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Evaluating Midwifery Units (EMU): A prospective cohort study of freestanding midwifery units in New South Wales, Australia.

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ABSTRACT

Objective: To compare maternal and neonatal birth outcomes and morbidities associated with the intention to give birth in different settings.

Design: Prospective cohort study.

Setting: Two freestanding midwifery units and two tertiary level maternity units in New South Wales, Australia.

Participants: 3651 low risk women with singleton pregnancies who were less than 28^{+0} weeks gestation and who intended to give birth at a participating maternity unit at the time of booking.

Primary and secondary outcome measures: Primary outcomes were mode of birth, Apgar score of less than 7 at 5 minutes and admission to the neonatal intensive care unit or special care nursery. Secondary outcomes were onset of labour, analgesia, blood loss, management of third stage of labour, perineal trauma, transfer, neonatal resuscitation, breastfeeding, gestational age at birth, birth weight, severe morbidity and mortality.

Results: After adjusting for relevant confounders women who planned to give birth at a freestanding midwifery unit were significantly more likely to have a spontaneous vaginal birth (AOR 2.44; 95%CI 1.90 to 3.14) and significantly less likely to have a caesarean section (AOR 0.38; 95%CI 0.29 to 0.51). There was no significant difference in the adjusted odds ratio of 5 minute Apgar scores, however babies from the freestanding midwifery unit group were significantly less likely to be admitted to neonatal intensive care or special care nursery (AOR 0.61; 95%CI 0.40 to 0.92). Analysis of secondary outcomes indicated that planning to give birth in a freestanding midwifery unit was associated with similar or reduced odds of intrapartum interventions and similar or improved odds of indicators of neonatal wellbeing.

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Conclusions: The results of this study support the provision of care in freestanding midwifery units as an alternative to tertiary level maternity units for women with low risk pregnancies at the time of booking.

ARTICLE SUMMARY

Strengths and limitations of the study

- This is the first prospective cohort study of maternal and neonatal outcomes of women who planned to give birth in freestanding midwifery units compared to women who planned to give birth in tertiary level maternity units in Australia.
- Selection bias was minimised by prospectively identifying women's planned place of birth at booking rather than at the onset of labour and analysing the data according to the place where women intended to give birth. Self-selection bias was eliminated through the use of a population database of all pregnant women who met the inclusion criteria during the study period.
- The study ensured comparability of the cohorts of women by evaluating risk at booking and controlling for confounding factors including risk at the onset of labour. However subtle differences may exist between women who plan to give birth in different settings. These differences cannot be quantified and may have a confounding effect on the outcomes.
- This study was not powered to detect clinically significant differences in perinatal mortality. Meaningful conclusions on longer-term perinatal outcomes could not be drawn from the datasource.

INTRODUCTION

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In New South Wales, the most populous state in Australia, most babies are born in a hospital setting. Of the 96,489 recorded births in 2010, 246 (0.3%) babies were born at home, 468 (0.5%) babies were born before arrival to hospital and 95,775 (99.3%) babies were born in a hospital maternity unit [1]. Contemporary hospital maternity services differ from each other considerably. The two hospital maternity services at opposite ends of the spectrum in terms of context and system of care are freestanding midwifery units and tertiary level maternity units. There are major gaps in the evidence associated with giving birth in these different settings.

Tertiary level maternity units offer care by specialist obstetricians and midwives. They cater for all pregnant women, regardless of risk status, and are the most appropriate place for women with complex and/or rare problems to give birth. Specialist obstetric, anaesthetic and paediatric consultation is available 24 hours a day [2, 3]. Some tertiary level maternity units have integrated alongside birth centres that have a home-like environment and offer a midwifery-managed model of care to women at low risk of obstetric complication [4].

