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COMPARISON OF A PRIVATE MIDWIFE OBSTETRIC UNIT AND A PRIVATE CONSULTANT OBSTETRIC UNIT

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A RESEARCH REPORT SUBMITTED TO THE FACULTY OF HEALTH SCIENCES, UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG, IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF PUBLIC HEALTH

JOHANNESBURG, 2006

DECLARATION

I, Bibi Ayesha Seedat, declare that this research report is my own work. It is being submitted for the degree of Master of Public Health in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

_____Day of _____ , 2007.

DEDICATION

I dedicate this research report to my husband, Shafique Sayed, without whose support I would not have completed my MPH or this report, to my parents for their belief in continuing higher education, and to my children, Suhail and Nabila, for their constant interruptions.

ABSTRACT

Background: The role of Midwife Obstetric Units (MOUs) as lead caregivers for low risk pregnancies has been a topic of much debate in recent years. It has been suggested that MOUs are more cost effective, and have a less interventionist approach to low risk pregnancies, when compared to Consultant Obstetric Units (COUs).

Objectives: The primary objective of this study was to compare intrapartum delivery procedures, methods of delivery, and maternal and neonatal wellbeing for low risk pregnancies between a MOU and a COU. The second objective was to investigate the predictors of key outcomes such as caesarean sections and perineal tears. The research was carried out at a private obstetric unit in Gauteng from January 2005-June 2006.

Materials and Methods: The study design was a retrospective cohort study, by means of a record review of routinely collected data. 808 subjects (212 COU and 596 MOU patients) satisfied the criteria for a low risk pregnancy during the defined period and were included in the analysis.

Results: Overall the MOU had fewer interventions than the COU, but had very similar maternal and neonatal outcomes. MOU patients were less likely to have an epidural than COU patients ($p<0.001$), and more likely to utilise a bath for pain relief ($p<0.001$)**.** The MOU was also less likely to induce a patient than the COU ($p=0.002$). Primiparous patients accounted for more than 95% of the caesarean section (C/S) rate ($p<0.001$), with the COU performing 2.2 times more C/S on primiparous patients than the MOU. Vaginal birth in the MOU was 2.6 times more likely to be an underwater birth (UWB) than the COU ($p<0.001$). Positive predictors for C/S were COU care, primiparous status and induction of labour. UWB was a positive predictor for grade 1 and 2 perineal tears. There were no maternal or neonatal deaths, in either unit, during the study period.

There were no significant differences between the MOU and COU for maternal morbidity indicators (tears, postpartum haemorrhage, and retained placenta) or neonatal morbidity indicators (Apgar < 7 at 5 minutes and neonatal ICU admission).

Conclusion: The MOU had fewer intrapartum interventions (epidurals and induction of labour) and lower C/S rates than the COU for low risk pregnancies, yet maternal and neonatal outcomes were similar. This study suggests that the MOU can function just as effectively as the COU for low risk pregnancies. Therefore the establishment of more MOUs would have immense resource implications for both the public and private health sectors in South Africa.

ACKNOWLEDGEMENT

I would like to acknowledge Linkwood Clinic for their help in this study, by allowing me access to their patient files. I would also like to thank Loveday Penn-Kekana (Centre for Health Policy), for helping to ensure this study would materialise.

Finally, I would like to acknowledge the support of my supervisor, Duane Blaauw, without whose guidance, I would not have completed this report on time.

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NOMENCLATURE

For the purposes of this study:

- **Low risk pregnancies** refer to pregnancies as defined by the South African Nursing Council under the Regulations relating to the Conditions under which Registered Midwives and Enrolled Midwives may carry on their Profession (South African Government notice R2488 1990). The regulation has an extensive list of circumstances/complications during pregnancy, labour and the puerperium during which the midwife has to call in or refer the patient to a medical practitioner.

These are the specific conditions listed in the Regulations during pregnancy, for which the midwife has to seek assistance from a medical practitioner:

- Excessive nausea and vomiting
- Abortion, actual or threatened
- Vaginal bleeding
- Apparent intra-uterine growth retardation
- Hypertension
- Albumin or sugar in the urine
- Oedema of the hands, face or feet
- Convulsions
- Abnormal vaginal discharge
- Sores on the genitals
- Any condition suggesting a disproportion between head and pelvis

- Abnormal presentation after the 32nd week
- Multiple pregnancy
- Tenderness or abnormal distension of the abdomen

Patients who fell into this category were considered high risk and were excluded from the study. In addition, patients seen by the consultants with previous C/S, C/S on request and prolonged pre-labour rupture of membranes were also excluded.

Intrapartum Delivery procedures include:

- Induction of Labour (IOL) either by Prandin Gel (per vagina) or Cytotec (oral or per vagina).
- Augmentation of labour by means of artificial rupture of membranes (AROM) or artificial oxytocin administration.
- Pain relief by means of opioid injections, epidural analgesia, Entonox (nitrous gas inhalation), water bath or TENS (transcutaneous electrical nerve stimulation).
- An Episiotomy.

Methods of delivery refer to vaginal births, assisted vaginal deliveries and caesarean sections. Vaginal birth is either a normal vaginal delivery or an underwater birth (UWB) where the final neonatal delivery occurs underwater in a bath. An assisted vaginal delivery is by vacuum or forceps.

Maternal wellbeing for this study was assessed by the absence of maternal morbidity and mortality. Maternal morbidity refers to complications relating to, or as a result of

the pregnancy. As this was a retrospective study, indicators obtained were limited to what was available in the records. Maternal morbidity indicators for this study included any tears, postpartum haemorrhage or a retained placenta. Postpartum haemorrhage was recorded by the doctors and nurses, and it was assumed they followed standard definitions.

Neonatal wellbeing for this study was assessed by the absence of any neonatal morbidity or mortality. Neonatal morbidity for this study was defined as Apgar score < 7 at 5 minutes or neonatal intensive care unit admission.

A midwife refers to a nurse with a diploma in midwifery, who is registered with the South African Nursing Council as a midwife.

A Consultant refers to a Consultant Obstetrician who is registered with the Health Professions Council of South Africa (HPCSA).

ABBREVIATIONS

AOL	Augmentation of labour
AROM	Artificial rupture of membranes
C/S	Caesarean section
COU	Consultant obstetric unit
IOL	Induction of labour
MOU	Midwife obstetric unit
NICU	Neonatal intensive care unit
NVD	Normal vaginal delivery
PPH	Postpartum haemorrhage
TENS	Transcutaneous electrical nerve stimulation
UWB	Underwater birth

1.0 INTRODUCTION

1.1Background

Midwife obstetric units (MOUs) have been in existence worldwide for many decades. In many countries there has been a shift in policy to review, and possibly increase, the level of autonomy and decision-making that midwives have regarding low risk pregnancies (Hundley et al. 1994). This is because it has been suggested that midwives are less likely to intervene in deliveries than doctors, and provide more choice of delivery for the mother (Hundley et al. 1994; Turnbull et al. 1996; Campbell et al. 1999; Waldenstrom et al. 1998).

In developed countries much research has been carried out to assess the different models of MOUs, often in comparison to consultant obstetric units (COUs) (Mahmood et al. 2003, Reddy et al. 2004). Although MOUs exist in both public and private sectors, the majority of the studies in this literature review were carried out in the public sector.

In South Africa MOUs exist in both the public and private sectors, with the majority being in the public sector. There are very few private MOUs in South Africa, with little research available to assess their rates of intrapartum delivery interventions, methods of delivery or delivery outcomes, on their own or in comparison to COUs. It would be beneficial to have some research comparing MOUs and COUs in South Africa in order to establish if there is a place for more such units countrywide. Research would need to be carried out in both the public and private sectors separately, as their resources vary greatly and results would not be able to be generalised to both sectors.

There are various different models of MOUs in developed countries. One model is a freestanding unit with midwives having sole responsibility for patients, with no doctors on site. Another model is an integrated model with doctors on site but only seeing patients at the midwives' request. The doctor could be either a general practitioner or an obstetrician.

Linkwood Birth Unit at the Linkwood Clinic is a private 11 bed obstetric unit in Johannesburg, Gauteng. It is not a freestanding MOU as it offers both midwife-led care and consultant-led care. It was established in 2001, and currently averages 800 deliveries per annum. Eleven midwives and three obstetricians deliver their patients regularly at Linkwood Birth Unit. There is an operating theatre at the Clinic, one floor below the birthing unit. The MOU is focused on maximal maternal input in the entire delivery plan. There is a rooming-in option for the patient's partner and children to stay at night in order make the birthing experience a more positive one.

There are two models of delivery in this practice. The first model is where the midwives are the lead practitioners for their patients. They do this without any consultant involvement The MOU performs normal vaginal deliveries, underwater births, and may sometimes also undertake vacuum deliveries themselves. Only if they feel it necessary, do they refer a patient for consultant care or for a caesarean section to the COU.

The second model is where consultants utilising the clinic do their own deliveries and caesarean sections. The deliveries include vaginal deliveries, underwater births and assisted vaginal deliveries (vacuum and forceps).

