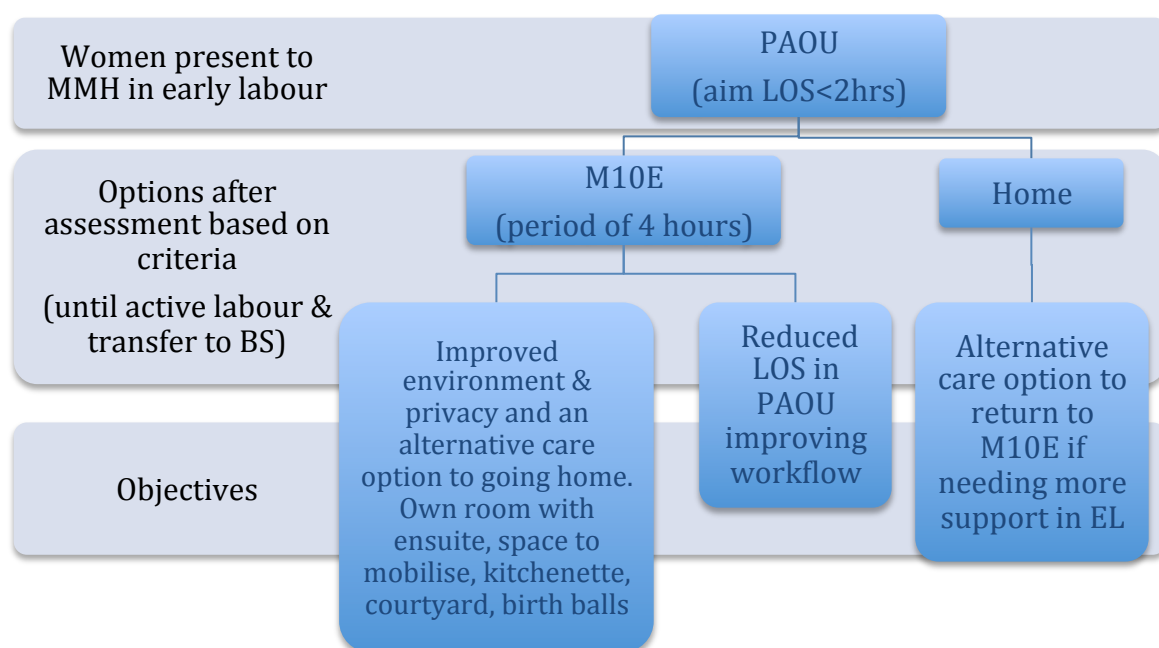


Figure 2. Post-Intervention Cohort: model of care for early labour (October 2012- January 2014)

1.3 Aims of the study

The aim of this study was to examine the birth outcomes of women presenting less than 4cm dilated, before and after a change in early labour care was implemented to identify any influences on interventions used in labour, in particular epidural rates. Additionally, secondary aims were to identify whether there was an association with an increased occurrence of obstetric interventions with a longer length of time spent in the PAOU as theorised.

This study was also part of a broader review, to assist with the evaluation of this new model of care for women seeking early labour support. The key findings provided feedback to members of the

MMH management team by comparing clinical outcomes of women: who presented to PAOU in early labour during two timeframes (Pre-M10E) and (Post-M10E) as a set of baseline measures. Additionally, the study explored possible associations with an increased length of time spent in the PAOU and the use of obstetric interventions as a way of measuring quality improvement. This study addressed the following research questions through comparison of women's birth outcomes pre and post the implementation of the new model.

Primary research question:

- Does a change in the model of care for women in early labour with a cervical dilatation less than 4cm reduce the frequency of epidural usage in labour?

Secondary research questions:

- Was an increased length of time spent in the PAOU (pre intervention), for women with a cervical dilatation less than 4cm, associated with an increased use of epidural pain relief in labour?
- Does reducing the length of time spent in the PAOU by using an early labour care model (intervention) have any association with birth outcomes: epidural use; augmentation of labour using oxytocin, instrumental or caesarean birth, or admission to the neonatal unit?

1.4 Thesis Overview

Chapter two reviews the literature on early labour management, discusses the evidence that lies behind the concerns for the reduction in normal birth rates as a result of the increasing use of interventions in labour, in particular epidurals. This chapter also outlines the changes that have occurred to Australia's maternity care system following government reforms aimed at improving services to better meet the needs of women and their families.

Chapter three presents the methods utilised for this study and describes the study design. The aims and objectives are outlined, as is the study population.

Chapter four presents the findings of data analysis and includes a demographic table describing the characteristics and birth outcomes of the women in both cohorts.

Chapter five discusses the findings in context to the literature, and outlines the strengths and limitations of the study. An overview of the recommendations made to the MMH management arising from the findings and suggestions for future research opportunities are also outlined.

Chapter Two: Literature review

2.1 Overview

This chapter discusses the evidence relating to changes to processes for early labour care in the healthcare setting and of women's experiences and preferences during this stage of labour. This chapter reviews the recent government reforms to maternity care that aim to benefit women and the promotion of normal birth in Australia. Lastly, this chapter describes the maternal characteristics that have been identified as predictors for epidural use.

2.2 Search strategy

Two literature searches were conducted using Mesh headings and key words for the topic of early labour care and epidural use. Publications retrieved included: Systematic review's, randomised controlled trials, populations-based and descriptive studies. Not all sources of literature came from direct literature search. Both government policy documents and chapters from books were accessed. In addition, the similar articles and cited references were used. The following databases were selected: PubMed, CINAHL, Scopus, JBI (Johanna Briggs Institute/JBI) and the Cochrane library. Key words included:

Search topic: " Early labour care AND admission"

"early labor assessment", "pregnancy", "early labour", "latent phase of labour", "early labour admission"

Search topic: "Confounder factors for epidural use in labour. Maternal characteristics: (age, ethnicity, parity, education, BMI, income, private insurance), labour outcomes."

Delivery, Obstetric [Mesh], Labor, Obstetric", "Analgesia, Obstetrical", "Anesthesia, Obstetrical", "Analgesia, Patient-Controlled", "Analgesia, Epidural"[Mesh], Anaesthesia, Epidural"[Mesh], maternal, demographic, ethnic, age, BMI, education*, epidural, intervention, "pain relief", anesthe*, anaesthe*, labour, labor, obstetric, "risk factors", "pregnancy characteristics"*

EndNote bibliographic software version X7 was used to record and manage references. The American Psychological Association (APA) 6th edition referencing style has been used. An author's first initial is used for in-text citation where two authors by the same name have been referenced as stated within the APA referencing style, which states:

"where there are two or more authors with the same surname, include the first author's initials in all text citations, even if the year of publication differs. Initials help the reader to avoid confusion within the text and to locate the entry in the list of references" (American Psychological Association, 2012, p. 176).

2.3 Preferences and practices in childbirth

Birth practices evolve constantly in response to economic and political changes as well as individual cultural practices, that shape a woman's decision-making (Tracy, Sullivan, Wang, Black, & Tracy, 2007). Globally, research on childbirth decision-making has revealed a variation in the meaning of childbirth, the role of the care provider and the assumed need for medical interventions and technology during pregnancy and birth (Haines, Rubertsson, Pallant, & Hildingsson, 2012; A. Miller & Shriver, 2012). Over the last century, birth has shifted away from traditional birth practices in most western countries, when women had continuous support by other women experienced in childbirth practices, reassuring them of their progress and the normalcy of birth (Bewley & Cockburn, 2002; E Hodnett, Gates, Hofmeyr, & Sakala, 2012; Janssen et al., 2009). The current culture of birth has become medically dominated, reflected negatively through media and birth stories, provoking an increase in childbirth fear (Fenwick, Hauck, Downie, & Butt, 2005; Fisher, Hauck, & Fenwick, 2006; McIntyre, Francis, & Chapman, 2011). This has ultimately affected women's decisions about mode of birth, choice of care provider, and setting. Removing women from traditional social ways of knowing and trusting birth, as well as moving birth knowledge and management into the medical system, has resulted in the reframing of childbirth as a medical event (Fahy, 2007; Haines et al., 2012; E Hodnett et al., 2012).

There is no universal standard of "normality in labour and delivery" (World Health Organization, 1996, p. 1), variations exist worldwide dependent on the setting and level of sophisticated services, as well as the care provider. Johansen, Newburn, and Macfarlane (2002) argue that a risk approach dominates birth in developed countries due to healthcare professionals acting defensively in order to avoid litigation. Birth, as previously mentioned has now become firmly embedded into the medical system with 97% of Australian women giving birth in a hospital setting, primarily in obstetric-led units (Li, Zeki, Hilder, & Sullivan, 2011). This reflects public acceptance that birth needs to be medically managed, many women relying on medical knowledge, technology and interventions as standard practice in birth (Bewley & Cockburn, 2002). Australia has been quoted as being a "society that has embraced the introduction of high technology across all aspects of life including childbirth" (McIntyre et al., 2011, p. 47). Thus rising rates of intervention to monitor, augment or accelerate the normal physiological processes of labour has resulted. In addition, increasing safety associated with anaesthetics over the last twenty years, has resulted in many women considering epidural analgesia as a routine and safe option for a low risk labour and birth (Lain et al., 2008).

Some authors have suggested the medicalisation of birth has ultimately led women to seek validation at the first signs of labour, rather than having confidence in themselves and their own instincts (Hatem, Sandall, Devane, Soltani, & Gates, 2008; A. Miller & Shriver, 2012). In many Australian settings midwives do not visit women in the home to assess and reassure them during early labour. This is due to the barriers to homebirth including the lack of funding, insurance for privately practising midwives and resources available through mainstream maternity care systems (Dahlen et al., 2011). Instead women are required to come to hospital for assessment and support.

2.4 Maternity Reforms

Currently, policy makers and care providers are working to reduce the rising intervention rate in western countries. International campaigns driven to inspire the promotion and protection of normal birth (defined in section 2.6) have resulted in policy directives being implemented which aimed to increase the normal birth rate (Maternity Care Working Party, 2007). In the United Kingdom (UK) an initiative called the Campaign for Normal Birth was launched in 2005, underpinned by the Royal College of Midwives' philosophy of pregnancy and birth as normal physiological process, with a commitment to reduce unnecessary medicalisation (The Royal College of Midwives, 2005). In Canada, the Joint Policy Statement for Normal Birth was published by joint organisations involved in maternity care (Society of Obstetricians and Gynaecologists of Canada, 2008).

In Australia consumers and midwives have lobbied for many years for reform of Australia's maternity care system to better meet the needs of women and their families (Dahlen et al., 2011; Hirst, 2005; Senate Community Affairs References Committee, 1999; The Australian Health Ministers' Conference, 2010). The vast majority of maternity models of care practiced in Australia fall into either: private maternity care, public hospital care or shared maternity care (see glossary). Of the women giving birth in hospital, most (72%) gave birth in public hospitals, with 28% giving birth in private hospitals (Australian Institute of Health and Welfare, 2015). Less than 10% of women are able to access midwifery models of care and very few women access birth centres or homebirth in Australia and these are expected to remain low despite demand (Dahlen et al., 2011; Department of Health, n.d).

Two distinct cultures of maternity care have been described in a report from a review of maternity services across Queensland (Australian State of study site). A wide range of stakeholders was consulted. The first, is that birth is "predominately a low-risk natural process requiring care and support and medical intervention only as needed" (Hirst, 2005, p. 1). The second, that birth is "a potentially high-risk situation that requires dedicated care and access to the best technology" (Hirst, 2005, p. 1). These opposing cultures often lead to challenges in implementing effective changes due

to disagreements over managing risk and achieving safety for mothers and babies. This review highlighted the need for improvement in maternity care services, as well as the difficulty in ensuring the change be agreed upon (Hirst, 2005). Women reported wanting more control and choice over their care during childbirth. Increasing access to continuity models of care was a strategy that tried to change the culture of birth. Several key factors have been identified to influence and facilitate a cultural change in maternity services, they include: collaboration, leadership, education, a shared philosophy, local knowledge and a commitment to change driven by government policy (Brodie & Homer, 2009). However resistance to change by some stakeholders and staff, a “distrust of midwifery care and a preference for the status quo” (Brodie & Homer, 2009, p. 188), are negative factors that challenge the change in culture and medical dominance.

The National Maternity Service Plan 2010-2015, endorsed by the Australian Government, promised women better access, choice, quality and control over their maternity care (The Australian Health Ministers' Conference, 2010). The plan provided a strategic framework that resulted from a national review of services and consultation with all stakeholders. This framework aimed to guide the vision for maternity services across Australia, after reviews identified the need to develop and enable greater access to midwifery models of care with a focus on continuity of carer (The Australian Health Ministers' Conference, 2010).

This plan was endorsed by Federal Health Ministers, and has led to changes in government policy, and changes to Medicare (see glossary) rebates. The change to Medicare has allowed women to claim a rebate for a range of midwifery services including, intrapartum care within the hospital setting. As a result, eligible midwives (see glossary) are expanding in numbers and women are more aware of their maternity care options. Queensland Health responded to the national maternity agenda by developing clinical practice guidelines on normal birth, and engaging private practice midwives across many hospitals. Similarly, several private obstetric practices are marketing their midwifery models to stay competitive and progressive. However, in general the uptake of these private midwifery services has been slow with significant structural barriers still in place. Briefly these include, a lack of available personal indemnity insurance for midwives to provide homebirth services and admission to hospital when under the care of a midwife, is reliant on doctors agreeing to collaborate with the midwife in writing. Very few doctors are prepared to do this, thus restricting access to hospital.

2.5 Benchmarking

Current reporting of maternity services in Australia is undertaken by a number of jurisdictions and professional organisations using clinical or performance indicators. Most notable is an annual Australian periodical mothers and babies report (Australian Institute of Health and Welfare, 2015). These reports provide reliable information and statistics for examining trends in the use of interventions in labour, of birth outcomes and monitoring changes in the quality of services over time. This form of benchmarking is an effective way for care providers and services to monitor, and evaluate standards in patient care, assisting with quality improvement (Thompson, 2012).

Women's Healthcare Australasia (WHA) is one such organisation that collects data annually from member hospitals for benchmarking key maternity indicators for standardisation purposes (Thompson, 2012). Where possible, internationally recognised definitions for each indicator are used, otherwise prepared and refined by a panel of clinical experts (Women's Healthcare Australasia, 2014). The members of WHA include the majority of tertiary women's hospitals in Australia and New Zealand (NZ). The WHA report back to their members each year a de-identified report with the results of the collated clinical indicators data, to use for the purpose of informed comparisons and shared learning (Women's Healthcare Australasia, 2014). These reports are useful to assist with identifying priority areas for clinical improvement and evaluating any quality improvement initiatives that have been implemented.

In Australia, there are ten national maternity core indicators used for benchmarking (Appendix 4) which were developed in conjunction with the Women's Healthcare Australasia (WHA), Australian Institute of Health and Welfare (AIHW), and the Department of Health, Western Australia (DoHWA). These indicators are important tools for monitoring and evaluating standards of patient care, establishing a baseline measure of both clinical management and health outcomes (Australian Institute of Health and Welfare, 2015). Being able to effectively monitor interventions used in labour from pooled data in different settings, provides a benchmark for care providers and services to compare performances and improve the quality of maternity services in Australia. They are particularly important monitoring tools for service providers focused on increasing the normal birth rate.

Epidural use for pain relief in labour is one of the WHA indicators used in benchmarking maternity services. There is considerable variability that exists for this indicator depending on the annual birth rate of the hospital. This is because the percentage of women receiving an epidural may reflect an

availability (as determined by access to an anaesthetist), rather than a true measure of maternal choice (Women's Healthcare Australasia, 2013). On average 25.1% of all women birthing in WHA member hospitals used an epidural for the period 2005-2012 (Women's Healthcare Australasia, 2013). The MMH (April 2013) WHA benchmarking maternity care report, for the same period, identified MMH performed within control limits or better in all clinical indicators except for the percentage of women giving birth vaginally who received an epidural for pain relief (Women's Healthcare Australasia, 2013). Reported clinical data for 2012 from the MMH, revealed 45% (37% publicly funded vs. 59% privately funded) (MMH, 2012) of labouring women used an epidural, far greater than the national average (33%) (Australian Institute of Health and Welfare, 2015) and the above mentioned WHA benchmark (25.1%) (Women's Healthcare Australasia, 2013).

2.6 Normal Birth & Government Policy

Spontaneous vaginal birth is a normal physiological event controlled by powerful hormones influencing emotions and behaviours (Odent, 2001). Normal birth is widely regarded as the safest method of birth for healthy low risk mothers and babies (E. Hodnett et al., 2008; Maternity Care Working Party, 2007). Normal birth remains the most desired outcome for women, resulting in fewer postnatal complications, ensuring women are more able to care for their newborn babies (Tracy et al., 2007).

A working definition for normal labour and birth, adopted by a multidisciplinary team in England states it is a birth “without induction, without the use of instruments, not by caesarean section and without general, spinal or epidural anaesthetic before or during delivery” (Maternity Care Working Party, 2007, p. 1). From this definition, a criterion for normal birth (Table 1) was established by the Maternity Care Working Party (MCWP) in the UK, and is now included in government policy documents here in Australia (New South Wales Health, 2010; Queensland Health, 2012). The criterion excludes births, which were induced or augmented with oxytocin, assisted by instruments or where women used an epidural in labour.

Table 1: Commonly accepted criterion for normal birth.

Criteria	UK MCWP Normal delivery	Queensland Normal birth guideline
Births included (except when exclusion criteria also met)	Spontaneous Onset, progression (without medication) and birth	Spontaneous onset, progression and birth in a vertex position
	Augmentation	Augmentation - artificial rupture of membranes (ARM)
	Nitrous oxide & Opioids	Nitrous oxide & Opioids
	Electronic fetal monitoring	Intermittent fetal auscultation
	Managed third stage	Physiological and active third stage
	Complications: Antenatal, Intrapartum & Immediate postnatal	Complications and risk factors not included.
Births excluded	Induction of labour	Induction of labour
	Epidural, Spinal or General anaesthesia	Augmentation with oxytocin infusion
	Forceps or ventouse	Epidural, Spinal or General anaesthesia
	Caesarean section	Forceps or ventouse
	Episiotomy	Caesarean section
		Episiotomy

The latest Australian labour and birth statistics showed the percentage of women achieving a spontaneous vaginal (non-instrumental) birth has fallen from 61% in 2003 to 55% in 2013 (Australian Institute of Health and Welfare, 2015). Spontaneous vaginal (non-instrumental) birth for selected women ¹ is also one of the ten national core indicators used to benchmark practice. The latest report indicated a decrease for normal birth over the reference period (2004-2009), whilst instrumental birth (another core indicator), showed an increase (AIHW National Perinatal Epidemiology and Statistics Unit, 2013). Instrumental birth has been identified as an outcome associated with medical interventions offered in labour such as epidurals (Anim-Somuah et al., 2011). Along with reporting on indicators, WHA also performs outcome associations on the data they collect from their member

¹ Women age 20 to 34 years, with a singleton baby positioned in a vertex position at the onset of labour born between 37 and 41 weeks gestation (AIHW National Perinatal Epidemiology and Statistics Unit, 2013)

hospitals. One statistically significant correlation reported was between the use of epidural for pain relief and instrumental births (Women's Healthcare Australasia, 2013). Hospitals, particularly tertiary level hospitals such as the MMH have a centralised culture of risk due to the number of high-risk pregnancies they receive. Some researchers have reported, midwives working within these organisations may adapt their practices to have this focus and somewhat normalise interventions such as epidurals (Mead & Kornbrot, 2004).

2.7 Early Labour

Early labour varies in its duration (McNiven, Williams, Hodnett, Kaufman, & Hannah, 1998), and in the way it is perceived and experienced by women (Beebe & Humphreys, 2006; Gross et al., 2009; Janssen & Weissinger, 2014). There have been increasing recommendations for improved understanding of the complexities of early labour management for both the women and health services, due to a range of studies suggesting delayed admission to hospital may result in lower intervention rates in labour (Chuma, Kihunrwa, Matovelo, & Mahendeka, 2014; Davey, McLachlan, Forster, & Flood, 2013; Hemminki & Simukka, 1986; Holmes, Oppenheimer, & Wen, 2001; Lauzon & Hodnett, 2001; McNiven et al., 1998; Neal et al., 2014). The focus of research has been on exploring and evaluating innovations for managing the timing of assessment and transfer to birthing suites for improving birth outcomes as well as women's satisfaction with their overall birth experience (Bayes, Fenwick, & Hauck, 2008; Brown & Lumley, 1998; Fenwick et al., 2005; McLachlan et al., 2012; Spiby et al., 2008).

Large international randomised controlled trials (RCT) have evaluated interventions aimed at keeping women at home for longer to reduce time from arrival into birthing suite and the active phase of labour (Cheyne et al., 2008; E. Hodnett et al., 2008; Janssen et al., 2006; Spiby et al., 2008). Interventions included comparing telephone advice/triage with home visits in early labour (Janssen et al., 2006), a structured care approach taught to midwives consisting of a formalised assessment criteria (E. Hodnett et al., 2008) and the use of an algorithm for diagnosing active labour (see glossary) (Cheyne et al., 2008). The largest study located in the literature was funded by the National Health Service (NHS) in the UK, where an Early Labour Support and Assessment (ELSA) trial was developed to investigate the impact of providing midwifery support to nulliparous women in their homes compared with standard hospital care (Spiby et al., 2008).

While some of these studies revealed a trend towards increasing the likelihood for a spontaneous vaginal birth (SVB) (E. Hodnett et al., 2008), all failed to meet levels of statistical significance for their primary outcomes: lowering caesarean section rates (E. Hodnett et al., 2008; Janssen et al., 2006; Spiby et al., 2008), or augmentation of labour using oxytocin (Cheyne et al., 2008). Epidural use was

a secondary outcome for all of these studies. No significant difference in the use of epidurals was shown for any of these RCT's. What these trials did identify is that women continued to seek permission to come to hospital, despite efforts to reassure them home was a safe place in early labour. Of importance is that these trials found an increase in maternal satisfaction with both the structured care approach, (Cheyne et al., 2008; E. Hodnett et al., 2008), and home visits (Janssen et al., 2006; Spiby et al., 2008) identifying support improved the women's experience, but not the clinical outcomes.

Concurrent with the ELSA trial, the Options for Assessment in early Labour (OPAL) study was implemented with the aim placing the findings of the ELSA trial into context by describing the different early labour care management available across England. One of the main conclusions of the OPAL study was that maternity care providers were introducing different services to support women in early labour without appropriate evaluation of the impact of these changes. This study contains important recommendations for maternity services considering changing services for the management of women in early labour. These include: examining clinical outcomes, women's experiences, the impact the change of service has on the workload of staff, and that the statistical data collected be of a suitable quality to allow further evaluation and monitoring (Spiby et al., 2007).