Freestanding midwifery units offer primary level care by a named midwife and have no routine involvement of medical staff. They are geographically separate from facilities offering onsite obstetric, paediatric or specialised medical consultation and procedures including epidural analgesia and caesarean section [2, 5]. These units provide a unique system of care to Australian women who have no identified risk factors and who either choose not to give birth at, or have limited access to other types of maternity care.

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New South Wales' maternity policy strongly supports tertiary level maternity care for all women [6-11]. Planning to give birth at a facility without on-site specialist medical support is largely perceived as hazardous and unsafe for women and their unborn babies [6, 12]. Consequently the majority of births occur in tertiary level maternity units; with only approximately 300 births per annum in freestanding midwifery units [13, 14]. However it is unknown whether the actual gains match the expected gains of concentrating all low risk births in large tertiary hospitals [5, 15, 16].

Robust international evidence has recently been published to evaluate the safety and cost effectiveness of planning to give birth at freestanding midwifery units for women with low risk pregnancies [17-21]. A landmark prospective cohort study by the Birthplace in England Collaborative Group [17] found that there was no significant difference in rates of perinatal mortality or morbidities relating to intrapartum events between women who planned to give birth in freestanding midwifery units compared to those who planned to give birth in tertiary obstetric units (adjusted odds ratio (AOR) 0.92; 95% CI 0.58 to 1.46). Furthermore, women who planned to give birth in the freestanding units were less likely to have a ventouse delivery (AOR 0.32; 95% CI 0.22 to 0.47), forceps delivery (AOR 0.45, 95% CI 0.32 to 0.63), intrapartum caesarean section (AOR 0.32, 95% CI 0.24 to 0.42) or syntocinon augmentation (AOR 0.26; 95% CI 0.20 to 0.33) than women who planned to give birth at a tertiary obstetric hospital.

Despite these findings, freestanding midwifery units remain an underutilised model of maternity care in Australia. This is likely to remain the case without robust Australian research that evaluates their safety.

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Objectives

The Evaluation of Midwifery Units (EMU) study was a prospective cohort study that aimed to fill in some of the gaps in current research evidence on giving birth in freestanding midwifery units compared to tertiary level maternity units. It was undertaken in two Area Health Services in New South Wales, Australia and in one District Health Board in New Zealand. The aim was to compare the maternal and neonatal birth outcomes and morbidities associated with the 'intention to give birth' or 'booking at' the freestanding midwifery units in each health district compared with a reference cohort booked at the three tertiary referral maternity hospitals integrated with the freestanding midwifery units. This paper reports the findings from the Australian arm of the study.

The researchers have adhered to the STROBE statement for improving the quality of the reporting of observational studies [22].

METHODS

Setting

Two freestanding midwifery units in regional and urban areas of New South Wales participated in the study. The most recent published data on the volume of births in these units is from 2005/2006, when 326 births were recorded over a 12-month period [13, 14]. Women receive antenatal, intrapartum and postnatal care from their midwifery group practice midwives. These midwives work in small groups and provide 24-hour on-call midwifery care. If the need for transfer to the referral tertiary level maternity unit arises, the midwifery

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group practice midwife often, but not always, transfers with the woman and continues to provide midwifery care in the tertiary unit [23]. The referral tertiary level maternity units are approximately 15 to 20 kilometers away from the freestanding midwifery units; and transfer time may take between 15 minutes and 65 minutes depending on traffic conditions. Intrapartum and postnatal transfers occur via car or ambulance depending on the urgency of the transfer.

The two tertiary level maternity units used as comparators in this study were the referral hospitals for the freestanding midwifery units described above. They recorded a combined total of 6072 births in 2010 [1]. They have a very wide catchment area, spanning 75 hospitals in New South Wales [24] and receive women and babies transferred from all other maternity units in the catchment areas. Women receive antenatal, intrapartum and postnatal care from a number of models of care, including obstetric and midwifery antenatal clinics, general practitioner shared care, birth centre and midwifery group practice [23].