The COU performs caesarean sections on their own patients, as well as the patients referred by the MOU. The COU patients sometimes arrive at the clinic before the consultant does, and clinic nursing staff will then carry out the doctor's instructions in his/her absence.

The Linkwood Birth Unit has routinely collected data, which was available for analysis. No research has been carried out in the South African setting to assess the efficacy of private MOU in comparison to private COUs. Access to the clinic's data provided an ideal opportunity to assess the functioning of a MOU and compare it to a COU, in this private unit in a South African setting.

1.2 Statement of Problem

The effectiveness of private MOUs in South Africa is not well documented. Little research has been carried out comparing the birth outcomes and rates of intervention between private MOUs and COUs in South Africa.

1.3 Justification for the Study

The Linkwood Birth Unit represents a relatively new concept in South Africa. However, there has been little analysis to evaluate the outcomes of this unit. This study will be beneficial to the Linkwood Birth Unit in assessing the overall functioning of their unit.

1.4 Literature Review

The aim of this literature review was to summarise research relevant to MOUs and COUs. This was specifically with regard to three main areas being explored by this study, namely: intrapartum delivery procedures (i.e. pain relief, induction and augmentation of labour); methods of delivery (i.e. vaginal birth, C/S and assisted vaginal delivery); and maternal and neonatal wellbeing. The majority of the available studies in the literature were from the developed countries. We were not able to find any similar studies on MOUs conducted in a public or private South African setting.

The first of the major studies comparing a MOU to a COU was by Hundley et al. in 1994. The study design was a randomised controlled trial with maternal and perinatal morbidity as its main outcome measures. The study setting was an integrated unit where the consultants were in close proximity to the MOU. The study looked at the antenatal and intrapartum transfer during labour from the MOU to COU, events during labour (for example monitoring, analgesia, mobility of pregnant women), outcomes of labour (for example mode of delivery, state of perineum, and placental delivery), and foetal outcomes (for example number of infants, mean birth weight, median Apgar scores, resuscitation, and NICU admission). MOU patients in comparison to the COU patients had increased mobility, utilised more natural methods of pain relief (bath, mobility, massage, and TENS usage) and had fewer epidurals. There were no significant differences in the mode of delivery or neonatal outcomes, even though this study showed that MOU patients had increased mobility and fewer interventions than COU patients. However, there were high rates of antepartum and intrapartum transfer from the MOU to the COU, which raised the question about the antenatal criteria being unable to determine which patients would remain low risk.

The evaluation of a freestanding MOU at the Royal Bournemouth Hospital by Campbell et al. in 1999 also compared the functioning of a MOU to a COU. This was a prospective cohort study with the main outcome measures being care given, morbidity in women and their babies, and transfers during the antenatal period and in labour. This study focused on labour and delivery (labour, induction, augmentation, analgesia, and length of labour), outcomes for women (for example state of perineum, blood loss over 500ml, and significant problems after delivery) and outcomes for babies (birth weight, Apgar scores, resuscitation required, NICU transfer, and congenital abnormalities). There were no differences in neonatal outcomes between the units. However the women delivering at the MOU had fewer interventions i.e. lower rates of induction and augmentation of labour, less use of pethidine opioid analgesia and epidural analgesia, and were more likely to use a water bath for pain relief.

The 2003 study in Nepal (Rana et al. 2003) was carried in collaboration with the Women's Health Project, the Patan Hospital and the Kathmandu Medical College. Its objective was to evaluate Nepal's first independent midwifery unit as a model for training and service provision for low risk pregnancies. This study evaluated the MOU in relation to an adjacent COU using standardised interviews and record reviews to assess intrapartum care for low risk pregnancies.

The key indicators specified as primary outcomes included AROM, number of vaginal examinations, augmentation of labour, duration of labour, perineal trauma, meconium-stained liquor, neonatal Apgar scores, special care baby unit admission and hospital stay.

The findings of this study showed that midwife led deliveries were associated with reduced rates of AROM, less augmentation of labour with oxytocin, fewer episiotomies and fewer cases of meconium-stained liquor. In addition to fewer interventions, the MOU had no significant differences in duration or complications of labour, mode of delivery, birth weight, neonatal Apgar score or admission to the special care baby unit. As with the studies discussed above, this study also concluded that intrapartum care for low risk pregnancies by midwives is effective, provided appropriate screening has taken place.

A further study by Reddy et al. in 2004 investigated a freestanding low risk MOU in the United Kingdom. This was by means of a retrospective analysis of computerised records. This study examined outcomes of labour (for example intrapartum transfers, different modes of deliveries, episiotomies, and epidurals), complications in the 3rd stage (primary postpartum haemorrhage, and manual removal of placentas) and outcomes of all babies (for example stillbirths, low birth weight babies, congenital anomalies, and NNU admission). The study concluded that this particular MOU was safe for low risk deliveries, under their existing protocol.

With regards to caesarean sections, the UNICEF/WHO/UNFPA international guidelines on the monitoring of obstetric care uses 5-15% as a reference level for acceptable C/S rates (UNICEF/WHO/UNFPA, 1997). Furthermore, it has been shown that doctors are more likely to perform C/S than vaginal deliveries, with C/S rates generally on the rise worldwide (Bateman 2004). In South Africa the C/S rates are high in both the public sector and the private sector, with the C/S rates being much higher in the private sector. This is demonstrated in the article by Tshibangu et al.

(2002) which showed the C/S deliveries in Pretoria were extremely high for the private sector at 57,43%. Furthermore, the article by Bateman (2004) cited that South African private sector C/S rates are around 65%, with the public sector C/S rates estimated at between 10 and 20%. When looking abroad, a study in Sydney over a 10-year period showed that C/S rates increased 17 times for private patients, and 2.7 times for the public hospitals (Blumenthal et al. 1984).

The generation of years of research on assessing the efficacy of midwifery-led models of delivery and its relevance in low risk obstetrics resulted in Walsh et al. (2004) undertaking a structured review of five controlled studies in order to look at the outcomes of free-standing midwife-led birth centres. This study examined six outcome measures across the five studies: normal spontaneous vaginal birth, C/S, intact perineum, episiotomy, babies not requiring transfer to secondary neonatal care, perinatal mortality and intrapartum transfer rates to a COU. Every study showed favourable outcomes for the MOU and the efficacy of consultant unit care for low-risk women was questioned. However this study exposed the lack of generalisation beyond the individual studies, and the need for further quality controlled studies.

Hatem et al. in 2004, via the Cochrane Database of Systemic Reviews, released a protocol for a study, which intends to review the available research comparing midwifery-led models of care versus other models of care delivery during pregnancy. They will undertake a meta-analysis of the available randomised controlled studies in order to reach some consensus on the overall topic. This systematic review is still currently underway.

All the studies reviewed here consistently raise the question about the necessity for consultant involvement in low risk obstetric patients. However, Mahmood et al. in 2003 evaluated an experimental midwife-led unit in Scotland and highlighted the risks of stand-alone midwife-led units. The study suggested that "present antenatal criteria are unable to determine who will remain at low risk throughout pregnancy and labour, especially among nulliparous women." The necessity to formulate local protocols was also highlighted.

As seen above, the last few years have produced a number of studies that have focused on assessing the different models of delivery care for pregnant women. One of the major problems encountered with these studies was the lack of standardisation between the studies. Studies varied with respect to their study designs, criteria for patient selection, interventions being analysed and the outcome measures selected. This limited the generalisation of the research beyond their individual settings.

The studies reviewed utilised a variety of study designs from a retrospective analysis (Reddy et al. 2004), to prospective cohort studies (Campbell et al. 1999), randomised control trials (Hundley et al. 1994, Turnbull et al. 1996), to a meta-analysis (Hatem et al. 2004) of studies.

The criteria for patient selection between these studies also varied. The earlier studies for example Hundley et al. 1994 had basic exclusion criteria including pre-existing maternal disease, infertility, poor obstetric history (previous C/S, difficult vaginal delivery or poor obstetric outcome), height and age restrictions and multiple pregnancies.

The later studies had much more comprehensive exclusion criteria, although the details were varied. For example in the study by Reddy et al. (2004), exclusion criteria included 3 or more miscarriages, whilst Campbell et al. (1999) excluded 2 or more miscarriages. Furthermore, Campbell et al. (1999) excluded multiparous women aged 38 years and over, whilst Reddy et al. (2004) did not exclude multiparous women based on age. Some studies did not give the sufficient details of their exclusion criteria (Turnbull et al. 1996, Rana et al. 2003).

With regards to intrapartum delivery procedures, most attention in the literature has focused on analysing the extent of intrapartum interventions being carried out by MOUs and COUs. However the interventions vary between the different studies. The majority of the studies focused on AROM, augmentation of labour with oxytocin, episiotomies and perineal tears. Some studies included other outcomes such as meconium-stained liquor (Rana et al. 2003), anaesthesia used (Campbell et al. 1999), and the number of vaginal examinations (Turnbull et al. 1996).

Overall MOUs were associated with fewer intrapartum interventions when compared to COUs. COU care resulted in higher levels of intervention for specific interventions example episiotomies, augmentation of labour with oxytocin and epidural analgesia (Campbell et al. 1999, Rana et al 2003).