More recently, two Australian RCT's compared the effects of continuity of care by a primary midwife (caseload midwifery) with standard maternity care on caesarean sections rates and interventions used in labour. The Comparing Standard Maternity care with One-to-one midwifery support (COSMOS) trial found the women in caseload model were less likely to have a caesarean, or instrumental birth, more likely to achieve a spontaneous vaginal birth and less likely to have an epidural than those in standard care (McLachlan et al., 2012). Further secondary analysis of this trial by Davey et al. (2013) explored the relationship between the degree to which labour was established on admission to hospital between the two groups and the method of birth. Augmentation and epidural use were each strongly associated with caesarean sections. Nulliparous women in standard care were those more likely to have their labours augmented (54.2% vs. 45.5%, $p=0.008$), but no more likely to use epidurals when compared to those in caseload midwifery. Whereas, multiparous women in standard care, were more likely to use an epidural in labour (10.0% vs. 5.3%, $p=0.047$) but no more likely to have their labours augmented compared to those in caseload. The study reported that "women allocated to caseload were admitted to hospital later in labour, and earlier admission was strongly associated with caesarean birth, suggesting that remaining at home longer in labour may be one of the mechanisms by which caseload care was effective in reducing caesarean section in the COSMOS trial" (Davey et al., 2013, p. 1301).

The COSMOS trial included only low risk women in their sample, whereas the Midwives @ New Group practice Options (M@NGO) trial (Tracy et al., 2013) sought to examine the maternal and perinatal clinical outcomes of caseload midwifery models for women with identified risk factors delivering at tertiary hospital settings. The findings of this RCT showed caseload midwifery remained a safe option for women of any risk, identifying no differences between caseload midwifery and standard midwifery care in the clinical birth outcomes (rate of caesarean sections, instrumental births or use of epidural analgesia) of women. In addition caseload midwifery was identified as more cost effective (Tracy et al., 2013).

The latest systematic review comparing midwife-led continuity models with other models of care for childbearing women (Sandall, Soltani, Gates, Shennan, & Devane, 2013), revealed women receiving their care through midwifery-led continuity of care models were less likely to use an epidural, or require an instrumental birth or episiotomy than those women in other models of care such as obstetric-led, GP share care or midwifery hospital clinics. No difference in the rate of caesarean section was found between the models. The majority of studies included in the review reported a higher level of maternal satisfaction with the midwifery-led continuity model. The review concluded midwife-led continuity models of care should be offered to all women, with caution about applying this advice to those with significant medical or obstetric risk factors (Sandall et al., 2013).

In summary, studies on early labour highlight women are seeking more support during the early stage of labour despite recommendations by care providers to keep them out of hospital for as long as possible. Evidence supports delaying admission to birth suite until the active phase of labour, for reducing the likelihood of requiring medical interventions, however the optimum setting for providing support is yet to be identified. Midwifery-led continuity care models have been shown to increase normal birth rates, decrease interventions used in labour and increase maternal satisfaction, yet are only accessible to a minority of women.

2.8 Women's experiences

A substantial body of research from developed countries such as UK, America and Scotland regarding women's experiences of labour and birth have identified that long-term memories and impressions of the attitudes of their care-givers are retained for many years (Haines et al., 2012; E. Hodnett, 2002; Simkin, 1991) contributing to perceptions of satisfaction with themselves, their care and their childbirth experience (Green, Coupland, & Kitzinger, 1998; Spiby et al., 2008). Narratives of women's experiences during the early stage of labour identify feelings of fear and uncertainty, and a sense of wanting to be in hospital for reassurance (Barnett, Hundley, Cheyne, & Kane, 2008; Fenwick et al., 2005; Fisher et al., 2006; Scotland, McNamee, Cheyne, Hundley, & Barnett, 2011). The

combination of fear and pain has been reported to influence women's early labour decision's (Cheyne et al., 2007) as well as the duration of labour (S. S. Adams, Eberhard-Gran, & Eskild, 2012). Women may express a preference for being admitted on their initial assessment (Scotland et al., 2011), feeling the decision to be sent home, if found to be in the early stage of labour is a professional one rather than a woman-centred response (Nolan & Smith, 2010; Petersen, Penz, & Gross, 2013).

Hospital admission has been identified as a time of disruption to a women's coping strategies (E. Hodnett et al., 2005). Women, particularly first time mothers, place a huge emphasis on themselves and their performance, facing challenges of recognising the onset of active labour and determining the right time to transfer to hospital (Beebe & Humphreys, 2006; Hatem et al., 2008). Women may become anxious about leaving the security of the hospital if found to be in early labour, as they are now unsure of the signs to look for, or how to cope, when previously they had considered themselves in labour (Scotland et al., 2011; Spiby et al., 2007).

Women's recognition of labour onset has been explored by Gross, Haunschild, Stoexen, Methner, & Guenter (2003) who identified women experience labour in a variety of ways, and report a range of symptoms (watery fluid, blood-stained loss, gastrointestinal symptoms, altered sleep patterns and feeling emotional). Furthermore, the time between their recognition of labour symptoms and admission to birth suite may influence a longer length of labour (Gross et al., 2009; World Health Organization, 1996) and epidural use (Janssen & Weissinger, 2014; Petersen et al., 2013). Studies on women's preferences for labour management revealed women disliked being turned away (Scotland et al., 2011) and most preferred to keep drugs use to a minimum (Green, 1993; Kpea et al., 2015; Scotland et al., 2011). Other authors have reported women value the encouragement and support they receive from a known midwife to labour without pharmacological pain relief, leaving them with feelings of confidence and empowerment after birth (Leap, Sandall, Buckland, & Huber, 2010).

On arrival to hospital, women may become impatient as most often they have the perception they have been in labour longer than the professional diagnosis of labour length (Janssen & Weissinger, 2014). Subsequent consequences of early presentation are possible embarrassment, increased cost of travel either for the families, or government if an ambulance is used, and issues with bed blockages and staff ratio's if remaining in hospital (Spiby et al., 2007). The combination of impatience and a concern for efficient resource use may explain why interventions such as amniotomy, oxytocin infusion and epidurals are used more commonly with early admission (Lauzon & Hodnett, 2001; Rahnama, Ziaei, & Faghihzadeh, 2006).

2.9 Childbirth Fear and the Normal Physiological Responses of Birth

Research has highlighted women now have a heightened sense of fear towards childbirth, regardless of their own personal risk factors, and a dependency on medical technologies (Maier, 2010). Studies have found up to 20% of pregnant women have a fear of childbirth (S. S. Adams et al., 2012; Haines et al., 2012; Waldenstrom, Hildingsson, & Ryding, 2006) which has been identified as a significant factor for increasing the duration of labour (S. S. Adams et al., 2012) and epidural use (Liva, Hall, Klein, & Wong, 2012; Raisanen et al., 2014). Positive factors for protecting against childbirth fear have been identified as a good relationship with the midwife (Fisher et al., 2006; Leap et al., 2010), and a strong support network (Fisher et al., 2006). Women often find it difficult to accept being at home is best for them as the public perception promotes being in the hospital as safer, a view that is reinforced through the media and negative birth stories from family and friends (Fenwick et al., 2005; Fisher et al., 2006; McIntyre et al., 2011).

Evidence reports associations between elevated levels of fear and an increased use of medical intervention in labour (Haines et al., 2012; E. Hodnett et al., 2008; Liva et al., 2012; Raisanen et al., 2014). The effects of fear in labour and its associated impact on birth outcomes, is described by Dr Sarah Buckley, who attributes this to the interruption to a women's primal sense of safety, altering the natural hormones of labour (Buckley, 2009). The hormones of labour are: *Oxytocin* (also known as the hormone of love), *Beta-endorphins* (responsible for the feeling of pleasure and reward), *Adrenaline/Noradrenaline* (also known as catecholamine's or CA's, provide the fight or flight response and feelings of excitement) and *Prolactin* (also known as the mothering/nesting hormone). These hormones are released by the limbic system, which is embedded deep in the middle brain and are responsible for our emotions, instincts and behaviours (Buckley, 2009; Odent, 2001).

Women instinctively seek a safe place to give birth, with hospital birth now the norm in Australia this contributes to the increase in early labour admissions. Prolactin, as mentioned previously is said to be the hormone responsible for causing this nesting behaviour of women when they prepare themselves for the birth (Buckley, 2003). Oxytocin is responsible for causing the uterus to contract, levels continue to rise throughout the labour with the peak triggered by the stretching of a woman's perineum as the baby is born (Buckley, 2009). Certain maternal and environmental factors can alter the balance of these rising levels and cause the labour to slow or stop (Odent, 2001). Often women entering the hospital environment experience a change in their labour patterns due to the unfamiliar surroundings and presence of being observed, despite them feeling this is the safe place to be (Buckley, 2003). Some may present to hospital multiple times, often highly anxious about the whole process. These alterations in labour patterns are a result of the release of adrenaline and noradrenaline (catecholamine's). These hormones are activated when the woman has feelings of

fear or danger (Lothian, 2004), and interfere with oxytocin release. This may explain why, if a woman fears labour, or is anxious about being at home leads to changes in labour patterns, possibly perceived as a reason to augment the labour. Other responses include a reduction in beta-endorphins, the body's natural pain-killer (Buckley, 2009), this may ultimately lead to an inability to cope with the pain of labour, leading to an increase use of analgesia such as epidurals.

2.10 Maternity Care Provider Views

In the Australian context, midwives working in the public sector are rarely able or permitted to visit women at home in early labour. Possible reason for this, may include the fear that this may result in accidental home birth, where this is not fully supported within the medically dominant system (RANZCOG, 2014). Many maternity care providers believe home is a better environment for women in early labour to reduce the likelihood of early admission into the birthing suite, and increased potential for interventions (Freeman, 2006). However this practice often results in a woman being home without professional support and clinicians acting as gatekeepers, this can be described as contrary to the philosophy of midwifery by not meeting the woman's needs, or providing woman-centred care (Eri, Blystad, Gjengedal, & Blaaka, 2011).

A systematic review of women's satisfaction with her overall care and childbirth experience identified, the attitudes and behaviours of their care givers was a more powerful predictor for overall satisfaction than the influence of pain, pain relief and medical interventions (E. Hodnett, 2002). A follow-up review by this group of researchers found the women's involvement in decision-making was one of four main factors identified for increasing satisfaction with care (E. Hodnett et al., 2005). A positive birth experience promotes feelings of confidence, self-worth and a sense of achievement, all of which are important for the transition to motherhood (Hildingsson, Johansson, Karlstrom, & Fenwick, 2013). However changes to the culture of western maternity care (lack of continuity, staff shortages and medical dominance) along with the social value of pain has brought about a 'pain relief' approach in many birth settings (Leap & Anderson, 2008).

Evidence is growing for supporting continuity of care model's as mentioned previously, as they are associated with lower intervention rates, higher normal birth rates and provide a more positive experience for women (Davey et al., 2013; Sandall et al., 2013; Tracy et al., 2013). These models however, are accessed by only a minority of women in Australia (Department of Health, n.d; The Australian Health Ministers' Conference, 2010). Irrespective of the model of care a women chooses, maternity care providers are in a unique position to educate women about early labour and identify practices to reduce early admission (Lauzon & Hodnett, 2001). Strengthening recommendations for further research to shift the focus away from keeping women at home as long as possible, to

examining the decision making process of maternity care providers and the provision of support for women at this important time.

2.11 Environment

The importance of the labour and birth environment is increasingly recognised in the literature, with reports of home-like settings, freedom of movement, availability of water as well as continuous support for the entire labour and birth to improve birth outcomes and use less analgesia (E. Hodnett et al., 2005; Odent, 2001; Overgaard, 2012; Scotland et al., 2011; Simkin & O'Hara, 2002). However, issues with the growing number of women presenting to hospital, staffing levels and the environment itself impact on optimal early labour care in larger facilities such as the MMH (Carolan-Olah, Kruger, & Garvey-Graham, 2015; Dennett & Baillie, 2002; Mead & Kornbrot, 2004).

2.11.1 Triage environment

Birthing suites have become busier with the majority of Australian women birthing in hospital settings. One approach to managing the number of women presenting in early labour or with pregnancy related concerns has been to introduce triage areas such as the PAOU into maternity care facilities (Mahlmeister & Van Mullem, 2000). However, unreasonable waiting times within these triage areas and extra workload on staff are created by not allowing midwives to work to their full scope of practice due to the risk culture within these organisations (Brodie & Leap, 2008; Dennett & Baillie, 2002). Many triage areas require midwives to perform clinical assessments and medical staff to order investigations and discharge planning, leading to duplications of assessments. This has led to dissatisfaction among all stakeholders (Haxton & Fahy, 2009). Authors Haxton & Fahy (2009) have investigated the length of stay within triage areas, in response to the growing number of women and reported waiting times for a management plan. These researchers developed clinical midwifery pathways and standing orders for common outpatient presentations, along with training and accrediting advanced practice midwives to assess, order investigations and make independent clinical decisions without being overseen by a medical officer. This study found a reduction in overall length of stay when midwives were able to work to their full scope, and no adverse event or patient complaints (Haxton & Fahy, 2009). For midwives to work to their full scope within policy driven environments, requires inter-professional trust and collaboration with medical staff (Brodie & Leap, 2008). When collaboration is achieved, a new organisational culture can be developed, which has the potential for improving staff satisfaction and a reduction in length of stay (Brodie & Leap, 2008).

2.11.2 Place of birth

Studies report the environment in which birth takes place may significantly influence midwives' practice in relation to information sharing (McLachlan et al., 2012; Newnham, McKellar, & Pincombe, 2015) and the perceived need for technology and intervention used in labour (Freeman, 2006; Liva et al., 2012; McDermott, 2010; Mead & Kornbrot, 2004). Previous authors have discussed the role of the midwife as a guardian, creating and protecting "spiritually and emotionally safe birth places" (Fahy & Hastie, 2008, p. 21). Over time as birth practices have evolved, medical science and technology have become more sophisticated, and a dominance of medical control in birth and changing public perceptions and expectations, has given way to the rise in obstetric-led units, changing the birthing environment or 'birth territory'.

The birth territory describes not only the physical environment in which birth takes place, but also the people within this space and the disciplinary power that challenges the control of childbirth (Fahy, 2008). This is backed by evidence of midwives' experiences and views of the factors that impede normal birth, revealing a number of barriers: time pressures, culture of risk, and women's expectations, challenge both a supportive environment and midwives' desire to promote normal birth (Carolan-Olah et al., 2015). The majority of midwives now work within organisations that have rising rate of intervention. Therefore, examining the real life culture in which midwives practice, in particular understanding the power dynamics and ensuring strong midwifery leadership are some of the key factors in being able to introduce reforms to the way in which maternity service provisions are organised (Brodie & Leap, 2008).

A large review of birthing outcomes undertaken in the UK, The Birthplace study (2011) supported a policy of offering low risk women a choice in birth setting (freestanding midwifery units, alongside midwifery units, obstetric units or home for multiparous women) after comparing the maternal and perinatal outcomes and interventions used in labour for 64,538 eligible women. The findings from this study, showed women were more likely to achieve a vaginal birth with less intervention in midwifery-led units when compared with women who planned to give birth in an obstetric unit, with no impact on perinatal outcomes (Brocklehurst et al., 2011). Of particular interest, the odds of women receiving an epidural or other interventions such as augmentation of labour or instrumental birth was lower in all three non-obstetric settings. Obstetric-led units had an epidural rate of 30.7% compared to 10.6% for Freestanding Midwifery Unit and 15.3% for Alongside Midwifery Unit (Brocklehurst et al., 2011).

A qualitative study conducted in Denmark (2012), examined the influence of birthplace by comparing freestanding midwifery unit (FMU) with two obstetric units (OU) on women's experience and satisfaction with care. The two cohorts of women in this study were socio-demographically matched, and identified a significantly lower level of satisfaction with birth experience and care received for those giving birth in OU compared to women birthing in the FMU, particularly in regards to participation in decision-making and information sharing (Overgaard, 2012).

The decline in midwives being the primary carer in Australia has been attributed to the expansion of medicine, dominating the disciplinary power "to control nursing, midwifery and childbirth" (Fahy, 2007, p. 26). The current climate has seen a trend away from medical dominance, supported by government initiatives (previously described), to extend midwifery-led models of care. Yet hospitals account for the vast majority of birth settings in Australia, ensuring there is an overarching theme of birth that is driven by risk management, rather than normality (Carolan-Olah et al., 2015; Newnham et al., 2015). Authors Brodie and Leap (2008) believe it is essential for midwives to value their place within organisations that are policy driven, and to understand and address the power imbalances that affect women's experiences. In order to create environments that promote physiological birth within hospital settings.

In summary, demands for more choice and access to maternity care options that support normal birth may conflict with public opinion about safety. This reflects the increasingly risk-averse culture surrounding childbirth. This is further impacted by reports many midwives working within large obstetric-led units tend to normalise intervention, or face challenges that lead to unmet support needs. Focus should be on ensuring maternity services and caregivers can provide an environment that protects women's emotional wellbeing, whilst meeting the needs of all women, regardless of risk. Considering how advantageous the perinatal outcomes of women birthing in midwifery units has been shown, as well for their psychological needs, outlines the importance for professionals and policy-makers to individualise care, especially for women planning to birth in obstetric-led units.

2.12 Epidural Analgesia

Women use a number of different techniques and methods of analgesia to manage the pain of labour and birth, and the debate continues over the choice and safety of the different types (Simkin, 2012). Advances in medical knowledge and increasing safety associated with anaesthetics over the last two decades, has resulted in many women considering epidural analgesia as a routine and safe option. As such, epidurals are increasing in popularity in Australia, with approximately 33% of women choosing to use an epidural for pain relief (Australian Institute of Health and Welfare, 2015). This is despite best practice guidelines indicating the potential for epidurals to change many of the

normal physiological processes of labour and birth (Australian and New Zealand College of Anaesthetists (ANZCA), 2014). The World Health Organisation (WHO) claims epidurals are “one of the most striking examples of the medicalisation of normal birth” (World Health Organization, 1996, p. 16), and a practice that is frequently used inappropriately. Below is a summary of factors influencing maternal request for epidural and the effects they have on the physiological systems, affecting birth outcomes.

2.12.1 Factors influencing women’s request for epidural analgesia

Women’s choice of pain management is influenced by a variety of factors including maternal socio-demographic, fear of labour and birth, the choice of maternity care provider and setting (Liva et al., 2012; Raisanen et al., 2014; Roberts, Tracy, & Peat, 2000; Sanders, 2015; Schytt & Waldenstrom, 2010; Steel et al., 2015; Walsh, 2009). Fewer epidurals are being used in hospitals with birth numbers less than 2000/year (Dahlen et al., 2012). It is most likely this reflects a lower risk population of women birthing in smaller hospitals (<2000 births per year) or less availability to access anaesthetist after hours (Women's Healthcare Australasia, 2014). Several previous population-based studies have reported women who use epidurals are most commonly nulliparous women (Bhattacharya, Wang, & Knox, 2006; Jeschke et al., 2012; Kpea et al., 2015; Raisanen et al., 2014; Schytt & Waldenstrom, 2010; Steel et al., 2015) with higher education levels (Koteles, de Vrijer, Penava, & Xie, 2012; Lancaster, Schick, Osman, & Enquobahrie, 2012) and income (Koteles et al., 2012); or women who have used an epidural previously (Jeschke et al., 2012; Scotland et al., 2011). Other predictors for epidural use are the woman’s ethnicity (Jimenez-Puente, Benitez-Parejo, Diego-Salas, Rivas-Ruiz, & Maanon-Di Leo, 2012; Lancaster et al., 2012; Ochroch, Troxel, Frogel, & Farrar, 2007), age (Bhattacharya et al., 2006; Carolan, Davey, Biro, & Kealy, 2011) weight (Bhattacharya et al., 2006; Ekeus, Hjern, & Hjelmsted, 2010) and those having larger size babies (Bhattacharya et al., 2006; Ekeus et al., 2010; Raisanen et al., 2014).

A women’s fear of childbirth, for most part, it is the fear of labour pain (Gibson, 2014; Wassen et al., 2013), has been associated with an increased request for epidural analgesia (Liva et al., 2012; Raisanen et al., 2014). The experience of labour pain has been described by Lowe (2002, p. 16) as a “complex, subjective, multidimensional response to sensory stimuli” that has both sensory and emotional components. Potentially negative physiological consequences of labour pain have been emphasized in the obstetric anaesthesia literature. An alteration in the mothers catecholamine-mediated stress response can lead to: hyperventilation, increased vascular resistance causing a higher maternal heart rate and blood pressure and as a result decreased placental perfusion. In addition, in coordinate uterine activity may result due to the changes to labour hormones leading to a diagnosis of dysfunctional labour (Lowe, 2002). In contrast, a fear of labour pain and self-doubt,

can be overcome through building a woman's confidence to view pain as something to work with and not manage (Leap & Anderson, 2008). This is backed by evidence, women receiving their care through midwife continuity models, use less epidurals and report an increased sense of empowerment (Leap et al., 2010; Sandall et al., 2013). As such, disagreement on the safety, side effects and role of epidurals in the evidence persists (Simkin, 2012).

2.12.2 The epidural debate: benefits vs. potential harm

While regional analgesia may be a suitable alternative to a general anaesthetic for those women having a caesarean section, their use remains disputed for the low risk labouring woman, as it transfers her out of the 'normal' category of birth as discussed previously (Newnham et al., 2015). Research studies examining the effects, benefits and potential harms of using epidurals have been ongoing, since epidurals became widely available in the 1960's. Although epidurals provide excellent pain relief, and an opportunity for the labouring woman to rest, evidence reveals an association with adverse maternal and neonatal labour outcomes (Anim-Somuah et al., 2011; Howell, 2005; Jones et al., 2012).

While some women respond positively to the pain relief, and mental awareness an epidural allows (Koteles et al., 2012), other women report being left with feelings of loss of control and autonomy (Hildingsson et al., 2013; Simkin, 2012; Tamagawa & Weaver, 2012). Ideally women should be informed about the advantages, possible complications, as well as alternative pain relief methods as part of antenatal (prenatal) education (Australian and New Zealand College of Anaesthetists (ANZCA), 2014). A recent review of the literature on the effects of antenatal education on labour and birth outcomes, between 2000-2012 revealed contradictory findings (Ferguson, Davis, & Browne, 2013). The authors of the review commented that many studies found antenatal education attendance to improve women's anxiety levels, increase partner involvement and prevent early labour admissions. Other studies however, found increased labour and birth interventions, such as epidurals and induction (Ferguson et al., 2013). The researchers put this down to a lack of adopted standards or guidelines, making evaluation difficult, identifying a gap in the evidence.

Side effects may exist following any elective intervention. Understanding the unintended effects on the natural process of labour and the "trade-off's – what is gained and what is lost" (Simkin, 2012, p. 328) is important in making informed decisions. It is doubtful women are making informed judgements concerning the advantages and disadvantages of using an epidural when in pain, during the anaesthetists consenting process. Epidurals have been described as bringing about a cascade of intervention, due to the physiological effects they cause and the number of interventions that follows, each carrying their own risk of further intervention (Tamagawa & Weaver, 2012). Whilst

epidurals are reported as the most effective method of pain relief (Anim-Somuah et al., 2011; Jones et al., 2012), unintended effects accompany them, often not explained to women before making her choice to have one (Tamagawa & Weaver, 2012). Prior knowledge may enable a reduction in some of the undesired effects or acceptance of an alternative.