Participants and data collection

Data custodians from each maternity unit used the ObstetriX database to identify eligible women who booked to give birth at the participating maternity units during the study period 1st April 2010 and 31st August 2011. ObstetriX is a statewide surveillance system used across New South Wales to provide point-of-care maternity data collection across the antenatal, intrapartum and immediate postnatal periods. Midwives contribute the data on each woman and her baby as soon after birth as is possible.

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Women with singleton pregnancies were eligible to participate in the study if they planned to give birth at a participating maternity unit during the study period. Eligible participants were less than 28^{+0} weeks pregnant at the time of commencement of antenatal care at their chosen maternity unit.

Only women considered to be at low risk of requiring ongoing obstetric and medical care were included in the tertiary level maternity unit cohort, as per the Australian College of Midwives (ACM) Guidelines for Consultation and Referral (Table 1). Women were defined as low risk if the ObstetriX database did not identify an ACM B/C or C risk factor at booking (Table 2) [25].

Table 1. ACM three levels of consultation and referral*

ACM A- Discuss	*ACM B - Consult*	*ACM C- Refer*
The woman's condition or situation requires discussion with another midwife or member of the health care team to plan for optimal care. Responsibility of care stays with the midwife.	The woman's condition or situation requires consultation with the medical practitioner, ideally in a 'face to face' consultation. Responsibility of care will either stay with the midwife or transfer to a medical practitioner.	The woman's condition or situation requires temporary or ongoing medical care at a tertiary or secondary level. Responsibility of care is transferred to a medical practitioner.

**ACM occasionally uses levels interchangeably by categorizing some conditions as A/B or B/C. Level of referral is left to the discretion of the midwife, in consultation with the woman, and a medical practitioner if required.*

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Table 2. ACM B/C and C conditions identified at booking and during pregnancy

Identification of risk	*Description*
At booking	Essential hypertension, renal disease, diabetes (not including gestational diabetes), adrenal disease, pituitary disease, asthma, cardiomyopathy, congenital heart disease, heart murmur, myocardial infarction, congenital renal disease, glomerulonephritis, antiphospholoid antibodies, rheumatoid antibodies, SLE, connective tissue disease, epilepsy, benign intracranial hypertension, thromboembolism, platelet disorder, clotting disorder, thalassaemia, organ transplant, neurological/spinal surgery*, classical caesarean section*, spina bifida*, fibromyalgia*, spinal cord disease* or any cardiac condition*, myomectomy, bicornate uterus, eclampsia or HELLP syndrome (hemolysis, elevated liver enzymes and low platelet count).
During pregnancy	Abnormal placental site, placenta praevia, placental abruption, eclampsia, preeclampsia, essential hypertension, renal hypertension, insulin dependent gestational diabetes, pre-existing diabetes, any new cardiac, endocrine, GIT, liver, gastrobiliary, haematological or infectious condition, pyelonephritis, uterine anomaly*, any new renal/neurological conditions*, any fetal anomaly, threatened premature labour, admission for cervical shortening/dilatation, antenatal steroid course, isoimmunisation, antibodies, cervical suture, feticide, intrauterine transfusion, breech/transverse/oblique lie or pre-term rupture of membranes.

**These condition were not listed in ACM guidelines, however they were considered to be equivalent to ACM B/C and C conditions.*

All women booked to give birth at the freestanding midwifery units were considered low risk and were included in the study, regardless of their specific ACM risk classification. This was a pragmatic a-priori decision taken at the beginning of the study. The rationale for this was that the midwifery and obstetric teams from the freestanding midwifery units in this study work collaboratively with women to ensure their suitability to give birth at the freestanding midwifery units. They use the ACM guidelines in conjunction with other information (such as detailed medical records and physical assessment) to determine with the women themselves whether they would be advised to proceed to give birth in a freestanding midwifery unit and, if necessary, when to transfer.