In addition, there were limitations to the consistency of outcome measures for the different measures being defined. Outcomes defined in one study could be classed as an intervention in another study. Therefore different outcome measures were used for most of the studies. These ranged from maternal and perinatal morbidity to

complications of labour, technical procedures, and care during the antenatal period and in labour.

Overall, despite there being variation in the types of interventions being analysed by the different studies, the main outcome measures comparing midwives to doctors were usually similar, in that they focused on maternal and neonatal wellbeing. The general consensus was that overall there were no significant differences in neonatal or maternal wellbeing in patients of midwives and doctors. Most of the studies were favourable with regards to the midwives being the lead caregiver for low risk pregnancies, showing conclusively that MOUs are as competent as doctors to handle low risk pregnancies. In addition, it is claimed that they are more cost-effective and perform fewer interventions. However, almost all the studies recommended more rigorous studies to be able to generalise these findings and ensure both maternal and neonatal safety.

The overall conclusion gauged from the literature reviewed, is that MOUs are as safe as COUs for low risk pregnancies. However, none of the MOUs evaluated in the literature review were in an African setting. It would be interesting to investigate how a private MOU, in a South African setting, compares with international models, as well as its potential for replication. Linkwood Clinic has a unique setup for comparison due to it having a private MOU and COU on the same site but functioning independently. This provides an ideal opportunity to assess the functioning of both units.

1.5 Study Aim and Objectives

Aim:

To compare the functioning of a private MOU and private COU in Gauteng.

Objectives:

1. To compare intrapartum delivery procedures, methods of delivery, maternal and-neonatal wellbeing for low risk pregnancies of a MOU and a COU at a private obstetric unit in Gauteng for the period January 2005 to June 2006.
2. To analyse the predictors of key outcomes related to intrapartum delivery procedures, methods of delivery, maternal and-neonatal wellbeing for low risk pregnancies.

2.0 METHODOLOGY

2.1 Study Design

The study design was a retrospective cohort study comparing the outcomes of women who delivered in the MOU to those that delivered in the COU. The study was undertaken by conducting a record review of routine data collected from the Linkwood Birth Centre, a private obstetric unit, at the Linkwood Clinic in Johannesburg Gauteng for deliveries occurring between January 2005 and June 2006.

2.2 Study Population

The study population included all low risk pregnant females delivering their babies at the Linkwood Birth Unit from January 2005-June 2006. Unlike consultants, midwives are not allowed by the regulations of the South African Nursing Council to handle specific complications of pregnancy on their own as defined by the South African Nursing Council. Therefore only low risk pregnancies were included in the study population in order to adequately compare midwives to consultants. A set of exclusion criteria was created. All patients that midwives are not allowed to manage alone were not part of the study sample, as they were considered high risk.

Patients with the following characteristics were excluded:

1 Previous obstetric history of

- previous caesarean section or hysterotomy
- previous stillbirth or neonatal death
- previous miscarriage
- infertility

- presence of rhesus antibodies

2 Current obstetric history of

- multiple pregnancy
- malpresentation
- antepartum haemorrhage
- pregnancy-induced hypertension

3 Gynaecological history of

- myomectomy
- pelvic floor repair
- cone biopsy

4 Previous or current medical disease including

- Diabetes
- cardiac disease
- renal disease
- epilepsy

5 Primigravida aged <18 or > 35 years of age

6 Patients booked for elective C/S

2.3 Study Sample

The study sample comprised all low risk pregnant females delivering at the Linkwood birth unit from January 2005-June 2006. All patients meeting the inclusion criteria for low risk pregnancies were included. Patients transferred from the MOU to the COU during the antenatal period were excluded from the study as they were considered high risk patients.

Patients transferred from the MOU to the COU during labour, requiring caesarean sections or assisted vaginal deliveries by the consultants, were still considered part of the MOU.

The key outcomes of interest for this study included C/S rates, use of epidurals and maternal and neonatal morbidity measures. These are all binary outcomes, therefore the sample size calculation was done using the formula for the comparison of two proportions. This was calculated by assuming a level of confidence alpha (α) of 5%, with a power of 80%, and being able to tell a difference in proportion of 15% between the two groups. Using these figures, a sample size of 170 was required of each group.

The primary reason that January 2005 -June 2006 was selected as the time frame was two-fold. Firstly, this period of time was more than likely to yield an adequate sample size given that the average annual delivery totaled 800. A second reason was the accessibility of these records on the Linkwood premises because all other records had already been placed into storage at a depot. The number of low risk pregnancies delivering during the study period totaled 808 subjects. These 808 patients consisted of 212 COU patients and 596 MOU patients, exceeding the required 170 patients per unit.

2.4 Data Capture

At Linkwood Birth Unit the majority of data capturing by the units is handwritten. Every patient is allocated a file in which all birthing details were captured. Once a patient is discharged, the file is stored in a filing cabinet.

For the purposes of this study, data was obtained from these filed records for the period January 2005-June 2006. The researcher physically went through every file for the designated period and assessed suitability for the study. The study inclusion criteria were utilised to assess patient eligibility for the study. Details of the study subjects were then recorded anonymously on a data capture sheet. All the variables collected are shown in Appendix A.

Variables measured focused on demographics (age and parity), intrapartum delivery procedures, methods of delivery and maternal and neonatal wellbeing. Potential confounders at this stage included primiparous status and assisted deliveries on the occurrence of perineal tears. Intrapartum delivery procedures concentrated on different methods of pain relief, and augmentation or induction of labour.

Methods of delivery looked specifically at vaginal births (either normal vaginal delivery or an underwater birth), an assisted vaginal delivery (vacuum or forceps), or an emergency C/S. Maternal and neonatal wellbeing included measures of morbidity and mortality that could be reliably obtained from the written records. Maternal morbidity focused on any tears, postpartum haemorrhage (PPH) and retained placenta. Indicators of neonatal morbidity were Apgar scores < 7 at 5 minutes after delivery, and neonates requiring Neonatal Intensive Care Unit (NICU) admission.

2.5 Data Processing Methods and Data Analysis Plans

The EpiInfo statistical analysis programme (Version 3.3.2, 2005) was utilised for both data capturing and the analysis of data obtained. The main focus of the data analysis was to compare the functioning of the MOU to the COU.

For intrapartum delivery procedures, methods of delivery and maternal-neonatal wellbeing in Objective 1, a statistical analysis was carried out in order to compare the functioning of the COU and MOU. A 5% level of significance was used to determine whether or not observed differences were statistically significant. Most of the variables in this analysis were categorical in nature (for example COU vs. MOU, C/S or no C/S done). Therefore the uncorrected χ^2 (chi square) test for comparison of proportions was used to evaluate statistical difference between the two groups. Two-tailed p values were used for the χ^2 test. The Fisher's exact test was utilised for variables where small numbers made the χ^2 test inappropriate. The relative risk was used to assess the strength of the associations for each of the variables. The t test was used to compare numerical variables (for example, age) between the MOU and COU.

The second research objective was to analyse predictors of caesarean sections and perineal tears. Initial bivariate analysis was conducted utilizing the χ^2 test. Bivariate relationships were then confirmed by multiple logistic regression. Multiple regression was used in order to deal with confounding and identify independent predictors for the outcomes of interest. Variables of interest were entered together rather than in a stepwise fashion. EpiInfo does not produce pseudo-r^2, and the likelihood ratio P value was used to test if the overall model was statistically significant. The adjusted odds ratio obtained from the multiple logistic regression was used to assess the strength of association for the variables in this analysis. Unadjusted odds ratios (rather than the more correct risk ratios) were also calculated for the bivariate comparisons to enable comparisons with the multiple regression results.

2.6 Pilot Study

A pilot study was initially carried out to assess the feasibility of data -capturing from the filed records. Ten files were utilised to fill in the data capture sheet to assess any problems with extracting the necessary data required for the study. The data collection tool was modified according to the results of the pilot study.

2.7 Ethical Considerations

This was a record review with all data only available at Linkwood Birth Centre premises. It was essential to protect patients' identities and ensure confidentiality of records. Permission was given by the Linkwood Birth Centre to look at patient files and analyse their data, with the prerequisite that findings will be shared with the centre. Only the researcher undertook the data capturing. This was carried out only at the Linkwood premises under the supervision of the manager of the unit in a specific designated room. Only a study number identified cases. No names of patients or hospital numbers were recorded. No files were removed from the clinic.

Ethical clearance was obtained from the Ethics Committee for research on human subjects of the University of the Witwatersrand prior to any data collection being carried out. Clearance was approved unconditionally: Protocol Number M060209, R14/49 Seedat (Appendix B).

3.0 RESULTS

The total number of recorded deliveries at Linkwood Clinic for the period January 2005-June 2006 was 1,398 (Table 3.1). This was made up of 815 (58.3%) MOU patients and 583 (41.7%) COU patients. Of the total 1,398 deliveries, 808 (57.8%) patients satisfied the criteria for inclusion in the study. This study sample of 808 subjects was made up of 596 (73.8%) of MOU patients and 212 (26.2%) of COU patients. Therefore, 73.8% of the study population was from the MOU, despite the MOU making up only 58.3% of the total deliveries. This was because a larger number of the COU patients were considered high risk and therefore excluded from the study.