2.12.3 Unintended effects and risks associated with epidural use

Relatively common and well-documented side effects of epidurals such as nausea, itching, and shaking, make the woman uncomfortable but are not medically serious (Mayberry, Clemmens, & De, 2002; Tamagawa & Weaver, 2012). Other clinically significant concerns are lowered blood pressure, urinary retention (Jones et al., 2012; Mayberry et al., 2002) and raised maternal temperature (Bailey & Steer, 2007; Jones et al., 2012), which can have significant detrimental effects on the baby in utero and following birth (Anim-Somuah et al., 2011; Buckley, 2005). These effects involve an increased incidence of the neonate requiring resuscitation (Leibermann & O'Donoghue, 2002) and assessment for sepsis, involving invasive tests, risk of separation from the mother, and most likely administration of antibiotics (Lieberman et al., 2000). Furthermore, a higher frequency of neonates requiring intensive care nursery admissions, occur with epidural use in labour (J. Adams, Frawley, Steel, Broom, & Sibbritt, 2015; Anim-Somuah et al., 2011; Herrera-Gomez et al., 2015).

Several studies have concluded epidurals have a direct negative effect on uterine function, causing labour to slow due to the significant interference with levels of endogenous prostaglandins and oxytocin, the major hormones involved in the natural process of labour and birth (Leighton & Halpern, 2002; Rooks, 2000). Epidurals lower the women's release of oxytocin and eliminate the peak in serum levels that occurs with the sensation of the stretching perineum (Rahm, Hallgreen, Hogberg, Hurtig, & Odland, 2002). This powerful surge of oxytocin release is said to contribute to the euphoria and emotional receptiveness in preparation for the transition to motherhood (Buckley, 2009), adding further evidence to reports of an interference with the mother-baby attachment (Buckley, 2005; Janssen et al., 2006).

Furthermore, epidurals relax the woman's pelvic floor muscles, which are important in guiding the baby's head into an optimal position in preparation for birth (Leighton & Halpern, 2002; Lieberman, Davidson, Lee-Parritz, & Shearer, 2005; Ponkey, Cohen, Heffner, & Lieberman, 2003). It has been reported women are four more times likely to have a baby in a persistent occiputo-posterior (POP) position than those women without epidurals (Howell, 2005; Lieberman et al., 2005; Ponkey et al., 2003). Due to the anaesthetising effect to the pelvic floor muscles, and reduced motor block felt by the woman, mobility and effective push is limited. This reduction in tone and maternal effort impairs fetal rotation causing an increased incidence of malposition (Leibermann & O'Donoghue, 2002;

Leighton & Halpern, 2002), which may explain the increased likelihood of requiring an instrumental birth.

The impact of epidural analgesia on the progress of labour and mode of birth remains a point of debate in the literature. Four systematic reviews including a Cochrane Systematic Reviews concluded there was no evidence epidurals were a contributing factor for increasing the risk of a caesarean birth overall (Anim-Somuah et al., 2011; Jones et al., 2012; Leibermann & O'Donoghue, 2002; Leighton & Halpern, 2002). However, most recently this association between epidural analgesia and caesarean section has been further explored in a meta-analysis, and identified a small significant trend (Bannister-Tyrrell, Miladinovic, Roberts, & Ford, 2015). Along with these reviews, a number of population based studies found an association with epidural analgesia and adverse maternal and neonatal labour outcomes, such as a longer second stage of labour (Howell, 2005; Kopas, 2014), an increase in oxytocin administration for augmentation of labour (Hung, T'sang-T'sang, & Hung-Pin, 2015; Kpea et al., 2015; Zhang, Klebanoff, & DerSimonian, 1999) increased instrumental birth rate (Jones et al., 2012; Poignant, Hjelmstedt, & Ekeus, 2012; Raisanen et al., 2014; Tamagawa & Weaver, 2012), urinary retention and maternal fever (Anim-Somuah et al., 2011; Jones et al., 2012; Leibermann & O'Donoghue, 2002; Leighton & Halpern, 2002) and breastfeeding cessation (Dozier et al., 2013; Herrera-Gomez et al., 2015; Tamagawa & Weaver, 2012).

Summary

Normal birth is regarded as the safest method of birth for healthy low risk mothers and babies and one of the ten national core maternity indicators used to benchmark practice, yet less than a quarter of Australian births meet this criteria. According to both international and local definitions of normal birth, women that use an epidural are excluded, yet epidural use continues to rise in Australia, being used by 33% of labouring women.

The majority of healthy mothers can give birth with minimal medical intervention given appropriate care and support, provided they feel they can cope and their baby is safe. There is a large body of evidence to support keeping women out of the birthing suite until the active phase of labour to avoid unnecessary intervention, however a growing awareness that some women feel unsupported in early labour preferring to be admitted if found to be in early labour on initial assessment. Women, who feel unsupported, have a greater sense of childbirth fear, leading to an inability to cope and are more likely to request to have an epidural.

The environment has been identified as a factor influencing the use of interventions, such as epidurals in labour. Since epidurals are almost always an elective procedure, with research identifying most women prefer to keep drug use to a minimum, better clinical evidence of the

effects of epidurals on labour, as an improvement in antenatal education is required to permit women to make truly informed decisions, especially if endeavouring to achieve a normal birth.

The International Early Labour Research Group founded in the UK, suggests women's experiences of their early labour care can set the tone for the rest of the childbirth experience, identifying the importance for women to feel supported and for more appropriate timing of hospital admission. Without recognising or responding to the issues women present with in early labour and providing appropriate support, then any intervention aimed at keeping women at home will encounter difficulties. Shedding light on reasons why attempts by researchers have been unsuccessful in reducing length of hospital admissions or the number of interventions used in labour.

The literature presented in this chapter has highlighted the importance of supporting women to navigate through this stage of labour, and explore areas for service improvement for all women. Recommendations have been made for maternity care providers to close the gap between the women's expectations of labour and birth and what occurs during the actual event. Additionally, the literature highlights health services need to provide environments and an optimal level of support for women to help them relax and feel secure, to reduce the number of medical interventions used in labour. With a national focus on protecting, promoting and supporting normal birth, maternity reforms and government reviews recognise the possibilities that appropriate labour care will reduce unnecessary interventions, and their potential consequences. The implementation of a change in management and early labour area at the MMH aimed to meet these recommendations.

Chapter Three: Methods

This chapter describes the aims, objectives and setting of this research study. The research design, methodology, data collection and challenges to data reliability are also described. Finally, a discussion on the outcome measures, variables of interest and data analysis techniques are presented.

3.1 Aims

This study aimed to examine the birth outcomes of women presenting in early labour who were less than 4cm dilated, to identify if a change in the management of these women had any influence on interventions used in labour, in particular epidural use. A secondary aim of the study was to explore if a longer length of time spent in the pre admission assessment area was associated with an increase in the occurrence of obstetric interventions.

3.2 Study Design

This study used a pre - post intervention design, and analysed routinely collected data from eligible women who birthed during two time periods May-September 2012 (Pre-Intervention Cohort) and October 2012- January 2014 (Post-Intervention Cohort). It was a retrospective design conducted at a large tertiary referral hospital. Pre-post intervention studies are a quasi-experimental study design (non-randomised experimental study), and aim to evaluate the benefits of an intervention on a specific population (Finkelstein, 2006). Quasi-experimental studies are frequently used when the researchers do not have complete control of the independent variable. The intervention may already be in place or it is not feasible or ethical to conduct a randomised controlled trial (RCT). The study relies on existing populations that occur naturally, hence a control group, however the participants are not randomly allocated (Finkelstein, 2006). For this study the population of interest were childbearing women presenting to the hospital in the early stage of stage of labour. It would not have been possible to randomise women away from the new model of care, nor would it have been ethical as the service was not going to continue with the old model. This would have caused considerable disruption across the service resulting in two early labour areas, making it difficult to ensure adequate staffing. Quasi-experimental studies are used in healthcare for demonstrating potential casual associations between an intervention and an outcome of interest as they are often quicker, and cheaper than randomised trials (Finkelstein, 2006).

Pre-post intervention studies deliberately introduce an intervention into practice, collect data pre and post intervention and then compare the data from both periods (Finkelstein, 2006). This enables comparisons between participant groups, and can examine trends over time in relation to the introduction of a new model of care (intervention). However, as they do not use random allocation,

the populations may differ in many ways that then need to be controlled for. Therefore the potential for bias is higher in these studies as other factors that may not have been examined may be responsible for any observed changes (Finkelstein, 2006). An advantage of this type of design is their use of routinely collected data. The ability to examine and analyse data from large numbers of subjects, generally makes them quicker to yield results, as the data is readily available. The pre-post intervention design was considered most appropriate for this study, as it enabled the use of medical records and data obtained from hospital databases from a large number of women who birthed before and after the change in model of care. Additionally, the timeframe for the study needed to fit into the expected length for a masters' candidature.

3.3 Research Setting

The PAOU is located within a large tertiary hospital, in South Brisbane an inner city suburb of a major metropolitan city with a large catchment area and tertiary referral base. The PAOU is the largest of its type in Australia, and is located within the hospitals birthing suite and provides care for both privately funded women (referred to as private women) and women utilising the Australian public health system (referred to as public women). With an annual birth rate of 10,000, the distribution between public and private is almost equal. The PAOU acts as the triage for birth suite admission in labour for all women. Clinical activity records show the PAOU provided labour assessment to approximately 8,000 women in 2012. In addition to labour assessment, the PAOU provides a number of other services, for acute, booked and emergency presentations for women who are from twenty weeks gestation to six weeks postpartum. It is a busy unit, with an aim to keep women for less than two hours.

Admission process

Women presenting to the PAOU in early labour, regardless of insurance status, were triaged and assessed prior to decision-making about clinical management and destination (i.e. home, postnatal ward or birth suite previously). Women are assessed in either one of the five assessment bays that are separated by curtains or in one of the additional five rooms (three with bathrooms, two without) that are used for more private examinations. A significant amount of variation in clinical care occurred between maternity care providers working in this unit, when women were found to be in the early stage of labour (cervical dilatation less than 4cm dilated). Women were most often recommended to return home if within a reasonable distance from the facility (10km). Alternatively they were encouraged to go for a walk within the grounds of the hospital or face an undetermined length of admission either in PAOU or on the postnatal ward, usually without their support people,

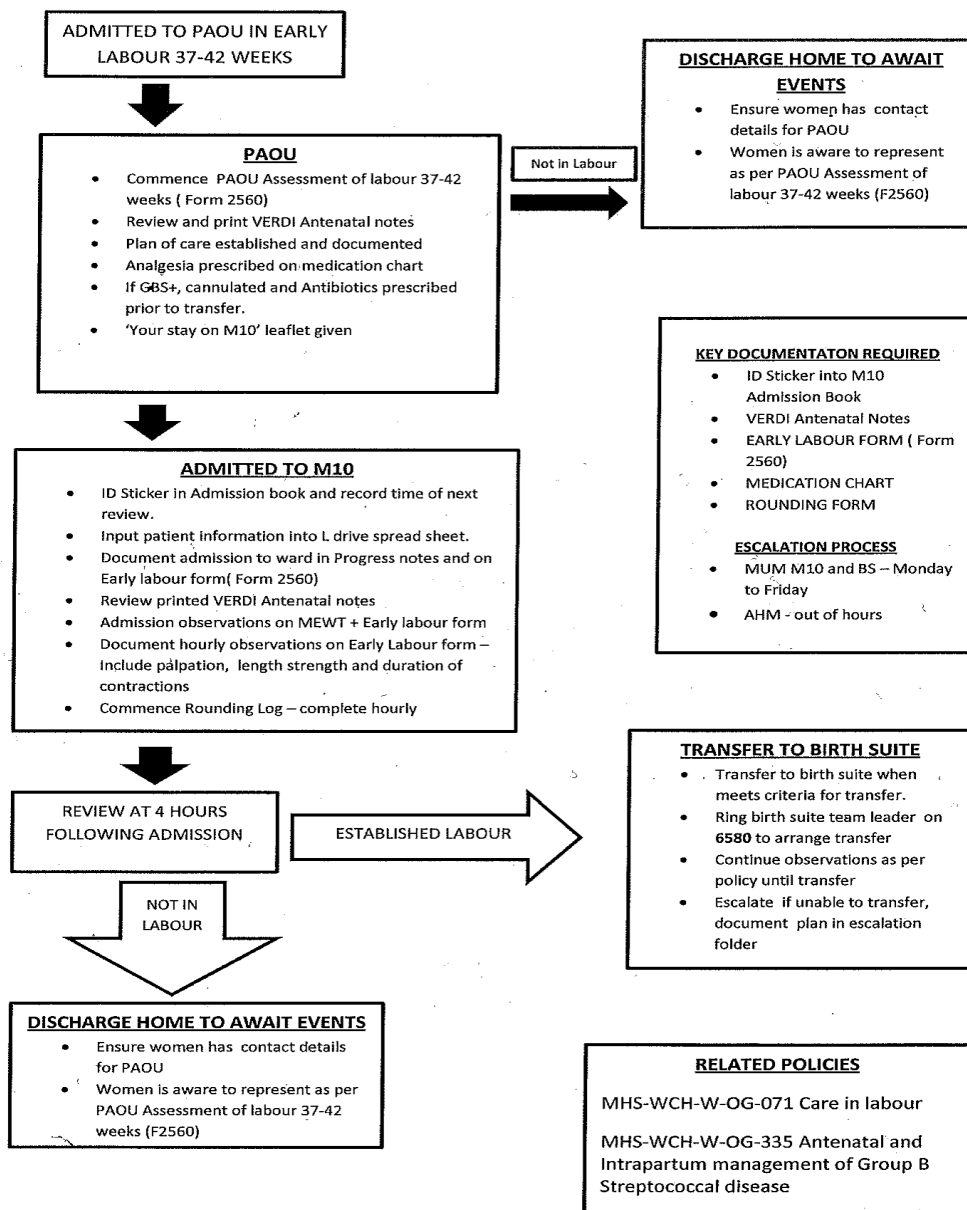
to await active labour. If support people did remain with the woman they faced paying a large parking fee.

Following a review of services in 2011 a new model of care for women in early labour was implemented on the 25th September 2012. Women presenting to the hospital in early labour after the implementation of this new model, continued to be triaged and assessed within PAOU, but were given an alternative option to be transferred to a designated early labour area within the hospital with their support people, instead of being sent home or transferred to the postnatal floor. The new admission procedure had more defined processes following the development of a clinical framework (Figure 3, pg. 32) created to standardise the management of women presenting in early labour. Midwives working in the PAOU triaged and assessed women based on both pain (subjective) and cervical dilatation (objective) symptoms. Women found to be in the early stage of labour and met the criteria for M10E, were given either the option to return home or be transferred to M10E for a period of 4 hours to await active labour.

3.4 Intervention

The intervention or exposure in this study was the introduction of an early labour care model, which included a clinical framework; clinical decision-making tool; clinical pathways and the creation of a dedicated early labour space on the eastern end of Level 10 of the MMH (M10E), with easy lift access to BS. The model attempted to standardise the care women received when presenting during the early stage of labour. However, the creation of M10E was not solely for the management of women in early labour, but also for the management of women booked for induction of labour, to remove this workload from PAOU also. For the purpose of this study, the early labour care model is what is being represented in this thesis.

Women who did not meet the criteria for admission to BS, or did not wish to return home in early labour, were transferred from PAOU to M10E for a period of four hours to receive early labour support. This support consisted of a private room with access to their own toilet and shower providing privacy and access to equipment such as birth balls, heat packs and analgesia (oral, narcotics or nitrous oxide) as well as midwifery support and advice. An outside courtyard provided women with an alternative environment other than their room to move around in, and a dining area with small kitchenette. The women were observed hourly (which included monitoring of fetal heart rate, strength and regularity of contractions and maternal observations such as pulse), with the aim to offer a level of reassurance and a sense of safety, until either her labour had established and she was transferred to BS, or the woman returned home if cervical assessment remained unchanged.



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Figure 3: M10E framework admission tool

The key differences between the Pre-Intervention and the Post-Intervention early labour care models are outlined in Table 2 below:

Table 2: Key differences between the management of early labour care Pre & Post M10E

(Pre-intervention Cohort) Women presenting to MMH in early labour May to September 2012	(Post-Intervention Cohort) Women presenting to MMH in early labour Oct 2012 – January 2014
<p>Assessed in PAOU (aim for LOS <2hrs)</p> <ul style="list-style-type: none"> • Clinical variances depending on model of care (public/private/group practice) • Most encouraged to return home to await active labour • If requiring more support remained in PAOU (indeterminate amount of time) or admitted to postnatal ward (without support people) • Care included small clinical room (where available, most without bathrooms) • No space to mobilise • Option of analgesia included (heat packs, paracetamol and narcotic) • Hourly monitoring of FHR and contractions by one or more PAOU midwives 	<p>Assessed in PAOU (aim for LOS <2hrs)</p> <ul style="list-style-type: none"> • Early labour clinical assessment tool used to standardise management • If meeting criteria given option to either return home or admit to M10E • Length of admission in PAOU reduced (used as a key performance indicator for monitoring the effectiveness of the new model for the hospital's operational objective) • Quieter environment and increased privacy with own room and bathroom with shower • Freedom to mobilise and easy access to an outside courtyard and kitchenette • Option for analgesia included (heat packs, birth balls, shower, and narcotic) • Hourly monitoring of FHR and contractions by allocated midwife
<ul style="list-style-type: none"> • Transfer to BS not always related to clinical assessments. Rather transfer often occurred before active labour due to the woman not coping and time pressures on midwives to provide appropriate care or needing to free up room in PAOU. • Care handed over to BS midwife <p>All interventions (amniotomy, epidural, oxytocin infusion) performed once in BS</p>	<ul style="list-style-type: none"> • Vaginal examination performed within the 4 hours if contractions increased or woman requesting more pain relief – transfer to BS • Vaginal examination performed at the end of the 4 hours, if no progress made encouraged to return home. Re-admit through PAOU • Care handed over to BS midwife <p>All interventions (amniotomy, epidural, oxytocin infusion) performed once in BS</p>

In addition to improving the environmental needs for the women and their families, the intention of a new location of early labour management was to improve the flow of work through the PAOU by:

- Reducing length of admission following assessment
- Reduce bed blockages
- Reduce workload on midwives working within the PAOU
- Reduce unnecessary interventions such as augmentation of labour and epidural use due to time constraints.

The length of admission to PAOU for women in early labour was a process outcome and one of the key performance indicators (KPI) the MMH Management team used to monitor the effectiveness of this new model of care (Appendix 5).

3.5 Objectives

The objectives for this research were to:

- Identify if the provision of an early labour area for women seeking support during the early stage of labour had an effect on the epidural rate in labour
- Explore the clinical outcomes associated with epidural usage across the total cohort
- Determine if an admission to PAOU of >2hrs during the early stage of labour increased the number and type of obstetric interventions used in labour, such as epidural usage and augmentation of labour (Two hours is the allocated time recommended for triage and assessment).
- Assist with evaluating the effectiveness of the early labour care model (M10E) by providing a comparison between the two subgroups of women

3.6 Hypothesis

To address the research questions the following hypothesis and null hypothesis were constructed:

H0: There will be no difference in epidural rates for women admitted to hospital less than 4cm dilated and cared for in a designated early labour area when compared to women cared for in PAOU.

H1: Epidural rates will reduce from 45% to 38% in women who are admitted to hospital less than 4cm dilated and are cared for in a designated early labour area when compared to women cared for in PAOU.

3.7 Participants and eligibility criteria

The participants were to come from the population of women who presented to the PAOU and gave birth between two timeframes:

- May-September 2012 (Pre-Intervention Cohort)
- October 2012-January 2014 (Post-Intervention Cohort).

Inclusion criteria:

Women who met the following criteria would be included in the study:

- Planned a vaginal birth regardless of model of antenatal care
- Had a singleton pregnancy
- Presented in spontaneous labour with intact or ruptured membranes (clear liquor only)
- Had a gestation greater than or equal to 37+0 weeks
- Were diagnosed to be less than 4 cm dilated in the PAOU.

Exclusion Criteria:

Women who:

- Were booked for a caesarean section
- Presented with malpresentation (e.g.: breech, transverse)
- Had an obstetric emergency (e.g.: cord prolapse, APH)
- Were pregnant with a multiple pregnancy
- Planned an induction of labour
- Presented in labour less than 37 weeks gestation
- Presented in established labour greater or equal to 4cm dilated
- Had a fetal death or baby/ies known to have a significant congenital abnormality.

3.8 Outcome measures

The primary outcome was the:

- Proportion of women who used an epidural in labour.

The secondary outcomes were the:

- Proportion of women undergoing augmentation of labour with oxytocin
- Proportion of women having an instrumental birth

- Proportion of women having an emergency caesarean birth
- Proportion of neonates admitted to intensive care nursery
- Proportion of women with blood loss greater than 1500mls
- Length of time spent in the PAOU in early labour (< or > 2hrs).

3.9 Power and sample size projection

A sample size calculation was undertaken using a type I (alpha) error of 0.05 and a power of 80% based upon the projected difference between the proportion of women meeting the inclusion criteria who used an epidural in labour before and after the introduction of M10E. The portion of women using an epidural in the Pre-Intervention Cohort was taken from MMH clinical activity records for 2012. As previously mentioned, this data identified 45% (37% publicly funded vs. 59% privately funded) of all labouring women used an epidural. The proportion in the Post-Intervention Cohort was estimated, based on an expected clinically significant reduction in epidural rates. After discussion with colleagues, a reduction in epidural rates of 8% (absolute reduction) was deemed to be clinically significant. Using the above parameters the estimated sample size to test this clinical reduction was calculated based on the difference between two proportions from 45% (control) to 37% (intervention). This resulted in 593 women in each group, with an additional 20% for attrition (n= 711).

3.10 Data Sources and selected variables

Women were selected for inclusion based on their reason for admission to PAOU within the timeframe estimated to achieve the required numbers. The initial data extraction method performed by the statistician, filtered these admissions from the PAOU folder in the hospital's obstetric database known as Matrix. Matrix is the obstetric database used by the hospital from which all maternal and neonatal outcomes were extracted. Matrix has different folders for the different clinical areas. Admissions to PAOU are recorded in Matrix under the relevant folder, from which data is available for extraction. It was anticipated approximately a thousand women over the course of a six month period would present in early labour based on the hospital's birth rate of 10,000 per annum. However, this initial electronic extraction identified very few eligible women indicating there was a significant issue with the data collection strategy chosen.