The two sample cohorts were further scrutinised to identify women who developed any ACM B/C or C risk factors during pregnancy that may have led to a higher risk of requiring

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medical or obstetric care during labour and birth (Table 2). This enabled 'risk at the onset of labour' to be controlled in the analysis.

The primary outcome measures were mode of birth, 5 minute Apgar score of less than 7 and admission to the neonatal intensive care unit (NICU) or special care nursery (SCN). Secondary maternal outcomes included type of onset of labour, use of analgesia, rates of postpartum haemorrhage, management of third stage of labour, rates of perineal trauma, stage of transfer and severe morbidity. Secondary neonatal outcomes included the need to resuscitate, breastfeeding at birth and upon hospital discharge, gestational age, birth weight, severe morbidity (defined as 5 minute Apgar score of less than 7 followed by admission to NICU/SCN, restricted to live born babies greater than 24 weeks gestation) and neonatal mortality.

Data were collected from the ObstetriX database, except for a limited amount of transfer data which were collected from maternal medical records. Neonatal data on reason for NICU/SCN admission, treatment details and perinatal mortality and morbidity recorded in data bases other than the ObstetriX data base were not available for this study.

Statistical analysis

The study was powered to detect a clinically relevant fall of 6.0 % in the rate of women requiring a caesarean section from 29.0% to 23.0%, with 90% power and a significance level of p=0.05. These numbers were also sufficient to detect a clinically significant reduction of 4.0% in the rate of instrumental birth (forceps/ventouse) from 11.0% to 7.0% with 90% power and a significance level of p=0.05. These differences were based on data available

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from the first report of birth outcomes at both freestanding midwifery units in the years preceding the study compared to statewide maternity data [13, 14, 26].

Analyses were by 'intention to treat' with outcomes attributed to planned place of birth at the time of booking. Odds ratios with 95% confidence intervals were calculated for the primary and secondary outcomes. Measures of categorical data were analysed with chi-squared tests and continuous data were analysed using the - test. Multivariate logistic regression was used for dichotomous outcomes to adjust for relevant known confounders. Adjustment was made for maternal age, smoking status, parity, risk at the onset of labour, gestation at the time of birth, induction and augmentation of labour where relevant. Women who had an elective caesarean section were excluded when calculating the adjusted odds ratios for analgesia during labour. Women who had a caesarean section were excluded when calculating the odds ratios for perineal trauma. Neonatal outcomes for live born babies were adjusted for maternal age, smoking status, parity, augmentation, induction and risk at the onset of labour. Caesarean section and gestation at birth were adjusted where relevant. Adjustments for all outcomes are outlined below the tables. Multivariate regression models were restricted to subjects with no missing values. No inferential statistics were carried out on severe maternal or neonatal morbidity and mortality outcomes due to the small numbers involved. Stata version 12 was used for all analyses.

RESULTS

Data were obtained for 3,651 women who met the inclusion criteria, of whom 494 planned to give birth at a freestanding midwifery unit and 3157 planned to give birth at a tertiary level maternity unit (Figure 1). Of the 494 women who planned to give birth at the freestanding

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midwifery unit 238 women (48.2%) gave birth at a tertiary level maternity unit, 244 women (49.4%) gave birth at the freestanding midwifery unit as planned, and a further 12 (2.4%) gave birth before arriving to the freestanding midwifery unit. Of the 494 women who planned to give birth in a freestanding midwifery unit, 256 (51.8%) transferred to a tertiary level maternity unit (34% antenatal, 13.2% intrapartum, 3.6% postnatal and 1% unknown stage of transfer). The majority of women who planned to give birth at a tertiary level maternity unit actually gave birth there (98%), with 28 women (0.9%) giving birth before arriving. 34 women (1.1%) who intended to give birth at a tertiary level maternity unit actually gave birth at a freestanding midwifery unit, and four of these women transferred to a tertiary level maternity unit postnatally.