Table 3.1 Summary of Linkwood Clinic Deliveries from January 2005-June 2006

	COU		**MOU**		**Total**	
	No.	**%**	**No.**	**%**	**No.**	**%**
Total recorded deliveries	583	41.7	815	58.3	**1,398**	**100.0**
Deliveries included in study	212	26.2	596	73.8	**808**	**57.8**

3.1 Age and Parity

3.1.1 Age

The age distribution of the MOU and COU patients is shown in Figure 3.1 and summarised in Table 3.2. Both units had a very similar pattern for their age distribution. The combined age range extended was 18-44. In addition the mean age for patients was 29.8 years for the COU and 29.2 years for the MOU, with no statistical significance (t=1.57, p=0.12). The similarity in the age distribution between the MOU and COU suggests that any differences in outcomes between the two units are independent of patient age.

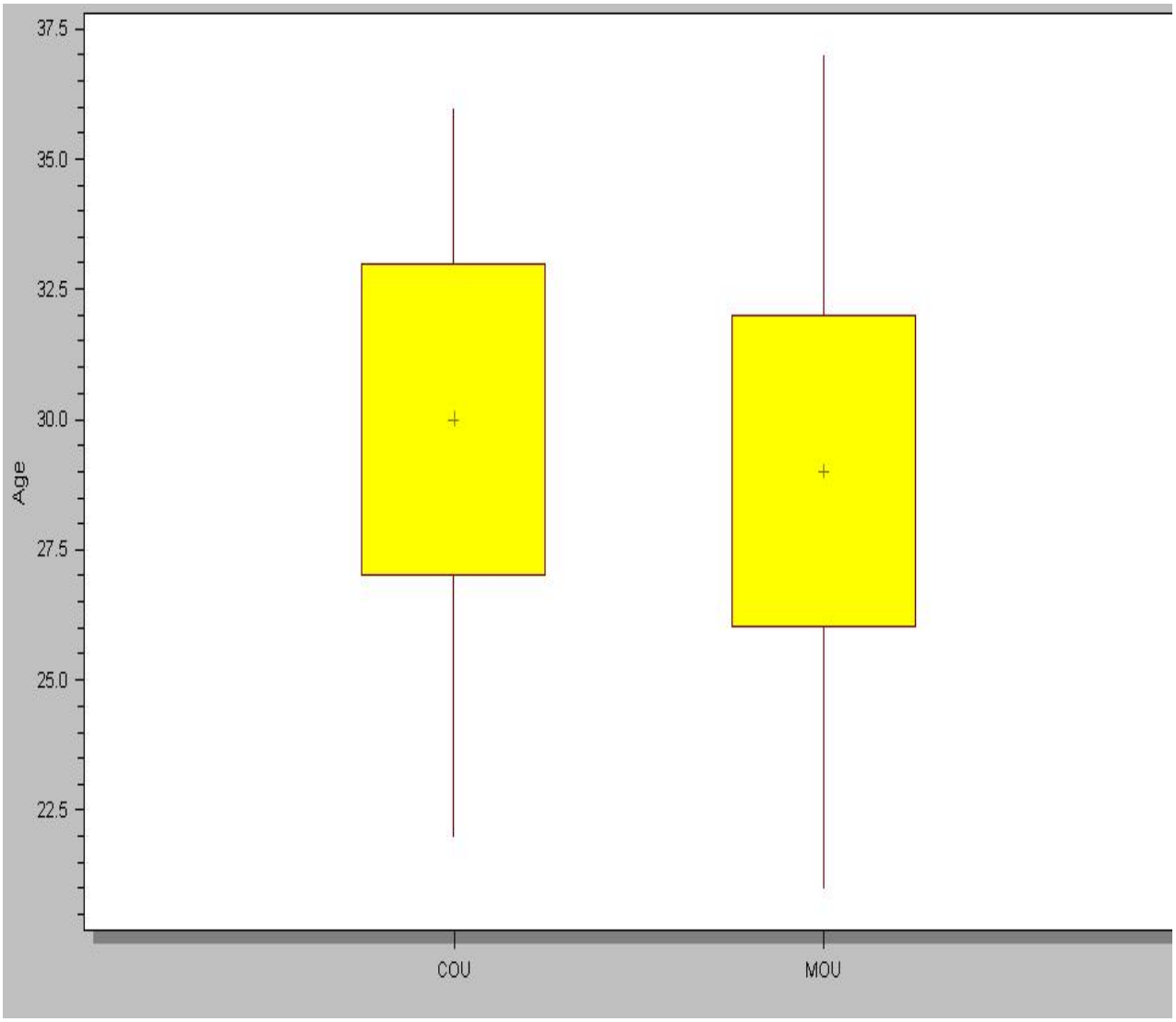
Table 3.2 Age Distribution for COU and MOU

	COU	**MOU**
Range	20 – 42	18 – 44
Mean	29.8	29.2
Std Dev	4.3	4.9
Total	**212 (26.2%)**	**596 (73.8%)**

T statistic = 1.57 p=0.12

Figure 3.1 Box-Whisker graph showing age distribution

for COU and MOU



3.1.2 Parity

Table 3.3 compares the proportions of primiparous and multiparous patients in the COU and MOU. Primiparous patients made up the majority of patients in the study sample (61.6%), with fewer multiparous patients (38.4%). This distribution was the same for both COU and MOU. Therefore there were no significant differences in the proportion of primiparous and multiparous patients in the samples from the two units (χ^2=0.0119**,** p=0.91). This similarity in parity between the COU and MOU ensured that confounding due to parity was limited.

Table 3.3 Parity for COU and MOU

	COU		**MOU**		**Total**	
	No.	**(%)**	**No.**	**(%)**	**No.**	**(%)**
Primiparous	130	(61.3)	368	(61.7)	**498**	**(61.6)**
Multiparous	82	(38.7)	228	(38.3)	**310**	**(38.4)**
Total	**212**	**(100.0)**	**596**	**(100.0)**	**808**	**(100.0)**

χ^2=0.0119 p=0.91

3.2 Methods of Delivery

The different methods of delivery for the COU and MOU can be divided into 3 main categories namely vaginal birth, C/S and assisted vaginal delivery. In Table 3.4 a comparison is made between the COU and MOU for the various methods. The most frequent method of delivery was vaginal birth for both units (77.5%), with COU (64.1%) and MOU (82.2). This was followed by a combined C/S rate of 16.0%, with COU (27.4%) and MOU (11.9%). Assisted vaginal delivery was the least frequent method of delivery (6.5%), with COU (8.5%) and MOU (5.9%).

Table 3.4 Different Methods of Delivery

Methods of Delivery	**COU**		**MOU**		**Total**	
	No.	**(%)**	**No.**	**(%)**	**No.**	**(%)**
Vaginal Birth	136	(64.1)	490	(82.2)	**626**	**(77.5)**
C/S	58	(27.4)	71	(11.9)	**129**	**(16.0)**
Assisted (Vacuum + Forceps)	18	(8.5)	35	(5.9)	**53**	**(6.5)**
Total	**212**	**(100.0)**	**596**	**(100.0)**	**808**	**(100.0)**

χ^2 =31.59 p<0.001

Overall, the methods of delivery employed by the COU and MOU were statistically different (χ^2 =31.59, p<0.001). However, when looking at the different methods of delivery individually in relation to the units, this statistical significance varied.

C/S was more common for the COU than the MOU, with caesarean sections being carried out 2.3 times more frequently by the COU (27.4%) when compared to the MOU (11.9%). This difference was statistically significant (χ^2 =27.8, p=0.001).

Assisted vaginal deliveries (either vacuum or forceps) formed only 6.5% of the total deliveries for the units. The COU performed assisted vaginal deliveries 1.4 times more frequently than the MOU. However when assessing these results in isolation for the individual units, no statistical significance was found in the rates of assisted vaginal deliveries for the COU and MOU (χ^2 =31.59, p=0.19).

Vaginal birth refers to a vaginal delivery, which can be a normal vaginal delivery (NVD) or an underwater birth (UWB). Overall, vaginal births were the most common method of delivery for Linkwood clinic at 77.5% (Table 3.3). When looking at vaginal births for the individual units, the MOU patient was 1.3 times more likely to have a vaginal birth than the COU patient. The breakdown of the vaginal births is further explored in Table 3.5. Although vaginal births were the commonest method of delivery overall, the COU preferred NVDs whereas the MOU preferred UWBs. A NVD was the most common method of delivery for the COU making up over 70% of their vaginal births. The MOU, on the other hand, favoured UWB as the most frequent method of vaginal births (55.9%), while the UWB rate for the COU was 27.2%. Overall there was a significant association for the method of vaginal birth between the COU and MOU (χ^2 =29.2, p<0.001), with MOU patients being 2.1 times more likely to have an UWB than COU patients

Table 3.5 Vaginal Birth

Vaginal Birth	COU		MOU		Total	
	No.	(%)	No.	(%)	No.	(%)
NVD	99	(72.8)	216	(44.1)	**315**	**(39.0)**
UWB	37	(27.2)	274	(55.9)	**311**	**(38.5)**
Total	**136**	**(100.0)**	**490**	**(100.0)**	**626**	**(77.5)**

χ^2 =29.2 p<0.001

3.2.1 C/S in relation to Parity

The potential relationship of C/S to parity is investigated in Table 3.6, where a positive link between primiparous status and increased C/S rate was found. Primiparous patients accounted for the majority of patients undergoing C/S as their method of delivery. Of the 129 C/S in the sample, 123 (95.3%) occurred in primiparous patients, and they were 12.8 times more likely (95 %C.I 5.6-28.6) than multiparous patients to have a C/S (χ^2= 73.8, p <0.001). Therefore primiparous status was a predictor of a patient having a C/S.