Less than one hundred women were identified in the initial Matrix extraction as eligible for inclusion (Appendix 6). An audit of all maternity records of women admitted to the PAOU over a six-week period was conducted and revealed significant degree of lack of compliance with completion of data

entry (Appendix 7). This challenge to the reliability of data for the Pre-Intervention Cohort meant electronic extraction was not an appropriate method to collect the data necessary for comparisons. To overcome this, a change of strategy was required and involved a lengthy process of manual audit of all admissions to PAOU for the first timeframe using data from another two hospital databases (iPM & Guardian Archive). The iPM hospital database is an administrative database, which records times, dates and transfers between hospital units. The Guardian Archive is a database used in all clinical areas to document assessments and fetal monitoring, and in general more often completed by staff working in the PAOU. The use of two sources provided the opportunity to triangulate data and ensure validity of findings. Further discussion of the challenges encountered and the changes made to the data collection strategy will be presented in the section 3.11.

Data for the Pre-Intervention Cohort used the woman's unique record number (URN), selected by the researcher manually using paper based administration records until enough women were recruited to power the study. An allowance of at least 20% more was collected in case of attrition due to exclusion after cleaning. In total, 875 admissions were manually collected; a number of these were deleted during the cleaning process because of missing data, duplications of URN or not meeting the eligibility criteria on further investigation with the data found in the Guardian Archive. The total number of eligible admissions reduced to 625 women in the Pre-Intervention Cohort, enough to power the study to detect a difference in the primary outcome. The timeframe for the Post-Intervention Cohort was a longer length of time. Data was extracted electronically from the Matrix database based on reason for admission, up until an equal number of eligible women allowing for approximately 20% to be excluded during cleaning. No manual data collection was required for this second timeframe, due to a number of quality improvements put in place as a direct result of the findings from the clinical audit conducted for this study to improve documentation.

3.10.1 Defining individual and health service related variables of interest

The variables selected as potential confounders were based on the evidence presented in the literature review, which are known to be associated with epidural use in labour, and included individual and health service-related variables:

Age

Maternal age is identified as a predictor for epidural use in the literature, and may impact the data in many ways. For example, women over the age of 35 years are more likely to give birth by caesarean section whether admitted publicly or privately (Biro, Davey, Carolan, & Kealy, 2012; Carolan et al., 2011), and are now more likely to have their labours induced due to changes in clinical practice

guidelines (Mater Misericordiae Health Services Brisbane Limited, 2015). Older women are more likely to have private health insurance, which in turn increases the likelihood of an elective induction or caesarean birth. Age was represented both as a mean and categorically: <20 years (represents the young women), 20-35 years and >35years (represents advance maternal age).

Parity

Nulliparity is defined as no previous pregnancies that resulted in a viable birth (>20 weeks gestation or 400grams in Australia) (Li et al., 2011). Multiparity is defined when a women has had more than one viable birth (Li et al., 2011). As first time mothers are considered to be a greater predictor for epidural use in the literature (Bailit, Dierker, Blanchard, & Mercer, 2005; Bhattacharya et al., 2006; Jeschke et al., 2012; Kpea et al., 2015; Raisanen et al., 2014; Steel et al., 2015) prior births were coded as a categorical variable (yes/no) to nulliparity.

Ethnicity

Ethnicity is self-identified and recorded in the Matrix database during the booking history, with over seventy different ethnicities recorded. A prior decision was made to code Ethnicity into four categories: Caucasian/European, Aboriginal/Torres Strait Islander, Asian and Other. The 'Other' category represents a wide variety of minority and mixed ethnicities including African, Indian, Maori, and Pacific Islanders. Studies have reported epidural use is less extensive among these minority ethnic groups (Dahlen et al., 2015; Jimenez-Puente et al., 2012; Lancaster et al., 2012; Ochroch et al., 2007).

Education

Level of education has been identified in the literature as a significant predictor for epidural use, with completion of secondary schooling or greater identified as more likely to request an epidural in labour (Lancaster et al., 2012; Liu et al., 2010; Orejuela et al., 2011). Education attainment is self identified and entered into Matrix during the booking history. Level of Education was coded into three categories: <Grade 10 (did not complete secondary education); Grade 10-12 (completed secondary education); Tertiary education (which included TAFE).

Body Mass Index (BMI)

Body mass index is calculated and entered into the Matrix database at the booking history. The WHO classifications of BMI were used to classify women: underweight (<18.5); normal weight (18.5-24.9); overweight (25.0-29.9) or obese 1 (30.0-34.9), obese 2 (35.0-39.9) and obese 3 (>40.0). Four categorical variables were created for this dataset and labelled as: Underweight, Normal, Overweight and Obese (>30.0) - grouping together the three categories of obese women. A BMI of greater than 30 at the booking history has been defined as obesity in pregnancy (Australian Institute

of Health and Welfare, 2015) and contributes to increased morbidity and mortality for both mother and baby. Additionally, heavier women have been found to be a significant predictor for epidural use (Bhattacharya et al., 2006; Ekeus et al., 2010).

Model of care at birth

Public women included those in standard care or continuity care models (Midwifery Group Practice) (see glossary). There are fifty possible models of care that women may be allocated to and can be selected in the Matrix database. For this study, standard care refers to all other allocated models in Matrix. The exception was those women in the high-risk clinic, maternal fetal medicine (MFM) clinic or those receiving obstetric only care. These women were excluded from this study due to significant maternal and obstetric factors not eligible to be classified as 'low risk'. Private women are associated with higher intervention, including epidural use (Dahlen et al., 2012; Roberts et al., 2000). Private women in this study are those admitted under the care of a private obstetrician, but may vary in risk status from low to high.

Gestational age at birth

Babies are considered term from 37 completed weeks of pregnancy to 41+6 completed weeks, and account for 90.8% of babies born in Queensland (Queensland Health, 2012). The average gestational age of babies born in hospital settings is 38.7 weeks, slightly lower than babies born in birth centres (39.5 weeks) or home (39.7 weeks) (Australian Institute of Health and Welfare, 2015). The inclusion criteria for this study included women labouring spontaneously from 37-41 weeks and therefore representative of the general population. Although no specific associations has been found between gestational age at birth and epidural use in the literature reviewed, babies growth accelerates during this period from 37-41 weeks gestation (Roberts & Lancaster, 1999), and a larger birth weight has been identified as a predictor for epidural use.

Birth weight

A birth weight of less than or greater than 4kg was used as a variable due to higher birth weights being identified in the literature as a predictor for epidural use (Bhattacharya et al., 2006; Ekeus et al., 2010; Rasanen et al., 2014). An Australian study presented birth weight percentiles by gestational age based on national data, and can be used as population norms for clinicians and researchers (Roberts & Lancaster, 1999). Although not relevant to this study, they found a significant difference between the birth weights of male and female infants, the norms are therefore reported according to this finding. The median birth weight at 39wks (median gestational age of women in this study) is 3471g for males and 3329g for females (Roberts & Lancaster, 1999). A birth weight of 4000g (4kg) was identified to be on the 90th percentile for males and 95th percentile for females,

therefore defined as a “higher birth weight”, and the reason for coding birth weight as < or > 4kg for this study.

Use of analgesia (Non-pharmacological and pharmacological)

Non-pharmacological methods of pain relief are non-invasive, and appear to be safe for mother and baby (J. Adams et al., 2015; Jones et al., 2012). Data was collected on whether women used non-pharmacological methods of pain relief: transcutaneous electrical nerve stimulation (TENS), sterile water injections (SWI), and water immersion as research identifies women are more motivated to try and avoid an epidural (J. Adams et al., 2015). Many women use these simple methods to relieve labour pain, whilst maintaining mobility and a sense of control (Simkin & O'Hara, 2002). Whilst not available on M10E, SWI and water immersion are non-pharmacological methods that are offered in active labour, and thus may lower epidural use. Women using TENS machines, are doing so as a self-help comfort measure, as the skills and equipment required to use them can be acquired for themselves and do not require hospital policy. Although there is insufficient evidence that TENS reduces the pain of labour there is no reported adverse events, recommending women should have the choice to use (Dowswell, Bedwell, Lavender, & Neilson, 2009).

Augmentation of labour

Early admission to hospital has been associated with augmentation of labour (Chuma et al., 2014; Holmes et al., 2001). Epidural use is also associated with augmentation of labour using oxytocin due to the interference with the natural hormones of labour (Hung et al., 2015; Kpea et al., 2015; Tracy et al., 2007). This study collected data on augmentation of labour using amniotomy (ARM), as well as oxytocin infusion as both are considered unnecessary interventions and both associated with epidural use (Tracy et al., 2007). However, this study was unable to identify in the results what came first, the epidural or the augmentation, a limitation of the retrospective data collection.

Mode of birth

As previously discussed assisted vaginal births (vacuum or forceps) are positively associated with epidural use (Anim-Somuah et al., 2011; Jones et al., 2012; Tracy et al., 2007). While some population based studies show a trend towards increasing emergency caesarean rates following epidural use, randomised control trials do not. However, most recently this association between epidural analgesia and caesarean section has been further explored in a meta-analysis, identifying a small significant trend (Bannister-Tyrrell et al., 2015). Elective caesarean was an exclusion criteria, therefore caesarean sections captured in this dataset are those performed for a medical reason – emergency caesarean section (EmLSCS) in labour.

Blood loss

A normal amount of blood loss post birth is commonly accepted as less than 500mls. The estimation of blood loss however, varies considerably, as the care provider in most instances subjectively calculates it. A loss of blood greater or equal to 500mls within the first 24 hours after birth is defined as a primary postpartum haemorrhage (PPH) and is used as a clinical indicator for benchmarking (Women's Healthcare Australasia, 2013). Blood loss was coded into four categories: <500mls, 500-1000mls, 1000-1500ml and >1500mls for this study.

Admission to neonatal nursery

A higher frequency of well, term neonates needing resuscitation and neonatal intensive care admission has been significantly associated with epidural use in labour (J. Adams et al., 2015; Anim-Somuah et al., 2011; Herrera-Gomez et al., 2015; Leibermann & O'Donoghue, 2002).

Length of admission to PAOU

A greater length of admission within the assessment unit was theorised to increase the likelihood of labour augmentation and epidural use. A raw audit conducted by the candidate (before commencement of this research project, discussed in the prologue) and analysis of this data by the hospital's statistician, suggested a correlation between a greater length of time spent in the PAOU and epidural use. Issues with data collection and multiple admission to PAOU for the same woman (to be discussed in section 3.10-3.11) meant the closest date and time of admission to birth was used for the Pre-Intervention Cohort.

3.10.2 Data collection for clinical outcomes

Obstetric and neonatal outcome data was obtained from the two hospital obstetric databases (Matrix & Guardian archive). This data included:

- Woman's unit record number (URN)
- Demographic information (age, ethnicity, BMI, level of education)
- Parity
- Gestation at birth
- Insurance status
- Model of care at birth (public, private, MGP)
- Use of analgesia (non-pharmacological and pharmacological)
- Augmentation of labour
- Mode of birth
- Blood loss
- Infant birth weight
- Admission to neonatal nursery.

Admission date and time, along with hospital transfers in early labour were obtained from the hospital administration database (iPM), to provide:

- Length of stay (LOS) in the PAOU.

3.11 Data reliability and audit trail

During the initial data extraction significant unavoidable documentation issues challenged the reliability of data, a limitation of retrospective data collection strategies. As previously mentioned, the initial extraction revealed very few admissions had been entered into the Matrix database by staff working in the PAOU (Appendix 6). To allow for the identification of records of eligible women not captured from the original Matrix extraction, a new data collection strategy was employed using the two additional hospital databases previously mentioned, iPM and Guardian Archive (Figure 4).

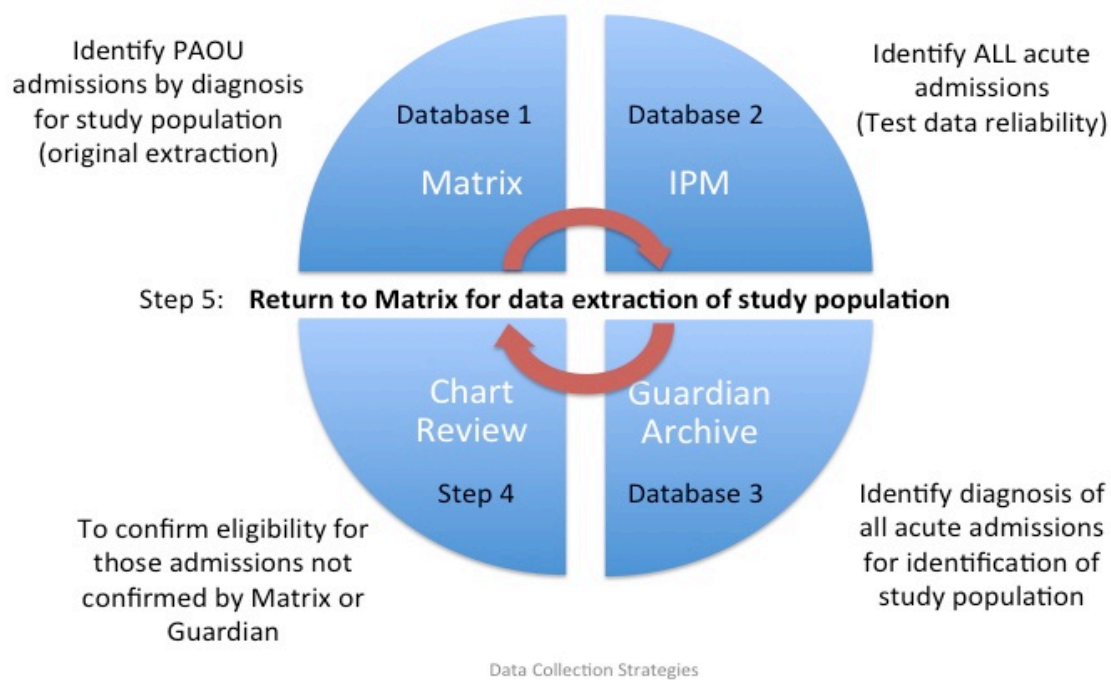


Figure 4: Data collection methods used for the pre intervention cohort

A list of all acute admissions (excluding those booked to present to PAOU for monitoring or preparation for CS) by URN was obtained from the administration coordinator and made into an excel spreadsheet. This spreadsheet held over 7,000 admissions to PAOU. Therefore a six-week audit was firstly performed to identify the degree of missing admissions before deciding to embark on the time consuming method of manually collecting all the data. Each URN during this six-week timeframe was manually checked against the Guardian Archive to identify whether the woman was admitted for early labour assessment. The researcher and one associate investigator performed this audit in order to improve reliability of results. Discussion and documentation of definitions prior to commencement of data collection occurred between the researcher and the associate investigator to ensure consistency with how the data was to be collected and interpreted so that both investigators interpreted the data in a similar manner.

The original extraction from the Matrix database identified nine eligible women for the selected six-week period; this alerted us to a significant issue with data entry. A total sum of 2,156 admissions were manually audited for this six-week period and uncovered a further 605 eligible women

(Appendix 7). This audit, although time consuming, identified a significant finding in that, 98.5% of early labour admissions for the selected six-week time frame were either not recorded or inaccurately coded in the Matrix database. A number of quality improvement initiatives were put in place to reduce further error. This included six new computers; education of staff on the importance of documentation, and a system for flagging incomplete admissions once the woman was discharged. This audit made for a more robust sample and the improvements reduced the requirement to manually audit the second time frame. Figure 4 above (page 41) provides an overview of the data collection methods for the Pre-Intervention Cohort.

3.12 Data analysis

Statistical methods

Simple descriptive statistics were used to describe the demographic profile of the women in the Pre and Post-Intervention Cohorts. These were displayed as frequencies and percentages, and assessed for any significant differences in the demographic characteristics of the women in each group. Univariate analysis assessed differences in birth outcomes based on cohort, epidural use and length of stay in PAOU and reported as the difference in proportion with associated 95.0% CI, and level of significance set at 0.05. Length of admission to PAOU was converted to a dichotomous variable (>2hrs: yes/no).

For the primary and secondary outcomes further bivariate analysis (t-tests, and chi-square tests) were undertaken on all the significant variables using Statistical Package for the Social Sciences (SPSS) version 22. The proportion of women using an epidural in labour was the primary outcome measure; therefore it was used as the dependent variable. Odds ratios were calculated with associated 95% confidence interval (CI) to quantify associations between these selected variables and epidural use.

Multivariate analysis was then undertaken, controlling for confounders identified through the literature and bivariate analysis to analyse if there was a relationship to the outcome. All variables except cohort and LOS >2hrs were identified as statistically significant in the bivariate analysis, however as these two variables are clinically relevant to the study they too were entered into a multiple logistic regression for analysis. The Backward: Wald method was used for doing stepwise logistic regression. The default level of significance of 0.05 for entry and 0.10 for removal was used.

3.13 Ethics

Ethics approval was provided by both the Mater Health Services (HREC/13/MHS/82/AM02) and the Australian Catholic University (2013 64Q) Human Research Ethics Committees (HREC) (Appendix 9-14).

Summary

This chapter has described the methods used for this Pre-Post Intervention study, including setting, sample, methodology, outcomes measures, data collection and analysis. A discussion on the challenges faced for the first timeframe and changes made to the data collection strategy for this cohort have also been outlined.

Chapter Four: Results

This chapter will report the findings of the study, specifically the maternal demographic profile and birth outcomes of the women in each cohort. The results for the primary and secondary outcomes are presented. The key findings from this study provided valuable feedback on maternal and infant health outcomes, following the implementation of a service improvement initiative at the MMH.

4.1 Sample

This study involved two timeframes: May 2012 – September 2012 (Pre-Intervention) and October 2012-January 2014 (Post-Intervention). All women meeting the eligibility criteria admitted to the PAOU in early labour were included for the two timeframes. The total number of women represented in this study is 1388 (Pre-Intervention Cohort n= 625; Post-Intervention Cohort n= 763).

4.2 Maternal characteristics

The baseline characteristics of the women in each cohort were compared to determine if both groups had similar demographic profiles, differences were shown across several key indicators (Table 3). The women in the Pre-Intervention Cohort were older, more likely to be multiparous, privately funded, Caucasian women who differed in their BMI status (more likely to be underweight or obese women) and educational attainment (more likely to have a tertiary degree). The Post-Intervention Cohort was made up of more publicly funded, first time mothers, of Asian and non-European ethnicity, with a normal weight range.

Table 3: Demographic profiles of the women across the total cohort

Maternal characteristic	Pre-cohort		Post-cohort		Total n= 1388	p value
	n= 625	%	n= 763	%		
Maternal Age, yr. (mean)	30.4	(SD 5.14)	29.0	(SD 5.21)		<0.001*
<20 years	105	16.8	82	10.7	187 (13.5)	0.003*
20-35 years	504	80.6	653	85.6	1157 (83.4)	
>35 years	16	2.6	28	3.7	44 (3.2)	
Insurance status						<0.001*
Public	403	64.5	581	76.1	984 (70.9)	
Private	222	35.5	182	23.9	404 (29.1)	
Parity						<0.001*
Nulliparous	346	55.4	493	64.6	839 (60.4)	
Multiparous	279	44.6	270	35.4	549 (39.6)	
Ethnicity						<0.001*
Caucasian/European	386	61.8	382	50.1	768 (55.3)	
Aboriginal/Torres Strait Islander	11	1.8	11	1.4	22 (1.6)	
Asian	112	17.9	168	22.0	280 (20.2)	
Other	116	18.6	202	26.5	318 (22.9)	
BMI **						<0.001*
Underweight (<18.5)	142	22.8	63	8.3	205 (14.8)	
Normal (18.5-24.9)	303	48.7	505	66.4	808 (58.4)	
Overweight (25-29.9)	115	18.5	139	18.3	254 (18.4)	
Obese (>30.0)	62	10.0	54	7.1	116 (8.4)	
Education Level ***						0.272
<Grade 10	20	3.3	27	3.7	47 (3.5)	
Grade 10-12	176	28.8	241	32.6	417 (30.9)	
Tertiary	415	67.9	471	63.7	886 (65.6)	
Model of care ****						<0.001*
Standard	343	55.1	512	67.1	855 (61.7)	
Continuity (MGP)	57	9.2	69	9.0	126 (9.1)	
Private Obstetrician	222	35.7	182	23.9	404 (29.2)	
Gestational Age, wks. (mean)	39.41	(SD 1.078)	39.48	(SD 0.978)		0.171

Note. * Statistically significant. Missing data: BMI ** 5; Education***38; Model of care****3

Maternal Age and Parity

A significant difference was seen in maternal age between the two cohorts (women in the Pre-Intervention Cohort were on average 1.5 years older, though this was unlikely to be clinically relevant). The mean age of women in the Pre-Intervention Cohort was 30.4 years, and the mean age in the Post-Intervention Cohort was 29.0 years. Significantly more women in the Post-Intervention Cohort were having their first baby (64.6%) compared to women in the Pre-Intervention Cohort (55.4%, $p = <0.001$).

Insurance status

The representation of private versus public women was not equal in this study. A total of 70.9% (n= 984) of women were from the public sector and 29.1% (n= 404) were from the private sector ($p < 0.001$), despite an equal distribution of public and private women presenting through the PAOU and birthing at the MMH. This difference may be a result of less private women presenting in spontaneous labour, as they are more likely to have elective induction or caesarean births than public women. More women under the care of a private obstetrician were represented in the Pre-Intervention Cohort (35.7% vs. 23.9%).

Ethnicity

Over half of all the women in the study were of Caucasian or European backgrounds, which is representative of the overall demographic of the facility. Significantly more Asian women and other ethnicity groups were represented in the Post-Intervention Cohort. No difference was shown in the number of Aboriginal or Torres Strait Islander women in each group.

Education

The demographic data is representative of a well-educated population with 67.9% of women in the Pre-Intervention Cohort and 63.7% of women in the Post-Intervention Cohort identifying as having a tertiary education. This educational attainment is comparable to the overall level of education data for the facility. No significant difference in education attainment was identified between the two cohorts, although completion of secondary school and women attending tertiary level education were more likely to use an epidural for pain relief, consistent with other sources of evidence.

Body Mass Index (BMI)

A significant difference in weight ranges was seen between the two cohorts with a higher percentage (66.4%) of women in the Post-Intervention Cohort compared with 48.7% in the Pre-Intervention Cohort categorised as being within a normal weight range. More underweight women (22.8% vs. 8.3%) were represented in the Pre-Intervention Cohort ($p < 0.001$).

Model of care at birth

No difference was reported in the number of women booked in Midwifery Group Practice (MGP) models in either cohort with 9% of the participants belonging to these continuity groups. There was however, a significant difference for women's allocated model of care between the two cohorts. More women representing standard care models (public) were in the Post-Intervention Cohort

(55.1%) vs. 67.1%, $p = <0.001$), and more privately admitted women (private) were represented in the Pre-Intervention Cohort (35.7% vs. 23.9%, $p = <0.001$).