Table 3 shows the mean age, mean parity, proportion of nulliparous women, ethnicity, smoking status, risk status at booking and risk status at the onset of labour by planned place of birth. There was no significant difference in mean parity and proportion of nulliparous women in each group. Women who planned to give birth at a freestanding midwifery unit had a significantly higher mean age, and significantly fewer women from this group smoked or had a risk factor at the onset of labour compared to women from the tertiary level maternity unit (this is despite no women from the tertiary level maternity unit group having an identified risk factor at booking). There were 27 women from the freestanding midwifery unit group who had a risk factor at the time of booking. Women who identified as an Oceanic ethnicity (representing women born in Australia, New Zealand, Papua New Guinea, Fiji and Western Samoa) made up most of the tertiary level maternity unit group (90.5%), while this ethnicity only represented 70.9% of the freestanding midwifery unit group.

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Table 3. Maternal characteristics by planned place of birth

Characteristics	*Freestanding n=494 No. (%)*	*Tertiary n=3157 No. (%)*	p*
Mean age	29.6	28.5[†]	**<0.001**
Median (mean) parity	1 (0.9)	1 (1.0)	0.8
Proportion of nulliparae	208 (42.1)	1364 (43.2)	0.6
Ethnicity			
African	5 (1.0)	40 (1.3)	
Asian	100 (20.2)	140 (4.4)	
European	27 (5.5)	92 (2.9)	
Oceania	350 (70.9)	2856 (90.5)	
Aboriginal/TSI	12 (3.4)[‡]	165 (5.8)[‡]	
South American	4 (0.8)	5 (0.2)	
North American	7 (1.4)	20 (0.6)	
Missing data	1 (0.2)	4 (0.1)	**<0.001**
Smoking status			
Smoker	27 (5.5)	546 (17.3)	**<0.001**
Risk at booking			
Category B/C or C	27 (5.5)	0	[§]
Risk at onset of labour			
Category B/C or C	65 (13.2)	598 (18.9)	**0.002**

**Statistically significant results in bold.*
[†]*From n=3156 women. Missing data from one woman.*
[‡]*Expressed as a percentage of the Oceania population in the corresponding cohort.*
[§]*Numbers too small, multivariate model cannot converge.*

Primary and secondary maternal outcomes

Table 4 describes the primary and secondary maternal outcomes and shows the unadjusted and adjusted odds ratios of maternal outcomes by planned place of birth. After adjusting for maternal age, smoking status, parity, risk at the onset of labour and gestation at the time of birth, compared to the tertiary cohort, freestanding midwifery unit women were significantly more likely to have a spontaneous vaginal birth (AOR 2.44; 95%CI 1.90 to 3.14) and significantly less likely to have a caesarean section (AOR 0.38; 95%CI 0.29 to 0.51). The reduction in the odds of women from the freestanding midwifery unit group having an

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instrumental delivery lost significance when adjusted for confounding factors (AOR 0.73; 95%CI 0.50 to 1.08) (Table 4).

After adjusting for confounding factors, women who planned to give birth in a freestanding midwifery unit were significantly less likely to experience: induction (AOR 0.53; 95% CI 0.42 to 0.67), elective caesarean section (AOR 0.33; 95%CI 0.21 to 0.53), augmentation of labour (AOR 0.54; 95%CI 0.41 to 0.71) or intramuscular (IM) or intravenous (IV) narcotic analgesia (AOR 0.24; 95%CI 0.17 to 0.35). Women who planned to give birth at a freestanding midwifery unit were significantly more likely to have spontaneous onset of labour (AOR 2.5; 95%CI 2 to 3.15) (Table 4).