Table 3.6 C/S Rates in relation to Parity

	Primiparous		Multiparous		Total	
	No.	(%)	No.	(%)	No.	(%)
C/S	123	(24.7)	6	(1.9)	**129**	**(16.0)**
Non-C/S	375	(75.3)	304	(98.1)	**679**	**(84.0)**
Total	**498**	**(100.0)**	**310**	**(100.0)**	**808**	**(100.0)**

χ^2 =73.8 p<0.001

3.2.2 C/S in relation to Units and Parity

Previously the relationship of caesarean sections was explored with respect to units and parity separately. COUs and primiparous status were shown to have an increased risk of resulting in a C/S individually. The stratified analysis in Table 3.7 further explores the relationship between C/S, parity and the COU. The COU had a much higher C/S rate for both primiparous and multiparous patients. The COU primipara C/S rate was 41.5% whilst the MOU primipara C/S rate much lower at 18.8%. Therefore a COU patient was 2.2 times more likely to have a C/S than a MOU patient (χ^2=26.8, p<0.001). Furthermore the COU was also 5.6 times more likely to perform a C/S on a multiparous patient than the MOU (χ^2=5.1, p=0.02). Therefore the COU has an increased C/S rate for both primiparous and multiparous patients.

Table 3.7 The Association between unit of delivery and C/S, stratified by Parity

	C/S Rate (n/N %)					
	COU N=212	**MOU N=596**	**Total**	**RR (95%CI)**	**χ^2**	**p-value**
Primiparous	54/130 (41.5)	69/368 (18.8)	123/498 (24.7)	2.2 (1.7-3.0)	χ^2=26.8	**p<0.001**
Multiparous	4/82 (4.9)	2/228 (0.9)	6/310 (1.9)	5.6 (1.0-29.8)	χ^2=5.1	**p=0.02**
Total	**58/212 (27.3)**	**71/596 (11.9)**	**129/808 (16.0)**			

3.2.3 Logistic Regression of C/S

The predictors of caesarean sections can be more accurately evaluated by multiple regression. In addition to COU patients and primiparous status, other factors such as induction of labour (IOL) and increasing age may be associated with an increased risk of a C/S. These relationships are explored in Table 3.8. The predictors for C/S were investigated by means of a bivariate analysis, and confirmed by multiple logistic regression. COU, primiparous status and IOL are all positive predictors of C/S, whereas age has no effect on C/S rates. The results of the overall logistic regression model are significant ($p<0.001$).

Table 3.8 Predictors of C/S

	Bivariate Analysis		**Multiple Logistic Regression**		
	Unadjusted Odds Ratio	**p -value**	**Adjusted Odds Ratio**	**95% CI**	**p-value**
COU MOU	2.78 1.00	**p<0.001**	2.88 1.00	1.9-4.4	**p<0.001**
Primiparous Multiparous	16.62 1.00	**p<0.001**	19.13 1.00	8.2-44.6	**p<0.001**
IOL No IOL	1.76 1.00	**p=0.002**	2.00 1.00	1.2-3.2	**p=0.005**
Age >30 Age < 30	1.08 1.00	**p=0.621**	1.48 1.00	1.0-2.2	**p=0.065**

COU-led care is a predictor of a patient having C/S ($p<0.001$). The COU performed more caesarean sections, even when adjusting for other variables such as primiparous status, IOL and advanced age. The odds ratio for the bivariate analysis was 2.78, with this ratio being very similar for the multivariate analysis at 2.88. The selection criteria for patients for MOU and COU limited complicated patients for both units. This was in order to ensure both units were compared only with regards to low risk patients. Therefore the results of the bivariate and multivariate analysis conclusively show that low risk patients have a greater risk of having a C/S when in the COU.

Similarly, primiparous status also carried a higher probability of a C/S. This increased risk was very high in the multivariate analysis at 19.13 ($p<0.001$), with similarly high odds ratio in the bivariate analysis (16.62).

IOL also increased the risk of a C/S by 1.76 in the bivariate analysis. This association between IOL and C/S was even stronger in the multivariate analysis at 2.00.

With regards to increasing age (grouped as < and >30 years), there was no significant association of age with C/S. Therefore older women were not at an increased risk of a C/S in this analysis.

3.3 Intrapartum Delivery Procedures

Intrapartum delivery procedures for this study were classified as pain relief, induction of labour and augmentation of labour. Each of these variables is considered individually in Tables 3.9-3.11 to assess if there were any significant differences between the COU and MOU.

3.3.1 Pain Relief Methods

The use of various methods of pain relief by the COU and MOU is explored in Table 3.9. These methods of pain relief included drugs (Pethidine and Aterax), an epidural, TENS, Entonox gas inhalation, and the use of a bath. The methods of pain relief between the MOU and COU, which showed significant differences, were the use of TENS, an epidural or a bath (excluding UWB). There were no significant differences in the use of drugs, gas inhalation or the lack of any pain relief for both units.

The different methods of pain relief were analysed individually and not all together in an overall test. This is because the variables are not mutually exclusive for example a patient having pethidine could also have an epidural. COU patients were 3.6 times more likely to have an epidural than MOU patients (95%C.I:2.5-5.1**,** χ^2 =55.9, $p<0.001$). The possible confounding of an epidural with C/S must be considered. MOU patients were 3.0 times more likely to utilise the bath as a pain relief method than COU patients (95%C.I: 1.7-5.1, χ^2 =18.6, $p<0.001$).

Table 3.9 Pain Relief Methods

Methods of Pain Relief	**COU No. (%)**	**MOU No. (%)**	**Total No. (%)**	**p-value**
Drugs (PETHIDINE+ ATERAX)	74 (34.9)	229 (38.4)	**303 (37.5)**	**p=0.4**
Epidural	59 (27.8)	46 (7.7)	**105 (13.0)**	**p<0.001**
Bath (Excl. UWB)	14 (8.0)	76 (23.6)	**90 (18.1)**	**p<0.001**
TENS	1 (0.5)	31 (5.2)	**31 (4.0)**	**p<0.001**
Entonox gas inhalation	12 (5.7)	27 (4.5)	**39 (4.8)**	**p=0.3**
None	25 (11.8)	59 (9.9)	**84 (10.4)**	**p=0.44**

When looking at the use of TENS, the MOU was 11.0 times more likely than the COU to use this as a method of pain relief (95%C.I:1.5-80.3**,** χ^2 =9.2, p<0.001). Therefore the MOU preferred TENS and the bath as non-pharmacological methods of pain relief. The COU preferred an epidural for their patients.

Both units utilised drugs (Pethidine and Aterax) and gas inhalation similarly for pain relief. In addition, approximately 10% of patients in both the units had no pain relief. The lack of pain relief between the units was not statistically significant.

3.3.2 Induction of labour

The MOU at Linkwood Clinic carried out inductions of labour (I OL) on their patients when necessary. Therefore the differences in frequency of IOL between the MOU and COU were analysed. Labour was induced either by Prandin gel or cytotec tablets. IOL is looked at in Table 3.10. IOL occurred far more frequently in the COU (25.0%) than in the MOU (15.6%). Therefore the relative risk for COU patients of having an IOL was 1.6 (95%CI:1.2-2.2) in comparison to MOU patients (χ^2 =9.3, p=0.002).

However details regarding reasons for IOL were not always clearly identifiable. Some of the reasons included the patient being postdates, or stated maternal request as the reason for the IOL. Therefore although IOL was significantly increased in the COU, it may have been medically indicated in many cases. Although the MOU did perform inductions of labour, patients may generally have been more inclined to go to a COU for an IOL. The COUs may have been more amenable to carrying out IOL for patient reasons, whereas the midwives may have been more inclined to carry out IOL for specific medical indications only.

Table 3.10 Induction of Labour

	COU		**MOU**		**Total**	
	No.	**(%)**	**No.**	**(%)**	**No.**	**(%)**
IOL	53	(25.0)	93	(15.6)	**146**	**(18.1)**
No IOL	159	(75.0)	503	(84.4)	**662**	**(81.9)**
Total	**212**	**(100.0)**	**596**	**(100.0)**	**808**	**(100.0)**

χ^2 =9.3 p=0.002

3.3.3 Augmentation of Labour

Differences between the units in augmentation of labour, with the use of artificial oxytocin or the artificial rupture of membranes (AROM), are shown in Table 3.11. There were no significant differences in the augmentation of labour for either unit.