4.3 Primary Outcome Analysis

4.3.1 Epidural use

The primary outcome for this study was the proportion of women using an epidural for pain relief in labour Pre and Post Intervention. A total of 46.8% of women in this study used an epidural in labour, consistent with the facility clinical data for the same time period (MMH, 2012, 2013). A higher epidural rate was observed in the Post-Intervention Cohort compared with the Pre-Intervention Cohort (45.1%, vs. 48.2% $p = 0.252$), however this did not represent a statistically significant difference. During the period 2012-2013 the rate of epidural use among women birthing at the MMH rose from 45% (2012) to 47% (2013) ($p < 0.01$).

4.4 Secondary Outcomes Analysis

A number of secondary outcomes including, length of admission in PAOU, and the comparisons of labour and birth outcomes of the women and neonates were used to evaluate the effectiveness of this new early labour care model.

4.4.1 Labour and birth outcomes

Univariate analysis was used to assess differences in birth outcomes between the Pre and Post-Intervention Cohorts. Table 4. below represents the univariate analysis of labour and birth outcomes for the women in the study. Where available, additional data obtained from annual clinical reports show the overall data for the facility. No significant differences in mode of birth were seen, however there was an increase in augmentation with amniotomy (36.6% vs. 51.4%, $p = <0.001$) and use of epidurals in the Post- Intervention Cohort. There was no difference in the proportion of women who had a defined PPH. Additionally, a greater percentage of the 3rd/4th degree tears were from women in the Post-Intervention Cohort (3.1% vs. 10.7% $p = <0.001$), and significantly more babies were admitted to the nursery (2.4% vs. 6.0% $p = 0.001$) if their mothers attended M10E for early labour support.

Table 4: Labour and birth outcomes of all women in the study

Labour and birth outcomes	Total No. (%)	Pre-cohort (n = 625)		Post-cohort (n = 763)		p value	Facility	
		No.	%	No.	%		2012 %	2014 %
LOS_2 hours in PAOU#						0.083		
Less than 2 hours	976 (76%)	455 (73.9)		521 (78.0)				
More than 2 hours	308 (24%)	161 (26.1)		147 (22.0)				
Analgesia								
Non-pharmacological methods (TENS*SWI*Water immersion)	159 (11.5)	60 (9.6)		99 (13.0)		0.049*		
Epidural/spinal epidural#	646 (46.8)	282 (45.1)		364 (48.2)		0.252	(45.0)	(47.0)
Augmentation								
ARM	621 (44.7)	229 (36.6)		392 (51.4)		<0.001*		
Oxytocin	538 (38.8)	245 (39.2)		293 (38.4)		0.761		
Colour of liquor#						0.002*		
Clear	986 (71.3)	474 (76.0)		512 (67.5)				
Bloodstained	74 (5.4)	30 (4.8)		44 (5.8)				
Meconium stained liquor	322 (23.3)	120 (19.2)		202 (26.6)				
Mode of birth#						0.664		
Spontaneous vaginal birth	885 (63.8)	405 (64.8)		480 (63.0)			(49.1)	(49.4)
Instrumental birth	272 (19.6)	116 (18.6)		156 (20.5)			(11.9)	(13.3)
Emergency caesarean	230 (16.6)	104 (16.6)		126 (16.5)			(17.8)	(16.5)
Genital trauma a) (n=1157)						<0.001*		
Intact/1st degree	600 (51.8)	281 (53.9)		319 (50.2)				
2nd degree	473 (40.8)	224 (43.0)		249 (39.2)				
3rd/4th degree	84 (7.3)	16 (3.1)		68 (10.7)			(4.0)	(3.4)
Episiotomy#	309 (22.3)	108 (17.3)		201 (26.4)		<0.001*		
Blood Loss#						0.038*		
<500mls	1097 (79.1)	485 (77.6)		612 (80.3)				
500-1000mls	228 (16.4)	119 (19.0)		109 (14.3)				
1000-1500mls	47 (3.4)	15 (2.4)		32 (4.2)				
>1500mls	15 (1.1)	6 (1.0)		9 (1.2)				
Birth weight						0.115		
<4 kg	1233 (88.8)	546 (87.4)		687 (90.0)			(89.3)	(90.2)
>4 kg	155 (11.2)	79 (12.6)		76 (10.0)			(10.6)	(9.9)
Admission to nursery								
SCN/ICN/NICU	61 (4.4)	15 (2.4)		46 (6.0)		0.001*	(10.6)	(10.8)

Note. * Statistically significant, a) adjusted crosstab to exclude women having emergency caesarean, # Missing data: LOS_2hrs = 104 (7.5%); Epidural use = 8; Colour of liquor = 6; Mode of birth = 1; Episiotomy = 2; Blood loss = 1

Incomplete Data

A number of records contained incomplete data. The majority of missing data was for: LOS_2 hours in PAOU due to either the admission time or discharge time not being recorded, therefore the total length of admission was unable to be calculated for 7.5% of the study population. Genital tract trauma had fewer women included in the analysis due to the exclusion of those who had a baby by emergency caesarean section as they would not usually have had any genital tract trauma. Episiotomy has been collected as a separate variable to genital tract trauma, as a woman can have both an episiotomy as well as a tear.

4.4.2 Length of time spent in the PAOU in early labour

The introduction of a dedicated early labour area demonstrated a reduction in the proportion of women remaining in the PAOU after triage and assessment longer than the recommended two hours (26% to 22%, $p=0.083$), but did not reach statistical significance. Women in standard care models were more likely to remain in PAOU greater than two hours compared to privately admitted women and women in continuity models ($p=0.015$).

Although not significant there was a higher use of epidurals and augmentation of labour with oxytocin for women with an increased length of admission in PAOU. Longer admission's to PAOU in early labour was positively associated with an increased emergency caesarean rate (<2hrs = 14.8% vs. >2hrs = 23.7%, $p=0.001$) and a decreased vaginal birth rate (<2hrs = 65.5% vs. >2hrs = 57.8%, $p=0.001$) (Table. 5).

Table 5: Differences in birth outcomes by length of admission to PAOU (greater than or less than 2hrs).

Outcome	All women (N= 1284#)		
	LOS in PAOU < 2hours (N=976)	LOS in PAOU > 2hours (N=308)	p value
Augmentation of birth (ARM)	436 (44.7%)	128 (41.6%)	$p= 0.337$
Augmentation of birth (oxytocin)	367 (37.6%)	132 (42.9%)	$p= 0.099$
Colour of Liquor			$p= 0.002^*$
Clear	703 (72.4%)	204 (66.4%)	
Meconium stained liquor	332 (23.3)	74 (24.1%)	
Blood stained	41 (4.2%)	29 (9.4%)	
Mode of Birth			$p= 0.001^*$
Spontaneous vaginal birth	639 (65.5%)	178 (57.8%)	
Instrumental birth	192 (19.7%)	57 (18.5%)	
Emergency caesarean	144 (14.8%)	73 (23.7%)	
Postpartum haemorrhage			$p= <0.001^*$
1000-1500mls	26 (2.7%)	13 (4.2%)	
>1500mls	7 (0.7%)	7 (2.3%)	
Admission to nursery	40 (4.1%)	14 (4.5%)	$p= 0.733$
Epidural	448 (46.2%)	151 (49.3%)	$p= 0.334$

Note. # adjusted crosstab (104 missing for LOS_2hrs)

* statistically significant

4.5 Bivariate Analysis – Primary Outcome

The relationship between epidural use (dependent variable) and several independent variables were chosen because of either a clinical relevance to this study (LOS and cohort) or they had been identified in the literature review as being predictors for epidural use. Level of education was compared against the lowest possible category as the literature identifies ‘higher education levels’ not a specific level. Augmentation of labour is well reported in the literature to increase the use of epidurals, however this study was unable to differentiate whether these interventions occurred before or after epidural insertion. ‘Other’ ethnicity was chosen as the category for comparison as women in minority ethnic groups represented within this category have been identified in the literature to be less likely to use an epidural in labour. Odds ratios were calculated to quantify associations between the selected variables and epidural use (see Table 6 below).

Table 6: Bivariate analysis of association between epidural use and selected independent variables.

Independent Variables	OR	95% CI	p value
Cohort	1.132	0.915-1.401	<i>p</i> = 0.252
Nulliparity	3.631	2.880-4.577	<i>p</i>= <0.001*
Ethnicity			
Other	1		
Aboriginal/Torres Strait Islander	0.957	0.390-2.351	<i>p</i> =0.924
Caucasian	1.697	1.297-2.221	<i>p</i>= <0.001*
Asian	1.581	1.139-2.196	<i>p</i>= 0.006*
Education level			
<10	1		
10 to 12	2.424	1.200-4.894	<i>p</i>= 0.014*
Tertiary	3.31	1.664-6.587	<i>p</i>= 0.001*
Model of care			
Standard	1		
Continuity	0.934	0.639-1.366	<i>p</i> = 0.726
Private	1.75	1.377-2.223	<i>p</i>= <0.001*
LOS >2hrs	1.135	0.878-1.468	<i>p</i> = 0.334
ARM performed	3.491	2.795-4.362	<i>p</i>= <0.001*
Syntocinon	14.965	11.390-19.663	<i>p</i>= <0.001*

Note. *Statistically significant

Several maternal factors were shown to be significant predictors for epidural use in the bivariate analysis and are consistent with those maternal characteristics identified in the literature. First time mothers, women of Caucasian and Asian ethnicity, those with higher education levels and booked with a private obstetrician were more likely to use an epidural in labour. Additionally, labours that had been augmented by any method (amniotomy or oxytocin infusion) were significantly more likely to use an epidural during the labour. Cohort and LOS in PAOU were not identified as significant predictors for increasing a woman's choice of using an epidural during labour, however these variables remained in the final regression model because of their clinical relevance to the study.

4.6 Multiple-variate Analysis – Primary Outcome

Multivariate logistic regression was undertaken with the dependent variable epidural use (yes/no) to identify potential predictors. Confounders identified through the bivariate analysis (Table 6) were included in the model. The same independent variables used in the bivariate analysis were used for the final regression model, due to their significant association with epidural use among women admitted in early labour. Although no statistical significance was identified for Cohort and LOS, they remained in the final regression model for their clinical significance to the study. The independent variables included in the final regression model were:

- Cohort (Pre-Intervention or Post-Intervention)
- Nulliparity (yes/no)
- Ethnicity (Aboriginal/Torres Strait Islander; Caucasian; Asian or Other)
- Education level (<grade10; grade 10-12; Tertiary)
- Model of care at birth (Standard; Continuity or Private)
- LOS more than 2hrs (yes/no)
- Augmentation of labour with ARM (yes/no)
- Augmentation of labour with Syntocinon (yes/no)

The collinearity diagnosis showed that there was no collinearity that existed between these predictors ($VIF < 2$, tolerance > 0.70), indicating they are independent of each other.

The final regression model (Table 7) did not identify Cohort or longer LOS in PAOU as having a significant association with the rate of epidural use. Instead maternal characteristics such as nulliparity (OR: 1.507, $p = 0.01$), Caucasian ethnicity (OR: 1.686, $p = 0.008$), private insurance status (OR: 1.437, $p = 0.037$) and whether a woman's labour was augmented with amniotomy (OR: 2.827, $p = < 0.001$) or syntocinon infusion (OR: 11.525, $p = < 0.001$) showed a positive association with a higher epidural rate. These findings are consistent with those maternal factors identified in the literature as predictors for epidural use.

Table 7: Significant predictors for epidural use following multivariate analysis.

Independent Variables	OR	95% CI	p value
Nulliparity	1.507	1.103-2.058	<i>p=0.010*</i>
Ethnicity			<i>p=0.059</i>
Aboriginal/Torres Strait Islander	1.333	0.431-4.122	<i>p=0.617</i>
Caucasian	1.686	1.149-2.472	<i>p=0.008*</i>
Asian	1.256	0.809-1.951	<i>p=0.310</i>
Model of care at birth			<i>p=0.066</i>
Continuity	0.872	0.513-1.485	<i>p=0.615</i>
Private	1.437	1.022-2.021	<i>p=0.037*</i>
ARM performed	2.827	2.126-3.758	<i>p=<0.001*</i>
Syntocinon	11.525	8.369-15.869	<i>p=<0.001*</i>

Note. * statistically significant

A Receiver Operating Curve (ROC) is a plot of the true positive (sensitivity) rate against the false positive (1-Specificity) and frequently used as a measure for the effectiveness of diagnostic markers or different possible cut points of a diagnostic model (Faraggi & Reiser, 2002). The area under the curve (AUC) is a measure of the test accuracy. There is traditional academic point system for classifying the accuracy of a diagnostic model: AUC 0.90-1=excellent, AUC 0.80-0.90=good, AUC 0.70-0.80=fair, AUC 0.60-0.70=poor and AUC 0.50-0.60=fail (Faraggi & Reiser, 2002). The AUC for the multivariate model presented in Table 7 is 0.844 as shown in Figure 5 below. This model would be considered to be 'good' at separating the factors that may be impacting on whether women are 'using an epidural' from those who are 'not using epidural' during labour.

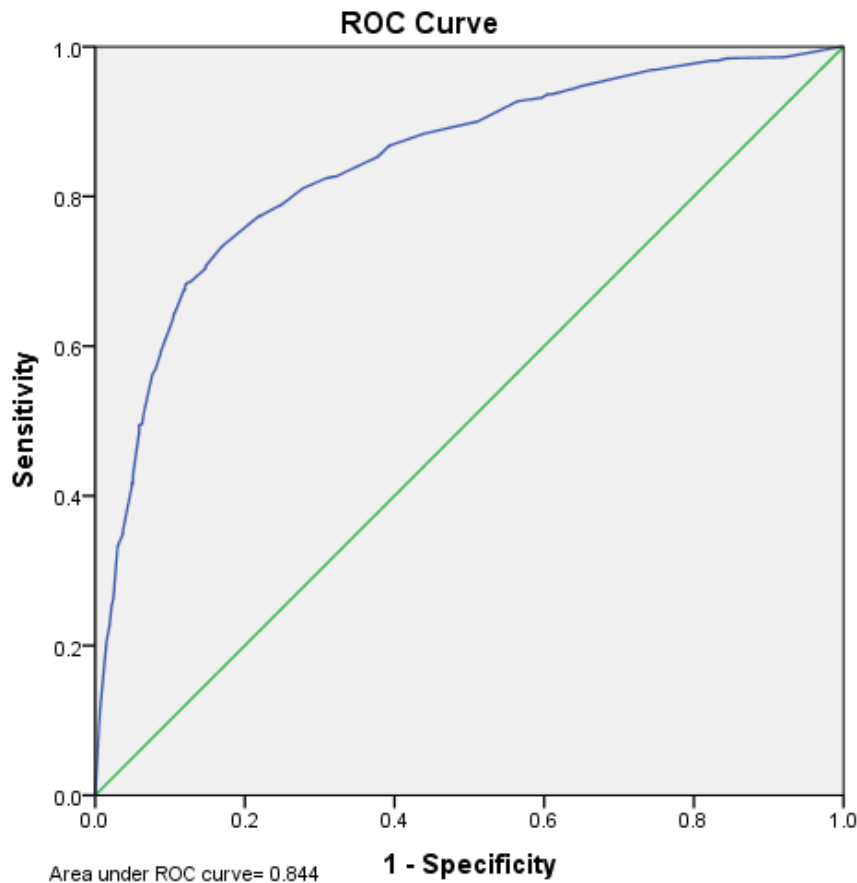


Figure 5: Receiver Operating curve (ROC) of using parity, ethnicity, model of care, artificial rupture of membrane and oxytocin induction to predict having an epidural or not in labour.

Maternal factors and birth outcomes associated with epidural use

Women booked privately were more likely to use epidurals than publicly funded women (56.6% vs. 42.8%, $p = <0.001$), as were first time mothers (76.0% vs. 24.0%, $p = <0.001$) and women with higher levels of education levels with 70% of women with tertiary education electing to use an epidural ($p = <0.001$).

A summary of the labour and birth outcomes for mother and baby are outlined in Table 8. Women who had their labour's augmented with either ARM and/or oxytocin infusion were more likely to use of an epidural for pain relief in labour, compared to those women who did not experience these types of intervention in labour (60.7%/68.7% vs. 41.6%; $p = <0.001$). Additionally, more women used non-pharmacological methods of pain relief (TENS, water immersion and SWI) during their labour in the Post-Intervention Cohort (9.6% vs. 13.0%, $p = 0.049$).

Women were less likely to achieve an SVB (42.9% vs. 82.2%; $p = <0.001$) when using an epidural. A greater proportion of women experienced an instrumental or caesarean section when they chose to

use an epidural (Table. 8). Of the 309 women requiring an episiotomy, 54.2% of them used an epidural compared with 44.6% (which maybe explained by more instrumental births with epidural use) ($p=0.003$). Significantly more babies were admitted to the nursery when their mothers used an epidural (6.5% vs. 2.6%; $p= 0.001$).

Table 8: Birth outcomes based on epidural use

Outcome	All women (N=1380#)		
	Epidural (n= 646)	No Epidural (n= 734)	p value
Spontaneous rupture of membranes	269 (41.6%)	511 (69.6%)	$p= <0.001^*$
Augmentation of birth (ARM)	392 (60.7%)	225 (30.7%)	$p= <0.001^*$
Augmentation of birth (oxytocin)	444 (68.7%)	94 (12.8%)	$p= <0.001^*$
Mode of Birth			$p= <0.001^*$
Spontaneous vaginal birth	277 (42.9%)	603 (82.2%)	
Instrumental birth	208 (32.2%)	63 (8.6%)	
Emergency caesarean	160 (24.8%)	68 (9.3%)	
Estimated blood loss			$p= <0.001^*$
<500mls	477 (73.8%)	613 (83.6%)	
500-1000mls	138 (21.4%)	89 (12.1%)	
1000-1500mls	24 (3.7%)	23 (3.1%)	
>1500mls	7 (1.0%)	8 (1.1%)	
Episiotomy	167 (54.2%)	141 (45.8%)	$p=0.003^*$
Admission to nursery	42 (6.5%)	19 (2.6%)	$p= <0.001^*$
LOS_2 hours in PAOU#			$p= 0.334$
Less than 2 hours	448 (74.8%)	522 (77.1%)	
More than 2 hours	151 (25.2%)	155 (22.9%)	

Note. # Missing data: No. of all women using epidural = 8; LOS_2hrs in PAOU = 112. * Statistically significant

Summary

This chapter presented the results of the quantitative data analysis for the primary and secondary outcomes explored in this study. The aim was to test a clinically significant difference between epidural rates used among women presenting to hospital for early labour care. Additional aims were to provide a baseline of measurable clinical outcomes, to assist with evaluating this change in service. And explore if an increased length of time spent in the PAOU was associated with a higher rate of obstetric interventions, such as augmentation and epidural use.

The study was powered to see a reduction in epidural rates by 8%. For this primary outcome the null hypothesis was accepted, in that no difference was seen between the two cohorts. The variables that were identified as significant predictors for epidural use after controlling for confounders were not place of care for early labour or length of admission to the PAOU as hypothesized. Instead maternal characteristics: nulliparity, Caucasian ethnicity, and private model of care, along with augmentation of labour were stronger predictors for epidural use, strengthening findings within the existing body of evidence. The secondary outcomes provided a baseline comparison between two cohorts of women presenting to hospital in early labour and identified significant differences between the groups. Data collection challenges impacted significantly the conduct of this study, including the time needed to compile the data and complete the study. This may have impacted the results and will be discussed further in section 5.3 under limitations.

Based on the study design, any assumption about whether a causal association between women attending M10E for early labour care and epidural use could not be made. The results of this study contribute to the existing body of evidence however, by suggesting admission to hospital is the issue as much as early admission to birth suite. Hospital management need to continue monitoring the clinical outcomes of women seeking early labour support and investigate the impact of non-clinical factors such as staffing and skill mix as well as modifiable service delivery and resources on intervention use.

Chapter Five: Discussion

This study aimed to provide a baseline of measurable clinical outcomes in particular the rate of epidural use among women admitted to hospital during early labour. In a broader review, these clinical measures aimed to assist the organisation to evaluate the effectiveness of a change in early labour care, by setting a benchmark and the identification of further service improvements. This chapter discusses the findings associated with epidural use and length of admission for this cohort of women, making reference to the available literature and commenting on the relevance to the facility. The limitations are discussed, as are recommendations for future research.

5.1 Overview

The introduction of M10E aimed to improve the flow of work through the PAOU, by introducing a new location in the hospital providing better accommodation and a higher level of safety and privacy for women seeking early labour care. This new early labour care model has met these operational objectives by relieving bed blockages and workload on midwives in PAOU, offering women a private room with own ensuite, enabling support people to remain with the woman, providing an alternative care option and access to equipment such as birth balls, shower, and freedom to mobilise. However the findings related to the outcomes for women (rates of augmentation, instrumental use, emergency caesarean and the number of babies requiring nursery admission) are not as positive as expected. The results from this study raise important questions about how to further improve the provision of early labour care for the women.

5.2 How should the benefits be evaluated?

Service improvement initiatives are a way for healthcare organisations to tackle variations in the quality of care and improve public satisfaction. They often involve a complex redesigning process (Locock, 2003). Service interventions are often theories based on a hypothesis: “if we manage services like so, then this will bring about some improved outcome” (Pawson, Greenhalgh, & Harvey, 2005, p. 22). Furthermore, they achieve their best effect via the actions of individuals involved. Interventions begin with policy makers, pass down to managers, educators and individual clinicians and then into the minds of the patients (Pawson et al., 2005). Authors Brodie and Leap (2008) write about the strategies that are important for the successful implementation of women-centred birth territories within maternity services in Western countries. First writing about the importance of developing an understanding of what is ideal and then planning changes that are possible within existing budgets (Brodie & Leap, 2008). Having identified what type of intervention to use to address the issues, the next step is to look at the research methods, to identify what needs to be measured

in order to evaluate the effectiveness of the service improvement and the interaction it has had within the organisation (Powell, Rushmer, & Davies, 2009).

As previously mentioned, the MMH developed a collaborative working party to review service provisions through the PAOU and identified an area of service improvement for the management of women presenting to the hospital seeking early labour support. The decision to implement a change in early labour care management was in response to the growing number of women presenting to the hospital during this stage of labour who did not want to go home. Additionally, the Australian National Maternity Services Plan set out a five year vision (2010-2015) for all women to have access to high quality, woman-centred, evidenced-based, culturally competent maternity care in a range of settings close to where they live (The Australian Health Ministers' Conference, 2010). Careful consideration by hospital management and members of the collaborative working party were made for both the benefits as well as the wider ramifications for the health service and the women.

As described in detail in Chapter Three (methods) the intervention for this study was a change in early labour management and the introduction of a dedicated early labour space away from PAOU and Birth Suites. The PAOU was not considered an environment conducive to normal labour due to its small clinical rooms and high acuity. These factors limited the services and care available to women identified as not suitable for transfer through to BS or reluctant to return home. Additionally the timeframe of keeping women for less than two hours may have impacted on the quality of service provided to women seeking support in early labour. Thus the new location on M10E was chosen to provide improved accommodation and privacy for women to have their own room and ensuite bathroom in an area away from the assessment unit.

Changes to infrastructure, policy, management protocols within PAOU, and role description of staff on level M10E are all system adaptations the hospital successfully implemented for this intervention to improve service delivery. The challenge then, for evaluating effectiveness lies in how the change in resources and outcomes for women can be measured or valued, and whether outcomes can be attributed to the change in service delivery. This study aimed to assist with this evaluation by making comparisons between the labour and birth outcomes of women presenting before and after the implementation of M10E. The results show a change in model and location of care did not improve upon the number of epidurals being used during labour, nor have a significant impact on the number of interventions.

This could be explained by the complex nature of the intervention, the new location is just one aspect of the change in care, not all women presenting in early labour were transferred to M10E.

This study was unable to differentiate these women as the data was collected retrospectively based on admission to PAOU. Therefore within the study population there are possibly three subsets of women presenting in early labour: those who return home after initial assessment (Pre or Post-Intervention), those who were admitted to the ward, BS or PAOU (Pre-Intervention) and those that were admitted to M10E, BS or PAOU (Post-Intervention).

5.2.1 Epidural use

With regards to the primary outcome of the study there was no reduction in the frequency of epidural use observed for women seeking early labour care following the introduction of the early labour area. Rather a slight increase in epidural rates (although not significant) was shown for the women in the Post-Intervention Cohort (45% vs. 48%; $p=0.252$).

One assumption is those women who remained in the hospital pre or post intervention were those women more uncertain about labour events and anxious about returning home. Women who are uncertain about recognising the signs of labour and identifying the right time to transfer to hospital, particularly first time mothers (Neal et al., 2014; Spiby et al., 2007), seek additional support and validation from health professionals at the first signs of labour. Buckley (2003) and Lowe (2002) suggests this has a flow on effect; a loss of confidence and increasing anxiety provokes an increase in fear. Fear activates the release of adrenaline and noradrenaline (catecholamine's) to enact the fight or flight reaction, causing an interruption to woman's sense of safety, and altering the natural hormones of labour. An alteration in the balance of rising labour hormone can cause the labour to slow or stop. Additionally this can cause an interference with the release of beta-endorphins, which are the body's natural pain-killers (Buckley, 2003) and a woman's ability to cope with the pain of labour.

A lower degree of coping, has been suggested in a recent cross-sectional study conducted across two neighbouring countries (Netherlands and Belgian) to be an independent factor for a woman's pre-labour preference for epidural analgesia (Wassen et al., 2013). This is consistent with earlier evidence, that identified an antenatal plan to use an epidural was strongly associated with a woman receiving one and of having earlier administration (Goldberg, Cohen, & Lieberman, 1999). Therefore maternal preference for epidural analgesia as part of a woman's birth plan, and whether a woman attended antenatal education are both important factors to consider. Neither of these factors, was an outcome measure for this study, but would have helped identify them as contributing factors, and should be considered for future investigation.

The change in model of care and length of admission to hospital were not identified as significant predictors for epidural use for the women in this study. Rather the study's regression model

identified maternal factors such as private model of care, nulliparity, level of education and Caucasian ethnicity to be the significant predictors for epidural, similar to the socio-demographic factors identified in the literature: older women (Biro et al., 2012; Carolan et al., 2011); having their first baby (Bailit et al., 2005; Schytt & Waldenstrom, 2010; Tracy et al., 2007); with higher income (Liu et al., 2010); and educational attainment (Ekeus et al., 2010; Lancaster et al., 2012; Orejuela et al., 2011). The different demographic profiles of the women in the two cohorts may therefore have contributed to the outcomes. As previously mentioned (section 4.2) the Pre-Intervention Cohort had a greater proportion of Caucasian women, with higher educational attainment who had birthed before, and were admitted under the care of a private obstetrician. The Post-Intervention Cohort had a greater proportion of first-time mothers of Asian or non-European decent admitted within standard care models.

Ethnic background was unlikely to have been a determinant in this study, as the final regression model identified Caucasian women as a stronger predictor and more Caucasian women were included in the Pre-Intervention Cohort. Additionally, the increased portion of Asian and non-European women in the Post-Intervention Cohort contradicts this finding, as more epidurals were used in the Post-Intervention Cohort. However, ethnicity has been identified across several population-based studies to be a determinant for acceptance of epidural analgesia (Dahlen et al., 2015; Jimenez-Puente et al., 2012; Ochroch et al., 2007).

The over representation of nulliparous women may explain the results in the Post-Intervention Cohort. There is strong evidence that first time mothers are more likely to use an epidural in labour (Bailit et al., 2005; Bhattacharya et al., 2006; Jeschke et al., 2012; Kpea et al., 2015; Raisanen et al., 2014; Steel et al., 2015; Tracy et al., 2007), the study's regression model contributed to this body of evidence. Perception of pain in early labour for nulliparous women, has been identified to be different to multiparous women (Lowe, 2002) after earlier sources of evidence indicate first time mothers on average experience greater sensory pain than multiparous women (Brown, Campbell, & Kurtz, 1989; Lowe, 1992; Shiener & Shoham-Vardi, 1998), however this pain decreases for both during the second stage (Lowe, 1992).

There is growing evidence women are delaying childbearing, and although the age cut-off is still being debated, a maternal age greater than 35 years continues to be associated with poorer outcomes (Biro et al., 2012; Callaway, Lust, & McIntyre, 2005; Carolan et al., 2011). In this study there was a statistically significant difference in the mean age of the women in the study (women in the Pre-Intervention Cohort were on average 1.5 years older than those in the Post-Intervention Cohort). However despite the cohort's mean age being less than 35 years, the epidural rates were

higher for the Post-Intervention Cohort. Maternal age may have impacted the results of this study in other ways. The women in the Pre-Intervention Cohort may be younger due to changes to clinical policy over the course of this study. Women over the age of 35 years are more likely to have their labours induced in accordance with current clinical guidelines (Royal College of Obstetricians & Gynaecologists, 2013). Women in this study over the age of 35 years were more likely to have had their labours induced at facility (Mater Misericordiae Health Services Brisbane Limited, 2015) in the last two years and therefore would not have been eligible for inclusion in the Post-Intervention Cohort.

Maternal age has not been found to be a factor for altering the attitudes or beliefs upon the use of intrapartum pain management, however is an important risk factor when considering intervention use due to many pregnancy morbidities (such as pre-eclampsia, pregnancy-induced hypertension, and multiple pregnancy) being associated with older women (Biro et al., 2012) and epidural use (Raisanen et al., 2014). Epidurals are commonly recommended within clinical guidelines for managing women with high blood pressure (Queensland Health, 2015) or multiple births. In Australia, the birth rates for women aged 35 years or more are increasing, and age-related trends for intervention use in labour such as induction of labour and epidural use has been identified (Biro et al., 2012; Carolan et al., 2011; Wassen et al., 2013). Further evidence from these Australian population based studies show older women are more likely to have private health insurance (Roberts et al., 2000), and privately insured women, are more likely to be booked for an induction or caesarean (Biro et al., 2012; Carolan et al., 2011; Roberts et al., 2000). This may explain the age difference between the two cohorts, as well as account for the difference seen in insurance status.

Women in this study under the care of an obstetrician were more likely to request an epidural, have their labour's augmented (either as a result of the epidural or for other factors not identifiable in this study) and more likely to have an instrumental birth compared to women in standard care models. This maybe because women without obstetric complications under the care of a private obstetrician are often encouraged to have continuous fetal monitoring (restricting mobility and optimal positioning) and epidural analgesia (Johansen et al., 2002). Two Australian population studies compared the risk profiles of low-risk women giving birth in private and public hospitals over a ten-year period, found the rates of obstetric interventions were highest for those giving birth in private hospitals (Dahlen et al., 2012; Roberts et al., 2000), particularly for first time mothers and after epidural (Roberts et al., 2000). The significance of these studies is that regardless of the low-risk status of the women, the intervention rates such as instrumental, caesarean births and epidural use

continued to rise year by year and was most likely associated with variations in individual practices of the practitioners than poor maternal health (Dahlen et al., 2012).

Publicly insured women accessing continuity of care models in this study were less likely to use an epidural in labour, consistent with recent findings in Australia and internationally (Davey et al., 2013; McLachlan et al., 2012; Sandall et al., 2013). Only 9% of the study population however, were women booked in continuity of care models (MGP), and this was equal between the two cohorts. Davey et al (2013) and Tracy et al (2013) attribute the high rate of normal birth in these models, to women being cared for by a known midwife. Women with a known midwife receive individualised phone advice and support before admission. They are therefore more likely to remain at home longer, reducing early labour admissions because they are better informed about the expectations of labour and birth, and feel comfortable to recognise when the active phase of labour has begun (Davey et al., 2013). Care with a known midwife should be an avenue to consider when reviewing future service improvements, to increase the number of women accessing these models of care at the MMH. A possible solution that warrants further consideration may be to allow the midwife from M10E to remain with the woman after transfer to birth suite, and investigation as to whether having a 'known' midwife from early labour may influence epidural rates.

Population-based studies conducted in Sweden and Australia identify that the decision to use an epidural in labour is influenced not only by maternal factors but also by the institutional and cultural practices in the maternity unit (Carolan et al., 2011; Kpea et al., 2015; Mead & Kornbrot, 2004; Newnham et al., 2015; Schytt & Waldenstrom, 2010). The risk culture often reflected within tertiary settings, such as the MMH, can affect midwifery practice and information sharing as well as maternal choice (Carolan-Olah et al., 2015; Freeman, 2006; McDermott, 2010; Y. Miller, Prosser, & Thompson, 2015; Newnham et al., 2015). Further evidence from a large cross-sectional study conducted in France studied factors associated with a woman's initial preference for and actual factors associated with epidural use. This study identified larger maternity units with around the clock availability of an anaesthetist as well as high midwife workload played a major role in a woman's intrapartum decision to use an epidural who initially preferred not to have one (Kpea et al., 2015).

Pain behaviours may vary among different cultures as a result of learned behaviour (Lowe, 2002). A woman's antenatal expectation of labour pain is created out of her exposure or experience (Ferguson et al., 2013; Wassen et al., 2013) and is associated with a prelabour preference for epidural use (Carolan-Olah et al., 2015; Wassen et al., 2013). Care providers have an opportunity in the antenatal period to help women build confidence in themselves and their ability to birth without

unnecessary interventions. Recommendations to close the gap between a woman's labour expectations and the actual event include improvement in antenatal education attendance (Y. Miller et al., 2015), as evidence has shown a reduction in anxiety and early labour admissions (Ferguson et al., 2013). However, as described previously, more research is required to evaluate the effect of antenatal education on interventions used in labour as they are largely unknown due to a lack of widely adopted standards and guidelines (Ferguson et al., 2013). A systematic review of maternal confidence for physiologic birth identified women have a desire for information during pregnancy and they want to be involved in decisions made (Avery, Saftner, Larson, & Weinfurter, 2014). Much of the research on enhancing women's confidence to give birth with minimal interventions is derived from qualitative studies. A recommendation for future research from this systematic review was to develop interventions aimed at helping care providers enhance a women's confidence and for the development of a tool to measure confidence for use in the antenatal period (Avery et al., 2014). With the rate of epidural use rising at the MMH, this is an area to consider for future research and service planning.

Summary

The overall frequency of women in this study who used an epidural was 47%. Far greater than the national average (33%) (Australian Institute of Health and Welfare, 2015) and WHA benchmark (25.1%) (Women's Healthcare Australasia, 2013), but reflective of the overall Mater clinical data for the same time period. The trend towards increasing epidural use in the Post-Intervention Cohort may therefore be a result of the statistically significant increase in epidural use at the facility over the study period previously mentioned from 45% (2012) to 47% in (2013) $p = <0.01$ (MMH, 2012, 2013). This is strengthened by suggestions made by Australian researchers the rise in epidural rates over the past two decades is only partially explained by changes in maternal and obstetric factors (such as increased age of first time mothers, induced labours, private health insurance and giving birth in larger hospitals), and that the unexplained increase maybe due to an increased availability, a change in anaesthetic practice or maternal preference for epidural as a chosen analgesic option. It may therefore be speculated that the differences in the use of epidural seen in the Post-Intervention Cohort could be partially explained by pregnancy complications, need for epidural and women's maternal request, rather than early labour management.

5.2.2 Labour and birth outcomes

The findings from this study have shown it is not enough to simply change the place of care for women in early labour. Early labour admissions have been identified as predictors for poorer labour and birth outcomes (Hemminki & Simukka, 1986; Holmes et al., 2001). The labour and birth outcomes data for the women in the Post-Intervention Cohort were in almost all categories sub

optimal, compared to the Pre-Intervention data, even though an assumption all women would have received comparable care in birth suite. These results may reflect changes in clinical practice that are not associated with location of early labour care. This is consistent with the evidence presented in the literature, that innovations in early labour care did not effect birth outcomes, only improved the women's satisfaction with care (Cheyne et al., 2008; Janssen et al., 2006; Spiby et al., 2008).

The commonly accepted normal birth definition (as previously described) has been demonstrated to have declined in high income countries with an increased use of medical interventions such as epidural use (Maternity Care Working Party, 2007; Y. Miller et al., 2015), especially in countries where private obstetricians have increasingly taken over the responsibility for normal birth in addition to high-risk obstetrics (Johansen et al., 2002). Here in lies the relevance for this study, the MMH is co-located public and private with an existing telephone and early labour assessment that has been identified as no longer meeting the needs of the women and the health service.

Mode of birth and augmentation of labour

Despite the differences in demographic profiles of the women in the two cohorts, there was no significant difference in mode of birth. However, fewer women achieved a vaginal birth and more women had their labours augmented when using an epidural, consistent with the current evidence (Anim-Somuah et al., 2011; Eriksen, Nohr, & Kjaergaard, 2011; Hung et al., 2015; Lancaster et al., 2012; Leibermann & O'Donoghue, 2002). The increased augmentation rates for the women in the Post-Intervention Cohort was an unexpected finding as early labour care initiatives previously reported such as M10E have been associated with lowering the use of oxytocin (Homer, Brock, & Matha, 1999; Lauzon & Hodnett, 2001; McNiven et al., 1998). The regression model found augmentation of labour using amniotomy and/or oxytocin infusion to be independent predictors for epidural use, however data collected on augmentation for this study did not identify whether the need for augmentation preceded, or was a result of the epidural which is a limitation of the findings in this study, making an opportunity for further study to look for possible cause and effect.

Perineal trauma

Another unexpected finding was the increased number of third and fourth degree tears (3.1% vs. 10.7%, $p=0.001$) and a significantly greater number of episiotomies performed for the women in the Post-Intervention Cohort (17.3% vs. 26.4%, $p<0.001$). There is no previous association between early labour admission and perineal trauma in the literature reviewed, however epidural analgesia is associated with an increase in the rate of severe perineal trauma because of the more frequent use of instrumental births (Anim-Somuah et al., 2011; Robinson, Norwitz, Cohen, McElrath, & Lieberman,

1999) which may also account for the increased rate of episiotomy observed. Women of Asian ethnicity have been strongly associated with increased rates of severe perineal trauma (Dahlen, Ryan, Homer, & Cooke, 2007). The higher portion of Asian women represented in the Post-Intervention Cohort, may have contributed to the significant difference reported. Or this may simply be a flow on effect of the intervention cascade, for example the perceived delay in second stage from the epidural.

Admission to nursery

In this study, more babies in the Post-Intervention Cohort were admitted to the nursery although this cannot be attributed to the increased epidural use in this group it again may be reflective of the overall increase in interventions associated with this cohort. It is not within the scope of this study to draw associations, but to identify this clinical outcome as an area that requires further investigation and monitoring.

Data collected on the colour of liquor revealed more meconium stained liquor was seen in the birth outcomes data of the Post-Intervention Cohort. Meconium stained liquor can be present in either post maturity or fetal distress however regardless of cause, the presence of meconium liquor was frequently managed with augmentation at the research site if labour was not well established, and a neonatologist is always present for the birth. There was no difference in the mean gestational age of women giving birth in either cohort (39.4 weeks). However, the reported increase in meconium liquor of the women in the Post-Intervention Cohort, may have contributed to the finding of increased augmentation and instrumental births in this group as well as the greater portion of babies being transferred to the nursery.

Summary

The labour and birth findings from this study identify the timing of when women are admitted to hospital for early labour care continues to be an important decision for healthcare services due to the influence on interventions used. One possible explanation why the change in early labour management did not improve birth outcomes, or the rate of epidural use, is the women in this study are representative of an anxious population. Therefore the benefits of an improvement in the management of early labour care may be restricted to a subset of women, for example those experiencing a short latent phase or who remained at home longer before transferring for initial assessment.

Maternal factors emerging from the literature as predictors for epidural use are strengthened further by results from this study, however due to the methods used cannot be represented as a

direct cause and effect. A number of possible explanations have been discussed for the increased proportion of women using an epidural in labour for the Post-Intervention Cohort. The profiles of women in each cohort were comparatively different with respects to their age, ethnicity, parity, education attainment and model of care. There was no difference with respect to their obstetric characteristics including mean gestational age and baby's birth weight. A greater percentage of women having their first baby, despite them being younger and publicly funded may have contributed to the increase in epidural use, as they are more uncertain about labour events and may fear labour regardless of their location. Other maternal factors not collected, such as antenatal education and a pre-labour preference for epidural use may also have contributed to the increase use of epidurals for the Post-Intervention Cohort. Without appropriate education, realistic expectations and confidence in their own ability, women may continue to seek reassurance from the professionals due to a drive to seek a safe place to birth.

Another possible explanation for the increase may have more to do with the risk-focused culture and availability of anaesthetists being a tertiary referral centre. The introduction of M10E provided an alternative option to remain in hospital supported during the early stage of labour, however the results may simply reflect women remain in a clinical environment. The MMH management and executive policy makers need to consider the social, institutional and cultural influences for the women and their decision to use an epidural in labour. In addition, reflect on the advantages of home-like environments, often seen in non-obstetric units and how these can be applied to support the efforts to expand services for low-risk women. Furthermore, care providers need to be sensitive to a woman's need for validation and see this as a opportunity to educate and support rather than act as gatekeepers. This will not only change a woman's beliefs about safety, pain and her own strength, but will inevitably change the political and medical climate surrounding normal birth.

5.2.3 Changes for Mater Mothers' Hospital

The change in model of care was not only to improve the flow through the unit but came in response to recommendations from government reforms to improve access to women-centred care and the body of evidence to produce guidelines on managing women admitted in the early stage of labour (The Australian Health Ministers' Conference, 2010).

In evaluating the effectiveness of this intervention for the organisation, several quality improvements have been implemented as a direct result of the clinical audit conducted for this study, leading to improved documentation systems, compliance and patient flow. Additionally, interdepartmental relationships were strengthened, as midwives not working in the birthing suites or PAOU were up skilled, broadening the availability of staff to work across these areas bringing with

it mutual respect and a change in culture. A number of changes to practice have occurred, midwives working within these areas have a better understanding of the importance of this stage of labour and less variances in clinical care.

Along with the quality improvements already implemented for the success of this intervention, a number of recommendations for further investigation and service planning have been provided in a report under consideration by MMH management. These include surveying the women and staff to further direct change, increase the student rotation to M10E, and consider environmental facets of care that may be modified easily such as availability of non-pharmacological forms of pain relief.

Pregnancy Assessment and Observation Unit

As described in Chapter Three all women presenting in early labour at MMH continued to be triaged and assessed within the PAOU as an approach to manage the number of women in birth suite who are not in active labour. There is a large body of evidence to support keeping women out of birthing suite until active labour has established to avoid unnecessary interventions (Bailit et al., 2005; Chuma et al., 2014; Davey et al., 2013; McNiven et al., 1998). Understanding the labour process and accurate diagnosis of active labour is required to achieve a normal vaginal birth (Reuwer et al., 2009). Hemminki and Simukka (1986) reported longer lengths of labours and an increased use of intrapartum interventions for women admitted with a mean cervical dilatation of 3cm or less. The onset of active labour has traditionally been at the point in which regular painful contractions are associated with an acceleration of cervical dilatation after 4-5cm. This criterion for active labour diagnosis was first created by Friedman more than 50 years ago and has since governed the management of labour. However, recently there is international debate on this definition of the onset, progress and duration of labour particularly for first time mothers. Data from a large population based study conducted in the United States between 2007-2009, found labour progress to accelerate after 6cm (faster in multiparous than nulliparous women) and dilatation from 4 to 6cm to be slower than previously described (Zhang et al., 2010). The researchers attribute changes to contemporary populations such as maternal age, and weight along with an increased use of obstetric interventions such as induction and epidurals to have alter the natural labour progress. Therefore making recommendation that the same criteria cannot be applied for current labour management, suggesting the onset of active labour begins at 6cm (Zhang et al., 2010).

Many of the women presenting to the PAOU in early labour choose to remain on hospital grounds rather than return home to await labour events, however it is beyond the scope of this thesis to comment on why women chose this management option. Reoccurring themes in qualitative studies describe how women have a preference to be admitted on initial assessment (Cheyne et al., 2007;

Nolan & Smith, 2010; Scotland et al., 2011). The MMH has a process for gathering women's satisfaction with elements of their care through rounding questions (Appendix 8). This study would be enriched by data from the women on their perceptions of care and what is important to them, as evidence from other Australian studies demonstrate the potential for new models of care to either have a negative or positive effect on women's preferences and overall satisfaction with their birthing experience (Bayes et al., 2008; Brown & Lumley, 1998; Fenwick et al., 2005; McLachlan et al., 2012).

The majority of the women in this study presenting in early labour were those in standard care models. The benefits of increasing women's access to midwifery-led models of care at the MMH has been previously mentioned, and may result in less women presenting before the active phase of labour (Davey et al., 2013; Tracy et al., 2013) or choosing to remain within the hospital setting.

Length of stay

An increased length of time spent in the PAOU (>2hrs) for women in early labour was theorised to increase the number and type of obstetric interventions used in labour, based on clinical observation, and raw data audit. The results of this study supported this hypothesis with women who remained in PAOU for longer, experiencing increased rates of emergency caesarean and reduced incidence of spontaneous vaginal birth. Augmentation of labour rose by five percent and an increase in epidural use was noted with longer admissions (although these did not reach statistical significance). However, the reasons for the longer admission were not explored, may include management of: reduced fetal movement, suspicious fetal heart rate patterns or vaginal bleeding. Continuous monitoring of the woman and fetus is a common expectation of management until the situation is resolved, or a decision to either induce labour or deliver by emergency caesarean. Hence these and other similar reasons may have accounted for the longer length of stay in PAOU and subsequent labour and birth outcomes.

With reference to current evidence it is possible that the unfamiliar surroundings of the PAOU and the reduction in privacy may have inhibited the levels of oxytocin, resulting in dysfunctional uterine activity and thereby lengthening the duration of labour (Buckley, 2009; E. Hodnett et al., 2005; Lowe, 2002; Overgaard, 2012). The high acuity and workload of having women remain in PAOU for longer lengths of time, may affect the staff's attitudes towards them, often feeling they should be at home (APPENDIX 1). This is supported by reports increased workloads on the midwives may impede midwives' desire to support normal birth (Carolan-Olah et al., 2015) and impact women's intrapartum decision to use an epidural (Kpea et al., 2015). This may have had a flow on effect for the women as they then may feel unsupported by their care provider or may have be presented with suggestions of augmentation to transition them through to the birth suite. The development of

clinical decision making pathways aimed to standardise these variances in practice, however this is reported by another research project at the MMH.