Overall, AROM was utilised almost 5 times more often than artificial oxytocin to augment labour. However, there were no significant differences by the COU and MOU in their utilisation of artificial oxytocin to augment labour (χ^2 =1.2, p=0.23). Both units performed AROM on a large percentage of their patients, COU on 77.6% of patients and MOU on 86.1% of their patients. Similarly as with artificial oxytocin use, there were no significant differences in the use of AROM for the units (χ^2 =2.1, p=0.15).

Table 3.11 Augmentation of Labour

	COU n/N (%) N=212	**MOU n/N (%) N=596**	**Total n/N (%) N=808**	**χ^2**	**p–value**
Artificial Oxytocin during Labour	24/212 (11.3)	51/596 (8.6)	75/808 (9.3)	1.2	**p = 0.23**
	COU n/N (%) N=154	**MOU n/N (%) N=525**	**Total n/N (%) N=679**		
ArtificialRupture of Membranes (Excl. C/S)	83/154 (77.6)	317/525 (86.1)	400/679 (49.5)	2.1	**p = 0.15**

3.3.4 Episiotomy

The routine use of episiotomy is considered an intervention during delivery, therefore this outcome was analysed. At Linkwood, episiotomies were performed by both the MOU and the COU. A comparison of this obstetric intervention is looked at in Table 3.12. Overall, episiotomies were performed on 7.2% of patients. However, the COU performed far more episiotomies (11.8%) when compared to the MOU (5.5%). This finding was independent of assisted deliveries. Therefore the relative risk of a patient experiencing an episiotomy was more than doubled with the COU (R.R 2.13, 95% C.I: 1.3-3.5).

Table 3.12 Episiotomy

	COU		**MOU**		**Total**	
	No.	**(%)**	**No.**	**(%)**	**No.**	**(%)**
Episiotomy	25	(11.8)	33	(5.5)	**58**	**(7.2)**
No Episiotomy	187	(88.2)	563	(94.5)	**750**	**(92.8)**
Total	**212**	**(100.0)**	**596**	**(100.0)**	**808**	**(100.0)**

χ^2 =9.2 p=0.002

3.4 Neonatal Morbidity and Mortality

Overall, neonatal morbidity indicators were similar for COU and MOU. In addition there were no reported cases of neonatal mortality for either unit. Neonatal morbidity (as defined by Apgar < 7 at 5 minutes and NICU admission) of the two units is compared in Table 3.12. Overall, neonatal morbidity comprised 2.5% of all deliveries. There were no recorded cases of Apgar <7 for the COU, and only 2 cases for the MOU. Similarly reports of NICU admission were low, with and only 5 admissions by the COU and 13 by the MOU. There were no significant differences between the units for these results. Therefore the MOU and COU had similar neonatal outcomes.

Table 3.12 Neonatal Morbidity

Neonatal Morbidity	**COU n/N (%) N=212**	**MOU n/N (%) N=596**	**Total n/N (%) N=808**	**Fisher's Exact test p value**
Apgar < 7 @ 5 minutes	0/212 (0.0)	2/596 (0.3)	**2/808 (0.2)**	**p=1.0**
NICU admission	5/212 (2.0)	13/596 (2.0)	**18/808 (2.2)**	**p=0.8**

3.5 Maternal Morbidity and Mortality

There were no reported cases of maternal mortality for either unit. Maternal tears are examined in Table 13.3 and maternal morbidity patterns (as defined by any tears, PPH or retained placenta) between the units are compared in Table 3.14.

Table 3.13 shows in more detail the distribution of various maternal tears occurring in each unit. Maternal tears need not be mutually exclusive, that is a patient experiencing a perineal tear could also simultaneously have a vaginal tear. However, in this particular study the different maternal tears being investigated were mutually exclusive, and did not occur simultaneously in the same patient. However, this could have been a recording error by the provider who might have recorded only the most severe tear and excluded the minor tears. Therefore tears could be totalled for the COU and MOU, and considered in relation to all 808 subjects. Perineal tears at 31.7% formed the major part of the total tears (36.3%). Both COU (32.5%) and MOU (36.7%) had similar rates of tears, with no significant differences between the units (χ^2 =1.72, p=0.19).

The majority of tears were grade 1 and 2 perineal tears at 31.7%. The MOU had the only recorded case of a grade 3 perineal tear, as well as two cervical tears and four paraurethral tears. The COU had no recorded cases of cervical, grade 3 perineal, or paraurethral tears. Overall there was no statistically significant difference for maternal tears between the COU and MOU (χ^2 =1.72, p=0.19).

Table 3.13 Maternal Tears

Maternal Tears		**COU** **No.**	**(%)**	**MOU** **No.**	**(%)**	**Total** **No.**	**(%)**
Perineal Tears	Grade 1	33	(15.6)	102	(17.1)	135	(16.7)
	Grade 2	29	(13.7)	91	(15.3)	120	(14.9)
	Grade 3	0	(0.0)	1	(0.2)	1	(0.1)
	Total	**62/212**	**(29.2)**	**194/596**	**(32.6)**	**256/808**	**(31.7)**
Vaginal Tears		7	(3.3)	24	(4.0)	31	(3.8)
Cervical Tears		0	(0.0)	2	(0.3)	2	(0.2)
Paraurethral Tears		0	(0.0)	4	(0.7)	4	(0.5)
Total		**69/212**	**(32.5)**	**224/596**	**(37.6)**	**293/808**	**(36.3)**

χ^2 =1.72 p=0.19

"Any tears", PPH and retained placenta were considered as important morbidity factors for this study and are looked in further detail in Table 3.14. "Any tears" refer to all perineal, cervical, vaginal, or paraurethral tears. Overall, there were no significant differences in maternal morbidity and mortality patterns were maternal morbidity patterns for either unit. Maternal morbidity using these indicators occurred in 40.2% of patients. Tears formed the majority of cases of maternal morbidity overall, as well as for the units individually. These differences between rates of tears between the units were not statistically significant (p=0.19).

Similarly PPH and retained placenta formed a small percentage of cases for both units, with no statistically significant differences between the units. Therefore, overall maternal morbidity and mortality patterns were similar for the COU and the MOU.

Table 3.14 Maternal Morbidity

Maternal Morbidity	**COU n/N (%) N=212**	**MOU n/N (%) N=596**	**Total n/N (%) N=808**	**RR 95% CI**	**p-value**
Any Tears	69/212 (32.5)	224/596 (37.6)	**293/808 (36.3)**	0.9 (0.7-1.1)	**p=0.19**
PPH	5/212 (2.4)	18/596 (3.0)	**23/808 (2.8)**	0.8 (0.3-2.1)	**p=0.62**
Retained Placenta	4/212 (1.9)	5/596 (0.8)	**9/808 (1.1)**	2.2 (0.6-8.3)	**p=0.25***

Any Tears = perineal, cervical, vaginal, paraurethral tears
PPH = postpartum haemorrhage
***Fisher's exact test p value**

3.6 UWB and Perineal Tears

UWB, by virtue of its location in water, is a potential factor for lack of perineal control during delivery, possibly influencing perineal tears. This relationship between UWB and perineal tears is investigated in Table 3.15. Perineal tears occurred in just under a third of all total deliveries (31.7%).

Overall perineal tears occurred more frequently with UWB (40.2%) when compared with non-UWB deliveries (26.4%). Therefore UWB carried a 1.5 times risk ratio of resulting in a perineal tear (grade 1 or 2 only) than non-UWB (95%C.I: 1.2-1.9). The association of perineal tears to UWB was significant with $\chi^2 = 16.9$, $p<0.001$.

Table 3.15 UWB and Perineal Tears

	UWB		**Non-UWB**		**Total**	
	No.	**(%)**	**No.**	**(%)**	**No.**	**(%)**
Perineal Tear	125	(40.2)	131	(26.4)	**256**	**(31.7)**
No Perineal Tear	186	(59.8)	366	(73.6)	**552**	**(68.3)**
Total	**311**	**(38.5)**	**497**	**(61.5)**	**808**	**(100.0)**

$\chi^2 = 16.9$ $p<0.001$

3.6.1 Logistic Regression of Perineal Tears

The occurrence of a perineal tear was the most important maternal morbidity outcome in this study. The various factors that influence the risk of a perineal tear were investigated by bivariate analysis and multiple logistic regression as shown in Table 3.16. The predictors evaluated included MOU care, vacuum deliveries, an episiotomy, primiparous status, and an UWB. UWB, vacuum deliveries and episiotomies significantly influenced perineal tear rates, whereas MOU and primiparous status had no effect on perineal tear rates. The overall logistic regression model was highly significant with $p<0.001$.