With the implementation of M10E, length of admission to PAOU for women in early labour reduced, but not significantly. Any aspects of a change process involves a period of adjustment, new ways of thinking or “cultural change” (Locock, 2003, p. 56) require individuals and organisations time to learn, to reflect and to implement (Locock, 2003). Regular review of KPI’s (see glossary) and quarterly management meetings continue to occur to further direct service improvement. These ultimately lead to changes in policy and procedures directed at staff. It is therefore likely that length of admission in PAOU for women presenting early is within the recommended two-hour timeframe for assessment now M10E is considered a routine practice.

Early labour management

As stated previously, the management of women presenting to the PAOU in early labour prior to this intervention was to encourage women to return home and maintain normal daily activities to reduce early admission and the potential for unnecessary intervention. This approach may increase anxiety levels in those women seeking support because they were struggling to cope on their own, and as a result were the subset of women choosing to be admitted. Along with the introduction of a new early labour care model, clinical-decision making tools and pathways (discussed earlier) were implemented for midwives to standardise the care provided. However these tools offered little real guidance on how to manage women in early labour, only direction on where to transfer them.

Variations in clinical practice, attitudes, and management of early labour were explored as elements that may have affected this intervention. The risk-focused culture of the MMH, hospital policies and introduced clinical pathways may have continued to influence the individual practices of the midwives and inadvertently normalise interventions. Evidence already outlined indicated midwives working within large tertiary centres, with all-risk models of care perceive intrapartum risks to be higher, generally underestimate women’s abilities to progress normally and normalise the use of interventions, particularly epidurals (McDermott, 2010; Mead & Kornbrot, 2004; Newnham et al., 2015).

The literature review explored the influence birthplace had for shaping both the midwives perceptions of risk but also the culture of the organisation and therefore the medicalisation of birth. The midwife’s role of promoting a physiology women-centred approach to birth, has been described as more important to the success of service improvement initiative, than installing or removing objects in an attempt to create the right environment (Brodie & Leap, 2008). This said, strong

midwifery leadership is required to enable a shift in culture and organisational change within maternity services in order to reverse the over medicalisation of birth and promote normal birth. The development of a shared philosophy of care for low-risk at the MMH is therefore required for women, midwives, obstetricians and the health service in order to create a cultural change among all care providers.

Staff characteristics have been shown to be a strong influence over how satisfied a woman is with her care (E. Hodnett, 2002), but also over the success of a change or redesign in practice (Locock, 2003). When policy makers search for new ways to address problems with dissatisfaction among patients or improve the quality of health care, the most important principle should be to consult the staff themselves to lead the change (Locock, 2003). Clinicians are best placed to know what happens and can develop creative ideas for improvement, allowing for gradual implementation that is more likely to be accepted. This is supported by redesign theories that an imposed change from above “rarely succeeds in getting autonomous clinical professionals to change practice” (Locock, 2003, p. 54) if there has been no consultation. Involvement of staff in the evaluation process has been identified by Spiby et al. (2007) as important as sometimes staff are not engaged in understanding the rationale for the change in service. Clinicians were involved during the initial stages of the intervention through the collaborative working party; however the reviewing stage only occurred at the management level. Consideration should be given to the midwives working on M10E and their perception of risk, which may have been influenced by the organisational culture and their lack of confidence in caring for labouring women. Further consideration should be given to investigating what staff feel could be improved, and to rethink current practices to ensure the change in service adds value to the women, and not just doing more of the same. Powell et al (2009) say it is an essential part of any quality improvement work to contribute to its own evidence base by ongoing evaluation (both Qualitative and Quantitative).

The area of M10E was not only converted into an early labour area, but also received the majority of admissions of women being induced. The labour intensive nature of inducing women impacts staff work load and ability to provide an appropriate level of early labour support. An explanation that warrants further investigation as to why this intervention has not improved the outcomes for women maybe a result of moving the workload from one area of the hospital to another. This may have resulted in the same organisational issues for staff working on M10E (dissatisfaction, bed blockages, and increased staff shortages), ultimately leading to less time to be able to provide the level of support these women are seeking. Continuous labour support (Simkin & O'Hara, 2002), freedom to mobilise (Y. Miller et al., 2015; Scotland et al., 2011; Simkin & O'Hara, 2002), privacy

(Buckley, 2003), availability of water, massage (Simkin & O'Hara, 2002), and home-like environments (Buckley, 2003; E. Hodnett et al., 2005) have been identified as comfort measures important to women and associated with lower epidural use. Although the introduction of a dedicated early labour area sought to provide an improvement in privacy and freedom to mobilise, these other factors warrant further consideration. Currently the hospital midwives work within designated areas, an opportunity exists to explore whether having a known midwife provide continuous care from early labour assessment through to active labour and birth may influence intervention rates.

One avenue to provide continuity and a solution for reducing the workload on registered midwives is to utilise the midwifery students as part of the workforce. This recommendation was made to MMH management in a report, suggesting they increase the rotation of midwifery students to M10E. Students rarely have the opportunity to witness women in the early stage of labour, as women are encouraged to remain at home. Student midwives in a supported education model may be able to engage and support women in this early stage of labour. Students in a supernumerary clinical position have the time to spend 'with woman' that often the registered midwives lack due to workload. In addition to the benefits for the women, this arrangement would also be beneficial for the organisation as students are a cost effective way of relieving some of the workload from the registered midwives whilst consolidating their knowledge into practice, making them more confident members of staff when rotating to birth suite.

Summary

Childbirth is a deeply significant event in a woman's life, however no journey is the same. Pain during labour is common across all cultural backgrounds but is only one component of the woman's birth experience. Attitudes of care providers, support, education and policy can all potentially influence a host of factors such as fear, environment, and midwifery practice that have also been shown to be important to the woman's experience of pain.

Simply changing the location of care and model surrounding early labour management did not influence a woman's choice of intrapartum pain relief. This study indicates the optimum setting for providing support is yet to be identified, place of care in early labour appears to be important in the causal pathway to epidural use, however not a predictor for the women in this study. Socio-demographic and lifestyle factors not collected such as level of antenatal education, income and postcode (locality to hospital) may have played a significant role in a women's decision-making about when to transfer to hospital, whether to return home in early labour or choice to use an epidural for pain relief. Furthermore, understanding the women's preferences and expectations of

early labour care within this cohort, has been identified as a gap in the knowledge for future research.

The intervention did not include one-to-one midwifery support, but did allow for support people to remain with the women on M10E. An opportunity exists to add value to the body of evidence on the management of early labour by engaging student midwives, especially those attending tertiary facilities for their practical experience. Students have the theoretical knowledge without the influence of the risk culture and may offer a solution to improving processes for organisations with limited resources by providing continuous labour support for those seeking it.

5.3 Strengths and Limitations of the Study

One of the strengths of this study stems from the data collection process. Data was hand collected by the candidate vastly improving the quality and reliability over routine collection. As a result, the data for the Pre-Intervention Cohort are likely to be a true measure of outcomes to benchmark against. Recommendations made by researchers, is for service providers to examine the implications and outcomes of new services, and ensure the statistical information collected, is of suitable quality to allow subsequent monitoring and re-evaluation. This Quasi-experimental study provided a generalised picture of the labour and birth outcomes for a subgroup of women, twelve months following the implementation of the early labour model of care. Within the limitations of the design, the study did achieve the service expectations, i.e. provided a baseline measure for which to continue an evaluation process and address the research question.

This study is limited by several factors. Firstly the study is observational (non-randomised) therefore having non-comparable groups (pre and post intervention) restricts how direct comparisons and conclusions can be drawn because all potential confounding factors are not necessarily even across cohorts. The results show vast differences in the maternal characteristics of the two cohorts, with no known reason as to why, although some possible explanations have been provided in the discussion. The results provide only a snapshot of birth outcomes within the first twelve months following the implementation of M10E, therefore must be interpreted with caution. Like all retrospective reviews the results cannot prove cause and effect, rather reflect on associations that have been suggested by the data (Finkelstein, 2006).

Secondly, studies that use existing collections of routine data are subjected to both data collection and documentation issues. This study identified significant problems with the initial routine data collection, which meant two different data collection strategies had to be employed for the two time frames. On one hand this made for a more robust sample for the Pre-Intervention Cohort, and allowed electronic extraction for the Post-Intervention Cohort. However after cleaning the manually

collected data for the Pre-Intervention Cohort a significant number of duplications of URN were found. This is likely due to women presenting multiple times through PAOU for pregnancy related concerns or assessment of labour, making the number of eligible admissions less than first thought. The student and principle supervisor made the decision to use the closest admission to birth as the admission date and time. This is because some duplicated admissions (of the same woman) were more than seven days from the birth date, therefore unlikely to have been admissions for labour assessment. This significantly impacted on the time constraints of this student's candidature.

Additional limitations of using retrospective data collection methods, meant this study was unable to explore other reasons for longer admissions in PAOU (i.e. reduced fetal movement, suspicious fetal heart monitoring) due to the time required to collect this data manually and would have been powered for within the study. All caesareans that occurred within this data were unplanned, this study was unable to differentiate between an epidural for labour or epidural anaesthesia for birth. Similarly, retrospective data collection did not allow for the identification of women who chose to use epidurals as part of their birth plan.

Data collected from women under the care of a private obstetrician was unable to account for those who could have had increased risk factors such as those excluded in standard care models (high risk clinic, maternal fetal medicine, obstetrician only clinic, diabetes clinic). However it is possible that women with complex pregnancies would have higher rates of both IOL and elective caesarean section under the care of an obstetrician, which would have excluded them from the study group.

Lastly, the population sample was collected from one institution, a tertiary facility with more high-risk pregnancies and a higher rate of intervention. Therefore the extent to which these findings can be generalised to all women presenting to hospital in early labour is limited. This is due to the large number of factors or threats to external validity identified in the discussion (risk culture, midwifery practice, environment, availability of anaesthesia and annual birth rate) that can impact on a woman's choice to use an epidural in labour.

The mentioned limitations impact the extent to which the results can be generalised to other women and organisations. The study contributes to the evidence regarding early admission in a unique way, by suggesting that admission to hospital is the issue as much as admission to a birth suite.

5.4 Conclusion and Recommendations

This study suggests further investigation is required into the individual and health-service related variables associated with epidural use to reduce rates of intervention and improve birth outcomes. The new model of care has been operational since September 25th 2012, with regular review and monitoring of KPI's (Appendix 4) as well as clinical outcomes. Although this initiative has met the operational objectives of the organisation, in particular improvement in patient flow through PAOU and provided some women with better accommodation and an alternative care option for early labour support, the results show a reduction in optimal clinical outcomes overall for this subgroup of women. The intervention did not reduce epidural use; therefore recommendations are for further investigation to explore environmental factors and facets of care delivery that maybe modified to support normal birth with future service planning.

5.4.1 Suggested recommendations:

- Continuing to monitor clinical outcomes of women presenting in early labour regardless of destination following assessment and discharge from PAOU
- Making pain relief options such as sterile water injection (SWI) and TENS machines accessible for women being supported in early labour on M10E
- Future service planning for a dedicated early labour space separate from the inductions with a focus on providing care within this setting that more closely resembles being at home
- Consider restructuring staff to allow rotation between M10E and birth suite to increase the level of continuity for a woman having a known midwife from early labour to active labour and birth
- Increase student rotation to M10E, to support clinical staff and provide support, reassurance and education to the women. In turn this would improve confidence in the students in readiness for their birth suite placement, hone their time management skills and make them feel more valued as a member of the work force
- Survey staff now M10E has been operational for three years to identify level of satisfaction with the management of women in early labour
- Survey women presenting in early labour regardless of their management decision to better understand their expectations and perceptions of care
- Increase women's access to midwifery group practice models at the MMH.

5.4.2 Recommendations for further research:

The outcomes of this project identify a number of areas for future research. The impact of non-clinical practices such as women's preferences and expectations of interventions such as epidurals needs further investigation, along with the impact of modifying clinical practices and facets of care. Further research is required on the factors that maximise normal birth rates in a tertiary setting in the short and long term. Further suggested research opportunities include:

- Comparison of birth outcomes and use of epidural among women cared for on M10E with those who returned home following PAOU assessment
- Qualitative study on women's perceptions of early labour care within a tertiary hospital
- Qualitative study on midwives and student midwives experience of caring for women in early labour, in a tertiary setting
- Multi-centre longitudinal study comparing birth outcomes of women presenting in the early stage of labour and the rate of 'normal birth'
- Further analysis of maternal factors such as attendance to antenatal education, pre-labour preference for epidural use and locality to hospital to test an association with early labour admission and epidural use

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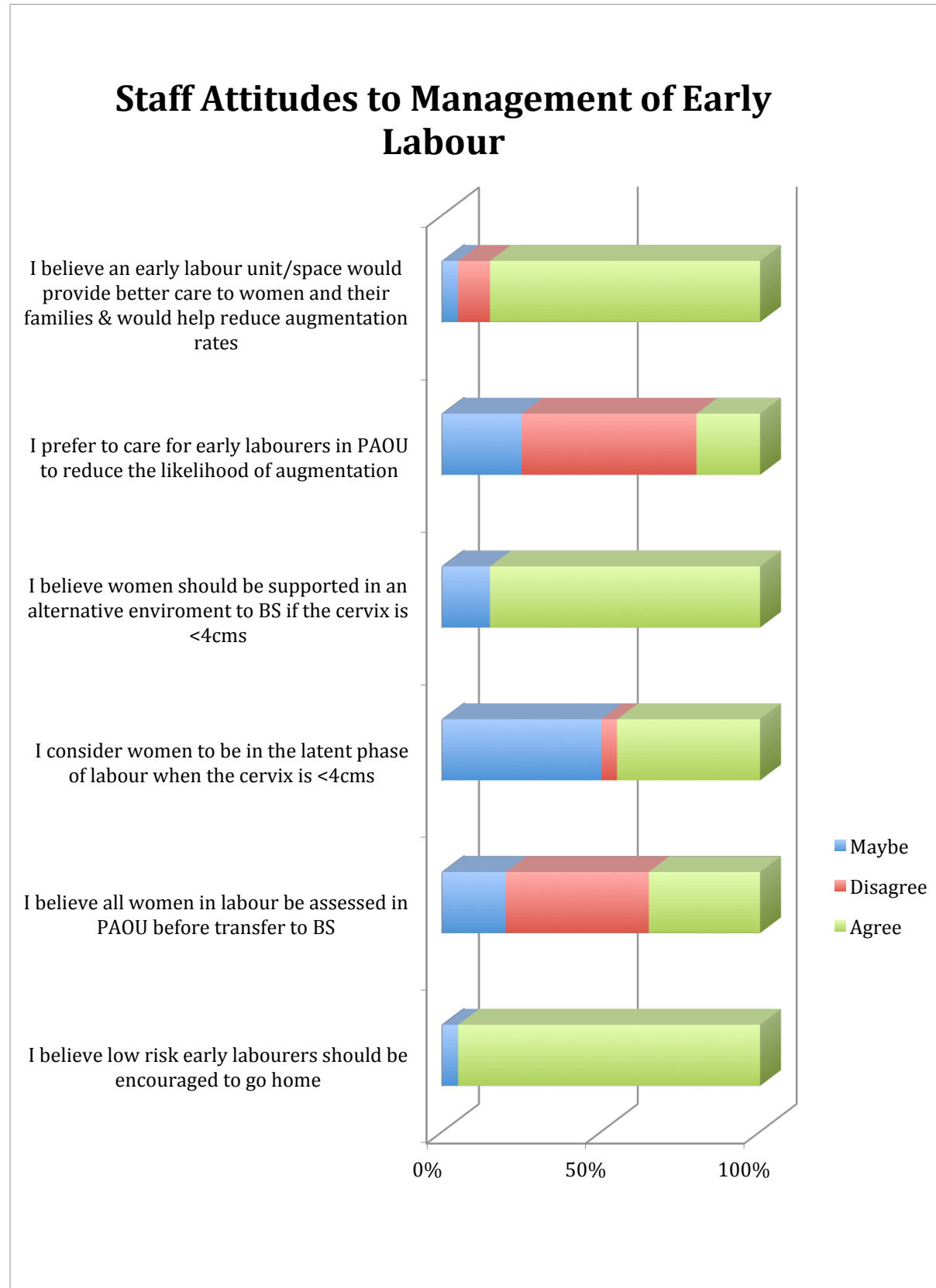
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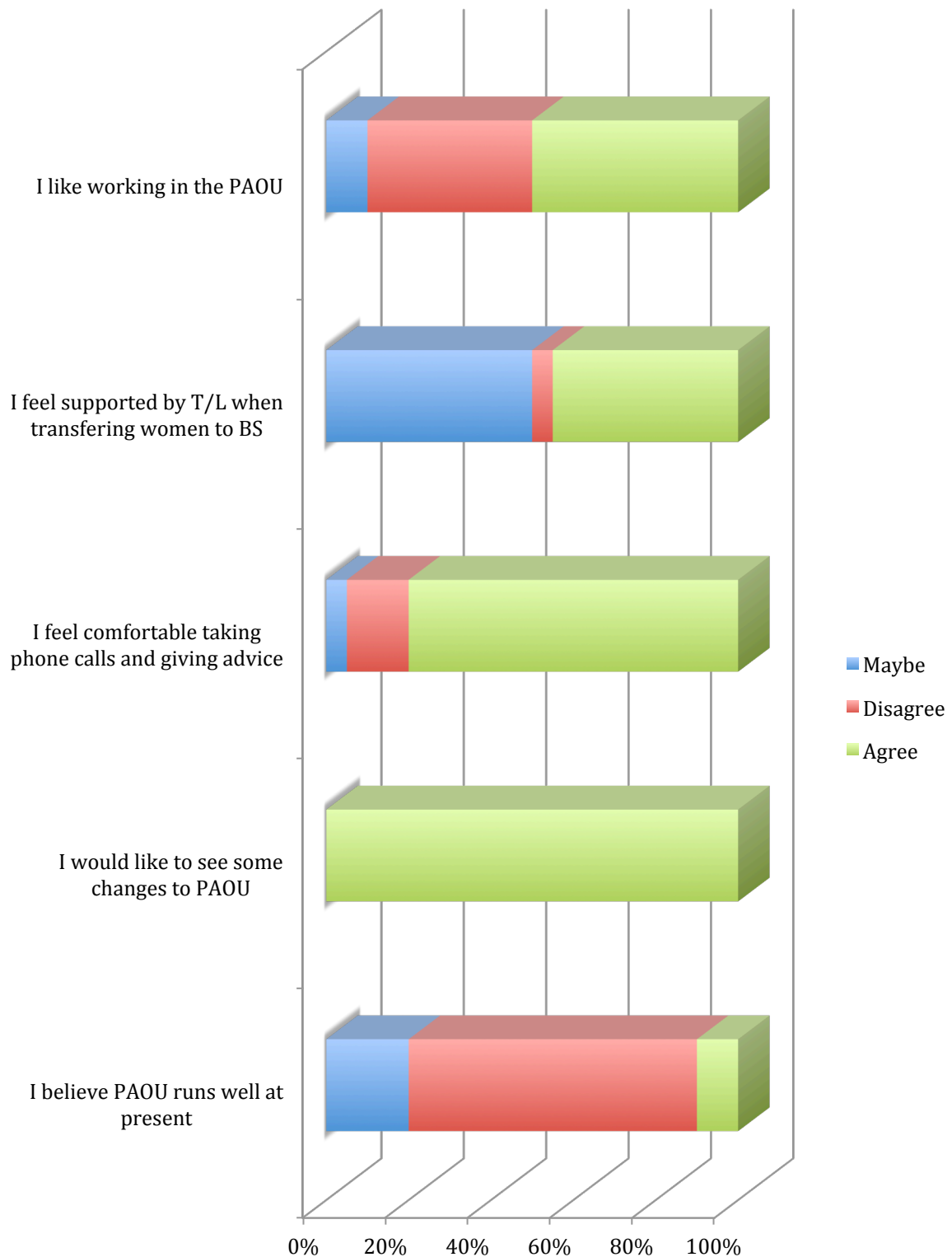
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Staff attitudes towards PAOU



Appendix 2: Staff feedback for working party

We appreciate all the feedback and patience with changes to the PAOU so far. We are working hard to listen to staff's ideas and preferences to ensure staff satisfaction and to improve the flow of the unit. Below are issues identified, some of which have already been raised by the working party and in process of restructure. Please be a part of the positive change, if there is an issue you want raised there will be an opportunity for you to do so when you receive the questionnaire for those remaining staff who have not yet completed one.

ISSUES IDENTIFIED

- ♦ Allow staff to work in their preferred area (x6)
- ♦ ANC to do more bloods/CTG's prior to transfer (x5)
- ♦ Need for early labour space (x5)...Careful this is not exploited
- ♦ Low Staffing Levels (x3)
- ♦ Employ permanent staff in PAOU (x3)
- ♦ Book less IOL's in PVT BS or staff more appropriately (x2)
- ♦ No junior medical staff in PAOU (x2)
- ♦ One person to answer phones in PAOU (x2)... no opportunity for junior staff to listen and learn
- ♦ Rotate through PAOU
- ♦ Breaks need to be addressed
- ♦ Midwife practitioners in PAOU (skilled up midwives)
- ♦ At least one member of core staff per shift
- ♦ Supernumary TL in PAOU responsible for coordinating and leading
- ♦ Confidentiality hard to maintain as workspace too small
- ♦ Need for guidelines for phone advice
- ♦ Need for proper waiting area (eg results)
- ♦ Work as a team
- ♦ Orientation to PAOU for staff who have not worked there recently

NB: red means issues currently being reviewed by working party

Appendix 3: Letter to staff and staff satisfaction questionnaire

Mater Mothers' Hospital
Raymond Tce
Qld 4101

Thursday, 19 July 2012

Dear Colleague,

As part of a quality assurance project looking at how to improve our service for women who present in early labour, I along with the support of hospital management, wish to identify current practices and management for women who present to the Mater Mothers Hospital in the early phase of labour. It is clear there has been a growing awareness for understanding the complexities of early labour management and its importance for both the women and the health service. The aim of this questionnaire is to help identify areas for improvement, and future service planning for these women and their families.

When completing the questionnaire please use pencil or biro to shade the most appropriate circle. Please do not use marker pens as they can leak through to the other side and cause an inaccurate reading when the forms are scanned. Please put completed forms into box provided in your work area.

Thank you for your help with this initiative.

Kind regards

Lauren Williams
Clinical midwife
Birth Suite

Current practices and management of women in early labour survey

Please **shade the circle** to indicate your response.