Table 3.16 Predictors of Perineal Tears

	Bivariate Analysis		**Multiple Logistic Regression**		
	Unadjusted Odds Ratio	**p-value**	**Adjusted Odds Ratio**	**95% CI**	**p-value**
MOU COU	1.17 1.00	**p=0.19**	0.93 1.00	0.64-1.34	**p=0.69**
Vacuum No Vacuum	1.78 1.00	**p=0.03**	3.83 1.00	1.96-7.45	**p<0.001**
Episiotomy No Episiotomy	0.07 1.00	**p<0.001**	0.06 1.00	0.01-0.25	**p<0.001**
Primiparous Multiparous	0.94 1.00	**p=0.33**	0.99 1.00	0.72-1.36	**p=0.95**
UWB No UWB	1.88 1.00	**p<0.001**	1.95 1.00	1.40-2.71	**p<0.001**

UWB carried a 1.88 times risk of resulting in a perineal tear in the bivariate analysis. This association of UWB to perineal tears is even stronger in the multivariate analysis with an increased odds ratio of 1.95. Therefore the odds of a patient experiencing a perineal tear during an UWB were almost doubled.

When looking at the association of perineal tears to MOU care, the bivariate analysis showed slightly increased odds ratio at 1.1.7, of an MOU patient experiencing a perineal tear. However, the multivariate analysis produced an adjusted odds ratio of only 0.93. However, neither of these results showed any statistical significance. Although the MOU carried out more underwater births, the risk of their patients experiencing a perineal tear was not increased. Therefore, there were no differences in the risk of perineal tears for the MOU and COU, even when adjustments were made for variables such as UWB, episiotomies, vacuum deliveries and primiparous status. The MOU patients did not have an increased risk of experiencing a perineal tear.

Vacuum deliveries also had an increased risk of perineal tears, and the association was even stronger with the multivariate analysis where the odds increased from 1.8 to 3.8. However, if an episiotomy was performed, the risks of a perineal tear dropped drastically as seen in the bivariate analysis. This is confirmed in the multivariate analysis where the odds ratio drops to far below 1 to 0.06. Any value >1 increases the association between episiotomies and perineal tears, whereas this value far <1 shows that the risk of a perineal tear actually decreased when an episiotomy was performed. These findings relate to the protective function of an episiotomy in relation to perineal tears. This is to be expected as an episiotomy further increases the size of the final delivery passage, with less strain on the perineum. Therefore, episiotomies do appear

to reduce the risk of a patient experiencing a perineal tear. However, since the majority of perineal tears were non-severe grade 1 and 2, the advantage of an episiotomy as opposed to a non-severe perineal tear is questionable.

Furthermore, the probability that primiparous status could impact on perineal tears due to a lack of previous deliveries was not supported in this analysis. Primiparous status has no increased risk of resulting in a perineal tear in either the bivariate analysis with an odds ratio close to 1, and even closer to 1 in the multivariate analysis.

4.0 DISCUSSION

In this study, COU patients made up 26.2% (212) of the total sample size while MOU patients made up the remaining 73.8% (596) (Table 3.1). The proportion of COU patients to MOU patients was lower because the COU had many more high risk patients and therefore more exclusions. Despite this, there were no statistically significant differences between the units with regards to age or parity. Both units had similar values for age ranges and means, and had almost identical rates of primigravidas and multigravidas.

4.1 Methods of Delivery and Intrapartum Delivery Procedures

UWB formed the majority of cases of vaginal birth for the MOU, whereas the vaginal births in the COU were primarily NVD although they did undertake UWB (Table 3.5). The consultants at Linkwood Clinic are quite flexible with delivery options, and had a high rate of UWBs (27.2%). This particular birthing centre, which favours maternal choice of delivery as well as serving as a well-known UWB centre, may be different in comparison to other private birthing units in South Africa. This may reduce the ability to extrapolate the findings of this study to all private birthing units, where delivery plans may be more provider-driven. None of the studies identified in the literature review focused on UWB between the MOU and COU, and much more research will need to be done to compare the use of UWBs between midwives and doctors. This study found that perineal tears occurred 1.5 times more commonly with UWB, although they were only grade 1 and 2 tears.

C/S was the second commonest method of delivery (Table 3.4). Primiparous status and COU were both strong risk factors for having a C/S as a method of delivery, as was reinforced by logistic regression. The COU had a significantly higher C/S rate than the MOU at 27.3% compared to 11.9% (Table 3.7).

However it must be noted that this study focused only on emergency C/S rates in order to compare the MOU to the COU. Therefore, in order to put the COU C/S rate in perspective with other studies, all caesarean sections (both elective and emergency) needed to be included for the 18-month study period. Of the 1398 total deliveries from January 2005-June 2006, the COU had 583 recorded deliveries of which 414 (71.0%) were caesarean sections (elective and emergency). This figure is greater than the 65% private sector C/S rate shown in the 2004 study by Bateman.

The intrapartum delivery procedures focused on in this analysis were pain relief methods, augmentation of labour, induction of labour and episiotomies. COU patients were 3.6 times more likely to have an epidural than MOU patients. MOU patients utilised the bath (excluding UWB) 3 times more frequently than the COU patients as a method of pain relief (Table 3.9). The increased use of epidurals for pain relief by the COU patients is in keeping with findings of the studies, specifically the randomised control trial by which showed that midwives have lower rates of intervention than consultant-led units for an epidural anaesthetic (Hundley et al. 1994, Campbell et al. 1999). COUs were 1.6 times more likely to induce patients than the MOUs (Table 3.10). However the files did not always clarify reasons for induction, therefore the necessity for an IOL could not be accurately defined. Therefore, the differences in IOL between the MOU and COU have to be viewed cautiously.

There were significant differences in the rates of assisted deliveries between the MOU and COU. Despite this, the COU patients had double the risk of having an episiotomy.

Overall, COUs had higher rates of intervention, namely epidurals, IOL, episiotomies and caesarean sections than the MOUs. These findings are in keeping with the studies by Hundley et al. (1994) and Rana et al. (2003). However, the COU did not have higher rates of assisted vaginal deliveries or augmentation of labour than the MOU. These latter findings are not in keeping with studies, which show doctors to have increased rates of augmentation of labour, and assisted vaginal deliveries (Campbell et al. 1999, Rana et al. 2003). These differences may be explained by the MOU autonomy at Linkwood Clinic. Midwives at Linkwood Clinic are able to carry out procedures such as vacuum deliveries on their own, augment labour or to order epidurals for their patients.

4.2 Maternal and Neonatal Wellbeing

Despite the different rates of interventions for the MOU and COU, the main outcome measures for this study, i.e. maternal and neonatal wellbeing, were very similar. In this study there were no reported cases of maternal or neonatal mortalities for COU or MOU patients. There were no statistically significant differences in maternal and neonatal morbidity patterns between the units. These results are in keeping with the overall findings of the literature review, which reinforced that there were no major differences in maternal and neonatal outcomes for low risk pregnancies between midwife and consultant units (Hundley et al. (1994), Turnbull et al. (1996), Waldenstrom et al. (1998), Campbell et. al 1999, Rana et. al. 2003).

These findings are a positive indicator as to the comparable level of functioning of the MOU to the COU.

However, this functioning is limited to intrapartum and immediate postpartum care. This study does not look at the level of antenatal care delivered by each unit, which is a limitation. Type of care received during the antenatal period may affect who remains low risk during the delivery, or who may be referred sooner. Despite this, this study paves the way for further studies to be undertaken in both the private and public sectors. The implications for the public sector could be far-reaching, especially in rural areas in our country where medical practitioners are in scarce supply. However studies will need to be carried out looking specifically at the public sector, as the findings of this study cannot be extrapolated beyond this particular private sector setting. Furthermore, this lack of generalisation extends to differences in experiences between the midwives in the public and private, as well as to the availability, or lack of, resources in the public sector influencing decision-making. Midwives in the public sector may not have as much autonomy to perform vacuum deliveries or augment the labour of their patients without a doctor's approval. In addition, their units may not have access to anaesthetists to perform epidurals when requested. Furthermore, they may not have any underwater birthing facilities available.

Nevertheless, if similar findings of no differences in maternal and neonatal outcomes can be replicated in the public sector, it will show that the MOU has the potential to be a safe, cost effective obstetric solution for low risk pregnancies. Midwives should be well trained, with good protocols and adequate referral systems.

Overall, the main findings of the study are in keeping with international studies (Hundley et al. 1994, Campbell et al.1999, Mahmood et al. 2003, Rana et al. 2003), which reflect two main results. Firstly, the equivalent functioning of the MOU in relation to the COU with similar maternal and neonatal outcomes, and secondly, the less interventionist approach of the MOU. Therefore despite Linkwood Clinic being a unique setup (with its UWBs, and its philosophy of prochoice and natural birth), the functioning of its MOU is comparable to many developed countries. Therefore this study serves as an encouraging template for further studies in a South African setting. If we could conclusively show MOUs to be as safe as COUs for low risk pregnancies in the public sector, we could possibly address staff shortages of doctors in the rural districts.

4.3 Possible Limitations

The most significant limitation to this study relates to the study period. This study showed no significant differences between the units for maternal and neonatal morbidity and mortality. However, the duration of the study only covers an 18-month period. A longer study for example a 20-year period may show significant differences, which a shorter study may not have uncovered. This is the case for our study where there have been no mortalities in this 18-month period.