1. I work as a:

VMO	Obstetrician MMH	Midwife	MGP	Registrar	RMO	Student Midwife
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

2. My main area of practice is:

Private B/S	Public B/S	PAOU	MM8	MM9
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
MM10	MM11	MM12	Home	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

3. I have worked with the MMH/MMPH for:

<1 Year	1-5 years	6-10 year	>10 years
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4. On average I am involved in the care or management of women in the early stage of labour.

8+ times/wk	3-7 times /wk	1-2 times /wk	1-3 of times /mth	<1 a month	Never
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

5. How would you rate your overall satisfaction with the care and options provided to women and their families in the early stage of labour at the MMH?

Very satisfied	Satisfied	Neutral	Dissatisfied	Very dissatisfied
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

6. What are your top three recommendations for improving our service to enable you to rate the care higher in terms of your overall satisfaction?

Recommendation priority 1:

Recommendation priority 2:

Recommendation priority 3:

Using the scale below, please indicate your level of agreement with the following statements by **shading the circle** on the scale provided.

7. There are clear guidelines regarding the management of women in the early stage of labour?

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

8. Resources required for supporting women and their families are readily available (eg. Written documentation, home- like environment).

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

9. I feel the management of women in early labour is woman-centred at the MMH/MMPH.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

10. I feel the management of women in early labour is evidenced based at the MMH/MMPH?

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

11. I feel confident providing early labour support and advice to women in the latent phase within my clinical role?

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Reflecting on your own individual practice, what options would you provide/suggest to the women in the following scenarios who present in the latent phase of labour? Please provide rationale for advice:

12. G1P0 K40+2, Contracting 2:10, Cx 2cm fully effaced, membranes intact. Not requiring pain relief, but reluctant to return home to establish active labour

13. G2P1 K39+4 second presentation to PAOU, Contracting 1-2:10 irregular, Cx 2cm dilated, 1cm long. Membranes intact, reluctant to return home again.

14. Please provide any comments or suggested changes you would recommend regarding any aspect of early labour care.

Thank you for taking the time to complete this survey. Your ideas are valuable.

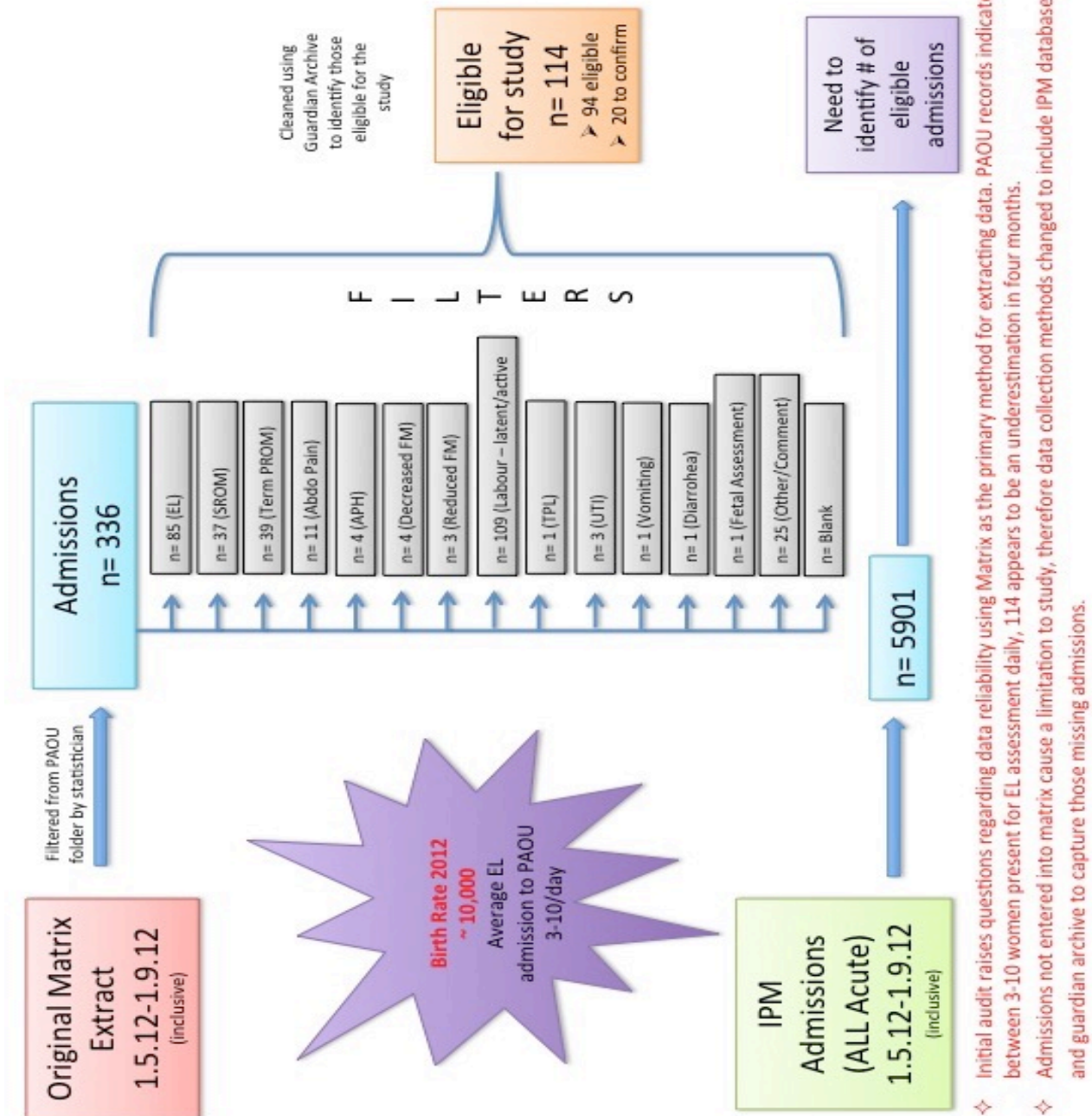
Appendix 4: The 10 National Core Maternity Indicators

- 1 Smoking in pregnancy for all women giving birth
- 2 Antenatal care in the first trimester for all women giving birth
- 3a Episiotomy for women having their first baby and giving birth vaginally without instruments
- 3b Episiotomy for women having their first baby and giving birth vaginally with instruments
- 4 Apgar score of less than 7 at 5 minutes for births at or after term
- 5 Induction of labour for selected women giving birth for the first time
- 6 Caesarean section for selected women giving birth for the first time
- 7 Normal (non-instrumental) vaginal birth for selected women giving birth for the first time
- 8 Instrumental vaginal birth for selected women giving birth for the first time
- 9 General anesthetic for women giving birth by caesarean section
- 10 Small babies among births at or after 40 weeks gestation

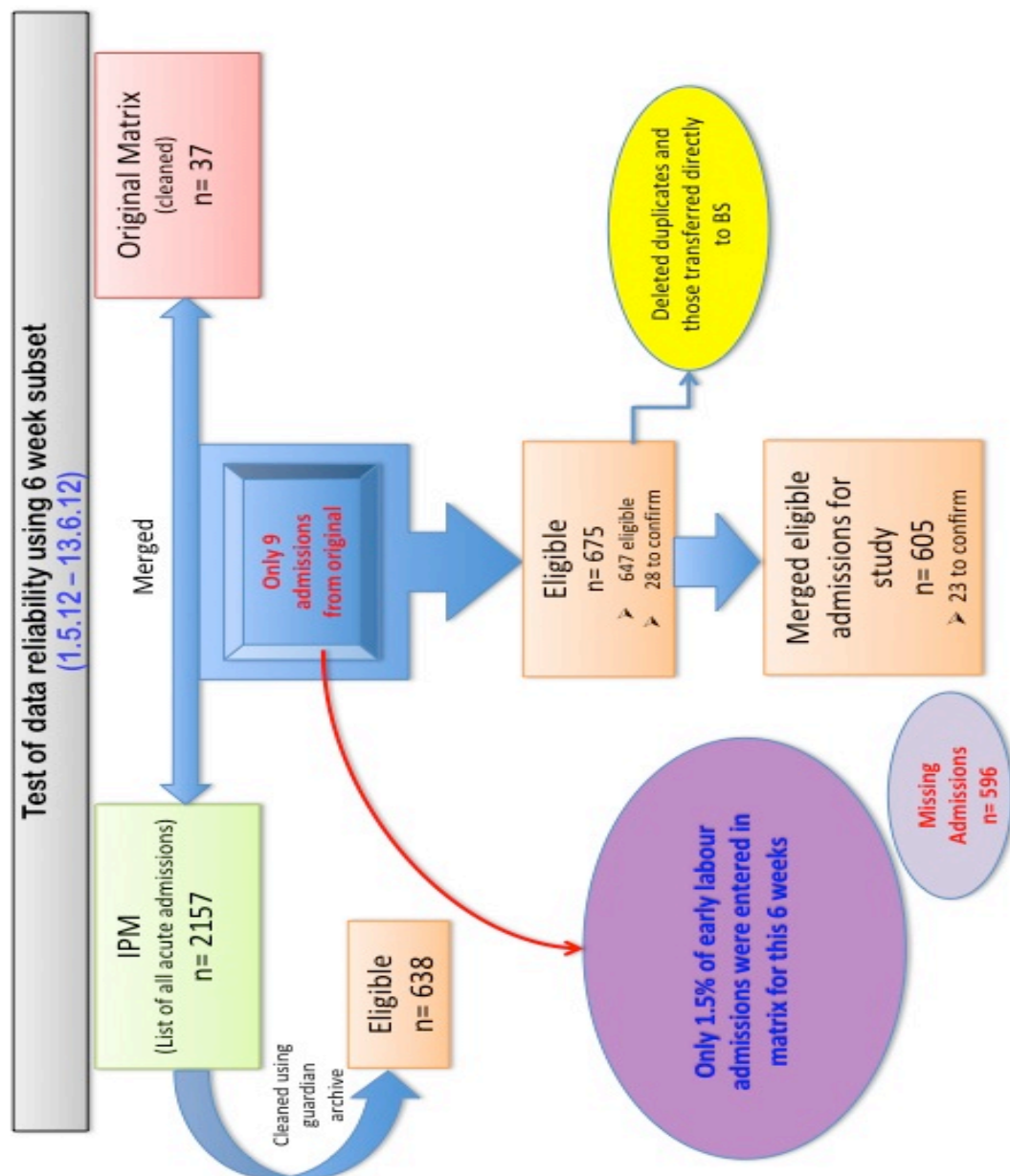
Appendix 5: Key Performance Indicators (KPI) – M10E

Quality Indicators	
PAOU	<p>Percentage of women having a LOS >2hrs in PAOU</p> <p>No. of babies born before arrival following contact with the MMH</p> <p>No. of general complaints from consumers regarding care in early labour (feedback from rounding on BS)</p> <p>No. of low risk women having prostin gel administered in PAOU/BS (0%)</p>
M10E	<p>Percentage of women admitted to M10E in early labour who have a review within 4hrs - Excludes women in the unit 00:00-06:00 (100%)</p> <p>No. of EL women who stay on M10E greater than 6 hours (10%)</p> <p>No. of EL women who go home</p> <p>No. of women in EL transferred to M10 for <1hr before transfer to birth suite</p> <p>No. of babies born on M10E (All to be fully reviewed regarding management - weekly)</p> <p>Number of general complaints from consumers regarding care in early labour (feedback from rounding on M10E)</p> <p>No. public women who had 1st dose of prostin administered on M10E <1.5hrs after initial presentation (100%)</p> <p>No. of private women who had 1st dose prostin administered on M10E <1.5 hrs. after initial presentation (100%)</p>
STAFF	<p>No. of staff competent in Vaginal Examinations (95% of ward M10E core staff)</p> <p>No. of staff competent in administration of prostin gel (95% of ward M10E core staff)</p>

Appendix 6: Original audit trail



Appendix 7: Six-week clinical audit to test reliability



Out of 2157 admissions to PAOU in 6 weeks, 605 were for EL assessment and eligible for this study. The original extraction revealed only 9 admissions eligible, identifying a significant limitation. 98.5% of eligible admissions were not entered into matrix, therefore data collection methods changed to manually audit IPM with guardian archive (and chart review where required) for consecutive admissions until required number is reached to demonstrate reliability. Power analysis and size estimation will be used.

Appendix 8: Rounding log



Rounding Log Details

Rounding Log Details

Rounding Type	Patient
Org Division	Mater Mothers' Public and Private Hospitals
Org Unit	Delivery Suites
Date	
Time	
Rounded Person Name	

Mandatory Questions

Is there anything I can do for you now?

Is there any staff member you would like me to recognise? Why?

Optional Questions

How well supported did you feel in early labour?

How useful was the telephone advice you received from the Pregnancy Assessment Unit.

Did you feel involved in making decisions and choices about your care during labour?

Is there anything that you would like to suggest that would improve our birthing services?

Staff Recognitions

Issues

Tuesday, August 14, 2012 9:27 AM



MATER HEALTH SERVICES HUMAN RESEARCH ETHICS COMMITTEE

29th May 2012

Mrs Lauren Williams
8 Alrex Street
Everton Hills
4053

Dear Mrs Williams

Re: Protocol Ref №.2012-22 Is an increased length of time spent in the pregnancy assessment unit, for women with a cervical dilation less than 4cm, associated with an increased use of epidural pain relief in labour, augmentation of labour and instrumental or caesarean birth and admission to the neonatal unit?

I write to advise that the Mater Health Services Human Research Ethics Committee considers the above study to meet the requirements of the *National Statement on Ethical Conduct in Human Research* (2007) and has granted ethical approval for your research proposal. Please accept our very best wishes for the success of this study. *In all future correspondence with the Committee please quote the Mater reference number.*

Documents reviewed and approved include:

- Cover letter dated 30th March 2012
- Mandatory Cover sheet dated 27th March 2012
- CV for Lauren Williams
- LNR Application Form

This approval is valid until 29th May 2015.

Please note the following conditions of approval.

- Any departure from the protocol detailed in your proposal must be reported immediately to the Committee.
- When you propose a change to an approved protocol, which you consider to be minor, you are required to submit a written request for approval to the Chairperson, through the Secretary. Such requests will be considered on a case by case basis and interim approval may be granted subject to ratification at the next meeting of the Committee.
- Where substantial changes to any approved protocol are proposed, you are required to submit a full, new proposal for consideration by the Human Research Ethics Committee.
- You are required to advise the Research Ethics Coordinator immediately of any complaints made, or expressions of concern raised, in relation to the study, or if any serious or unexpected adverse events occur.
- Under the *NHMRC National Statement on Ethical Conduct in Research Involving Humans*, research ethics committees are responsible for monitoring approved research to ensure continued compliance with ethical standards, and to determine the method of monitoring appropriate to each project. You are required to provide written reports on the

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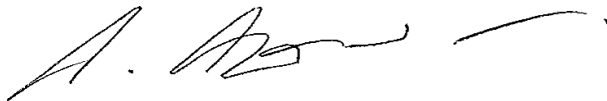
progress of the approved project annually, the first report being due on and finally on completion of the project. *(The Progress Report is located at <http://www.mater.org.au/Home/Research/Human-Research-Ethics-Committee.aspx> or can be accessed through the Mater Intranet, Applications, Research Register then under the project name or alternately can be emailed to you).* Please inform the Committee of publications, presentations at Conferences, education and quality improvement outcomes from this study. The Committee may also choose to conduct an interim audit of your research.

- Please be aware that all study procedures including follow up of participants and data analysis should be completed within the approval time frame or an extension should be requested.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project until authorisation from the Research Governance Office has been obtained.

Please contact the Executive Director in the participating hospital/hospitals prior to commencing of the study. To access medical records, for the purpose of this study, please provide a copy of this approval letter to the Corporate Health Information Manager. I would also be grateful if you could confirm the date of commencement. (All correspondence should be directed to the Mater Research Ethics Coordinator.)

Yours sincerely



A/Prof Andrew Crowden
Chairperson
Mater Health Services Human Research Ethics Committee



MHS & MMRI Human Research Governance - SSA Authorisation

6th June, 2012

Mrs Lauren Williams
8 Airex Street
Everton Hills
4053

Dear Mrs Williams

Re: HREC Protocol Ref N^o. 2012_22 Is an increased length of time spent in the pregnancy assessment unit, for women with a cervical dilatation less than 4cm, associated with an increased use of epidural pain relief in labour, augmentation of labour and instrumental or caesarean birth and admission to the neonatal unit?

Thank you for submitting an application for authorisation of this project. I am pleased to inform you that authorisation has been granted for this study to take place at the following site(s):

Mater Mothers Hospital, South Brisbane

The following conditions apply to this research proposal. These are additional to those conditions imposed by the Human Research Ethics Committee that granted ethical approval.

1. The Research Governance Officer must be informed of any problems that arise during the course of the study which may affect conduct of the study at the site.
2. Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, and which are submitted to the HREC for review, are copied to the research governance officer;
3. Proposed amendments to the research protocol or conduct of the research which only affects the ongoing site acceptability of the project, are to be submitted to the research governance officer;

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4. Proposed amendments to the research protocol or conduct of the research which may affect both the ongoing ethical acceptability of the project and the site acceptability of the project are to be submitted to the research governance officer after a HREC decision is made.

We wish you every success in undertaking this research.

Yours sincerely



Patricia Murray, PhD
Research Governance Officer
Room 51, Lvl 3, Quarters Building
Mater Medical Research Institute
Raymond Terrace
South Brisbane Qld 4101

Ph: (07) 3163 2559

Fax: (07) 3163 1588

Email address: research.governance@mmri.mater.org.au





MATER HEALTH SERVICES HUMAN RESEARCH ETHICS COMMITTEE

17th October 2012

Ms Lauren Williams
8 Alex Street
Everton Hills
4053

Dear Ms Williams

Re: Protocol Ref No. 2012-22 Is an increased length of time spent in the pregnancy assessment unit, for women with a cervical dilatation less than 4cm, associated with an increased use of epidural pain relief in labour, augmentation of labour and instrumental or caesarean birth and admission to the neonatal unit?

I write to advise that the Mater Health Services Human Research Ethics Committee has granted ethical approval for the proposed amendments for the above study.

Documents reviewed and approved include:

- LNR Application Version 3, dated 26th September 2012

You are reminded that this letter constitutes ethical approval only. You may also need to consult with the Research Governance Office to ensure the amendments comply with the existing authorisation that has been obtained.

Please accept our best wishes for the remainder of the study and should you have any queries, please do not hesitate to contact the Research Ethics Secretariat on 3163 1585. *In all future correspondence with the Committee please quote the Mater reference number.*

Yours sincerely

A/Prof Andrew Crowden
Chairperson
Mater Health Services Human Research Ethics Committee

Research Ethics Secretariat Room 56 Level 3 Quarters Building Ph: 07 31631585 Fax: 07 31631571 Email: research.ethics@mater.mmi.org.au

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26 August 2013

Mrs Lauren Williams
Clinical Midwife
8 Alex Street
Everton Hills Qld 4053

Dear Mrs Williams

HREC Ref N°: HREC/13/MHS/82 (2012-22)
Amendment Ref N°: HREC/13/MHS/82/AM01
Project title: Is an increased length of time spent in the pregnancy assessment unit, for women with a cervical dilation less than 4cm, associated with an increased use of epidural pain relief in labour, augmentation of labour and instrumental or caesarean birth and admission to the neonatal unit?

I refer to your letter of 25 July 2013 and email of 21 August 2013 requesting an amendment to the above study.

I write to advise that a subcommittee of the Mater Health Services Human Research Ethics Committee (MHS HREC) (EC00332) reviewed this amendment on 12 August 2013 and further reviewed on 21 August 2013 and has granted ethical approval for the proposed amendments between meetings.

Documents reviewed and approved include:

Document	Version	Date
Covering Letter		25 July 2013
HREC Coversheet		
LNR Application/Protocol	4	25 July 2013
Memorandum from Mater Foundation granting funding		12 April 2013
Response to Further Information		21 August 2013

You are reminded that this letter constitutes ethical approval only. You may also need to consult with the Research Governance Office to ensure the amendments comply with the existing authorisation that has been obtained.

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007), updated in 2013. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

Mater Research HREC Office
Room 270 Level 2 Aubigny Place

Ph: 07 3163 1585 Fax: 07 3163 2278

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25 March 2014

Mrs Lauren Williams
Clinical Midwife
8 Alrex Street
Everton Hills Qld 4053

Dear Mrs Williams

HREC Ref N°: HREC/13/MHS/82 (2012-22)

Amendment Ref N°: HREC/13/MHS/82/AM02

Project title: Is an increased length of time spent in the pregnancy assessment unit, for women with a cervical dilation less than 4cm, associated with an increased use of epidural pain relief in labour, augmentation of labour and instrumental or caesarean birth and admission to the neonatal unit?

I refer to your letter dated 4 March 2014 requesting an amendment to extend the date range for retrospective data collection for the above study.

I write to advise that on behalf of the Mater Health Services Human Research Ethics Committee (MHS HREC) (EC00332), I reviewed this amendment on 20 March 2014 and grant approval for the proposed amendment.

Documents reviewed and approved include:

Document	Version	Date
Covering Letter		4 March 2014
LNR Application/Protocol	5	6 March 2014

You are reminded that this letter constitutes ethical approval only. You may also need to consult with the Research Governance Office to ensure the amendments comply with the existing authorisation that has been obtained. It is a requirement that the approved documents as listed above are provided to the Research Governance Office.

Please accept our best wishes for the remainder of the study and should you have any queries, please do not hesitate to contact the Research Ethics Secretariat on 3163 1585. *In all future correspondence with the Committee please quote the Mater reference number.*

Yours sincerely

Dr Conor Brophy
Chairperson

Mater Health Services Human Research Ethics Committee

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007), updated in 2013. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

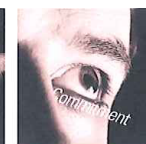
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Appendix 14: ACU HREC



Human Research Ethics Committee Registration of External Ethics Approval

Principal Investigator/Supervisor: Prof Sue Kildea

Co-Investigators:

Student Researcher: Lauren Williams

Ethics approval has been noted for the following project:

Is an increased length of time spent in the pregnancy assessment unit, for women with a cervical dilatation less than 4cm, associated with an increased use of epidural pain relief in labour, augmentation of labour and instrumental or caesarean birth and admission to the neonatal unit?.

for the period: 30/06/2014

Human Research Ethics Committee (HREC) Register Number: 2013 64Q

Ratification of External Ethics Approval

The Australian Catholic University Human Research Ethics Committee has considered your application for registration of an externally approved ethics protocol and notes that this application has received ethics approval from Mater Health Services [Reference: 2012-22].

The ACU HREC accepts the ethics approval with no additional requirements, save that ACU HREC is informed of any modifications of the research proposal and that copies of all progress reports and any other documents be forwarded to it. Any complaints involving ACU staff must also be notified to ACU HREC (National Statement 5.3.3)

A handwritten signature in black ink, appearing to read 'K. Pashley'.

Signed: Date: 14/03/2016...
(Research Services Officer, McAuley Campus)