The results obtained are limited to the private sector and may not be reflective of the public sector. This is mainly due to the fact that in private practice more resources are at the disposal of the midwife/doctor, which expands their decision-making field, whereas in the public sector decision-making may be restricted by budgetary constraints. For example the use of an epidural in a private setting is probably more

common than in a public setting as anaesthetists are more available, and are paid per procedure performed. In addition, the referral networks in rural public sector settings are not as efficient as private settings (geographical location, availability of specialists). Furthermore, the very nature of private practice being an incentive-based environment may further influence decision-making. The public sector, not being incentive-based may result in more objective decision-making, or alternatively may be a limitation with reduced resources guiding decision-making. Linkwood Clinic, being a private clinic, has far greater access to resources for example staff to patient ratio, theatre access, medication including epidurals, and patient involvement in decision-making.

This study population is not representative of the general population with regards to socioeconomic status since all patients are either medical aid or private patients. They therefore have better nutrition, more frequent antenatal visits and ultrasound scans than public sector patients. This may improve their chances of a better delivery outcome when compared to public sector patients.

Furthermore there were no patient interviews to assess patient satisfaction with level of care received. By not conducting patient interviews, the level of patient choice in the delivery plan could not be ascertained. It could be argued that patients who chose to attend this particular MOU may have been seeking a less interventionist approach to childbirth, as opposed to patients attending the COU. Linkwood Clinic encourages more autonomy of patient in birthing decisions as opposed to numerous other institutes. Therefore the results obtained from this study may be related to this particular group of patients only, and results may be different in another MOU.

Alternatively, decision-making may have been more a result of a patient's wishes, rather than a midwife or consultant's decision. Therefore the extent to which the delivery plan is patient or provider driven needs to be further investigated.

Another limitation of this study is the study design. Since this was a retrospective cohort study undertaken via a record review, there are limitations to the type of data that one is able to collect, as opposed to a prospective study design. The types of indicators used in this study are limited to the information available in the patient records. It would have been use to have obtained information on foetal heart monitoring, more details on antenatal visits and so forth. In addition, there was non-randomisation of the study as all subjects were included from the sample period. Since the subjects were not randomised, we are not certain if the two groups are exactly comparable. Although we only focused on low risk pregnancies, there may have been slightly less complicated cases going to the midwives than the consultants. Randomisation would be important in dealing with unknown confounders. Randomisation may have also been useful in dealing with some of the previously mentioned limitations including patient versus provider driven interventions. Although a prospective randomised controlled trial might produce better results, it might be more difficult to carry out in practice. Randomisation is unlikely to be acceptable to patients in the private sector, which may also influence results. Since they are on medical aids or paying private rates, they may wish to have input into who their service provider is. Furthermore, it would be unethical to randomise patients without their consent.

Prospective studies with both patient and provider interviews need to be carried out in order to better assess the functioning of the MOU in relation to the COU. Since this study compared the functioning of a MOU (that only accepts low risk patients) to a COU, high risk patients were not considered. Therefore, the findings of this study are only applicable to low risk pregnancies.

Measurement biases could have arisen during the initial recording of data by the caregiver, with incorrect capturing of treatment given, delivery outcome or delivery method. The MOU may have had more meticulous capturing of data than the COU or vice versa. This could potentially have affected the completeness of records, especially the COU as smaller numbers were included in the study sample.

Another potential source of error could have occurred with the researcher incorrectly recording data on the capture sheet. Steps were taken to minimize this occurring with the researcher at random crosschecking handwritten data with computer-captured data. These errors were unlikely to result in bias since they would have been random and equal for both COU and MOU.

5.0 RECOMMENDATIONS

With regards to the private sector, this study shows that the MOU functions just as well as the COUs for low risk pregnancies. The use of MOUs rather than COUs would lessen the necessity for a consultant, who would only need to be on standby. Furthermore, this may have cost-cutting implications for patients and medical aids.

Prospective studies, including randomised control trials should be undertaken, with patient and provider interviews, and antenatal aspects of care included in the study. Furthermore, indicators to assess level of functioning should be standardised for the studies. This would give a much more accurate depiction of the functioning of the unit. In addition, the studies must be relevant to the public sector MOUs, to assess if their level of functioning is similar to the private sector. In the setting of standard indicators of measure, the public sector must be taken into account. For example epidurals as an indicator would not be suitable as they are not carried out as often in the public sector. If future studies show similar positive results for MOUs in both the public and private sectors, the potential for large-scale replication of the MOU will have great financial and human resource-saving implications.

Judging by this study, there is clearly a demand for MOUs in the private sector. It is not clear what the demand for MOUs is in the public sector. Women in the public sector might prefer a unit where there is greater involvement of a doctor, rather than only midwives, and may not utilise that facility. This needs to be investigated further.

Midwives can function just as well as doctors for low risk pregnancies. They just need adequate training, standard protocols to follow and good referral systems.

6.0 CONCLUSION

The MOU at Linkwood Clinic has proven to be an excellent example of a private midwife unit with the potential to be replicated countrywide. Their performance in comparison to the COU was of a comparable standard with similar maternal and neonatal outcomes despite different levels of experience and interventions. However this comparison is only with respect to low risk pregnancies, and is limited to this particular private setting. This comparable performance of the MOU to the COU are in keeping with the majority of the findings from the literature review which point towards MOUs being a viable option for managing low risk pregnancies independent of consultants. The results of this study are promising for the creation of many more autonomous MOUs. However, the non-randomisation of this study design is a limitation, which necessitates that conclusions drawn be looked at with caution.

Many more studies need to be undertaken, both in private and the public sector in South Africa. The studies need to have more rigorous study designs (for example randomised control trials, prospective cohort studies) with patient involvement in order to achieve a more accurate overall picture. Other factors will also need to be considered as they affect delivery outcomes. These include examining antenatal visits for frequency, duration, tests carried out, level of experience of midwife to name but a few. Furthermore, reasons for referral and referral rates need to be looked at in closer detail. Most importantly, consistent standardised variables to be measured as well as exact outcome measures need to be laid out, in order for different studies to be comparable to one another and for findings to be extrapolated to both public and private sectors.

MOUs could be a cost-effective, low interventionist gold standard for low risk pregnancies, provided they have well-trained midwives, with set standardised protocols, and a good referral system to deal with complications.

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APPENDIX A:

DATA ENTRY SHEET

Category	Variable	VariableName	Revised Variable Name
ID	Pt no.	Uniquekey	ptno
	Age	Age	age
Unit	COU	Cou	cou
	MOU	Mou	mou
Parity	Primipara	Primipara	primipara
	Multipara	Multipara	multipara
Type Of Delivery	NVD	Nvd	nvd
	UWB	Uwb	uwb
	Vacuum	Vaccuum	vac
	Forceps	Forceps	forceps
	C/S	Cs	cs
Reason For C/S	Neonatal distress	NeonatalDistress	fd
	CPD	Cpd	cpd
	Failure to progress	FailureToProgress	ftp
	Failed IOL	FailedIol	fiol
	Prolonged 2nd stage	Prolonged2nd	pro2
	Prolonged latent phase	ProlongedLatent	prol
	OP presentation	OpPresentation	op
	Transverse lie	Transverse	trans
	Deep transverse arrest	DeepTransverse	deep
	Failed vacuum	FailedVaccuum	failvac
Labour Type	Spontaneous	SpontaneouS	spont
	Induced	Induced	induce
Method of Induction	Prostaglandin gel	PrandinGel	pg
	Oral cytotec	CytotecOral	cytor
	PV cytotec	CytotecPv	cytpv
ROM	Spontaneous	SpontaneousRupture	srom
	AROM	ArtificialRupture	arom
Artificial support	Oxytocin during labour	Artificial	oxy
Pain Relief	Pethidine	Pethidine	peth
	Aterax	Atarax	aterax
	Epidural	Epidural	epidural
	Gas	Gas	gas
	Tens	Tens	tens
	Bath	Bath	bath
	None	None	nopain

Maternal Well-Being	Intact perineum	IntactPeriNEUM	intact
	1st degree tear	N1stDegree	t1st
	2nd degree tear	N2ndDegree	t2nd
	3rd degree tear	N3rdDegree	t3rd
	Labial tear	LabialTear	tlab
	Vaginal tear	VaginalTeaR	tvag
	Cervical tear	CervicalTear	tcx
	Paraurethral tear	ParaurethrAL	tpu
	Episiotomy	Episiotomy	epis
	PPH	Postpartum	pph
	Retained placenta	RetainedPlACENTA	retplac
	Mortality		
	No morbidity or mortality	NoMorbiditY	nomatmm
Neonatal Well-Being	NICU admission	NicuAdmissiON	nicu
	Apgar<7 @ 5min	Apgar7At5MIN	apgar7
	Mortality		
	No morbidity or mortality	NoMorbidityOR	nopaedmm

APPENDIX B:
ETHICS CLEARANCE CERTIFICATE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Seedat

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER M060209**
PROJECT	Comparison of a Private Midwife Obstetric Unit and a Private Consultant Obstetric Unit
INVESTIGATORS	Dr BA Seedat
DEPARTMENT	School of Public Health
DATE CONSIDERED	06.02.24
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 06.02.27 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Dr D Blaauw

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10005, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Bseedat
21/08/06