Despite the significantly higher odds of physiological management of the third stage of labour amongst women from the freestanding midwifery unit group (AOR 18.55; 95%CI13.68 to 25.14), they were significantly more likely to experience blood loss of less than 500mls (AOR 1.56; 95%CI 1.18 to 2.06) and significantly less likely to experience blood loss of 500 to 999mls (AOR 0.60; 95%CI, 0.44 to 0.83). There was no significant difference in major postpartum haemorrhage of greater than 1000mls (AOR 0.86; 95%CI, 0.52 to 1.43) (Table 4)

The adjusted odds of having epidural/spinal analgesia, no analgesia or any type of perineal trauma (including episiotomy extending to third or fourth degree tear) did not differ significantly between settings.

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Table 4. Maternal outcomes by planned place of birth

Outcome	*Freestanding n=494 No. (%)*	*Tertiary n=3157 No. (%)*	*Unadjusted OR (95% CI)* *	*Adjusted OR (95% CI)* *†	p*
Mode of birth					
Spontaneous vaginal	400 (81.0)	2044 (64.7)	**2.32 (1.83-2.93)**	**2.44 (1.90-3.14)**‡	**<0.0001**
Instrumental	34 (6.9)	331 (10.5)	**0.63 (0.44-0.91)**	0.73 (0.50-1.08) ‡	0.113
Caesarean section	60 (12.1)	782 (24.8)	**0.42 (0.32-0.56)**	**0.38 (0.29-0.51)** ‡	**<0.0001**
Labour onset**					
Spontaneous	378 (76.5)	1782 (56.4)	**2.51 (2.02-3.13)**	**2.50 (2.00-3.15)**	**<0.0001**
Induction	97 (19.6)	1010 (32.0)	**0.52 (0.41-0.66)**	**0.53 (0.42-0.67)**	**<0.0001**
Elective caesarean	20 (4.0)	369 (11.7)	**0.32 (0.20-0.51)**	**0.33 (0.21-0.53)**	**<0.0001**
Labour intervention					
Augmentation	66 (13.4)	690 (21.9)	**0.55 (0.42-0.72)**	**0.54 (0.41-0.71)**	**<0.0001**
Analgesia					
Epidural/ spinal	62 (12.6)	577 (18.3)	**0.64 (0.48-0.85)**	0.81 (0.59-1.11)§	0.188
IM/IV narcotic	38 (7.7)	856 (27.1)	**0.22 (0.16-0.31)**	**0.24 (0.17-0.35)**§	**<0.0001**
No analgesia	115 (23.3)	556 (17.6)	**1.42 (1.13-1.78)**	0.96 (0.75-1.23)§	0.77
Blood loss					
<500mls	428 (86.6)	2533 (80.2)	**1.60 (1.22-2.10)**	**1.56 (1.18-2.06)**‡	**0.002**
500-999mls	48 (9.7)	485 (15.4)	**0.59 (0.43-0.81)**	**0.60 (0.44-0.83)**‡	**0.002**
>1000mls	18 (3.6)	139 (4.4)	0.82 (0.50-1.35)	0.86 (0.52-1.43)‡	0.563
Third stage					
Physiological	185 (37.4)	93 (2.9)	**19.7 (15.0-26.0)**	**18.55 (13.68-25.14)**‡	**<0.0001**
Perineal trauma					
None/graze	241 (48.8)	1752 (55.5)	**0.76 (0.63-0.92)**	0.85 (0.69-1.07)¶	0.162
1st/2nd degree tear	229 (46.4)	1273 (40.3)	**1.28 (1.06-1.55)**	1.16 (0.94-1.44)¶	0.164
3rd/4th degree tear	24 (4.9)	132 (4.2)	1.17 (0.75-1.83)	0.99 (0.62-1.58)¶	0.968
Episiotomy					
Episiotomy	38 (7.7)	315 (10.0)	0.75 (0.53-1.07)	0.73 (0.50-1.07)¶	0.103
Extended to 3rd/4th	7 (1.4)	37 (1.2)	1.2 (0.53-2.71)	1.38 (0.59-3.23)¶	0.453

**Statistically significant results in bold. p values reported for adjusted ORs.*

†All adjusted ORs adjusted for maternal age, smoking status, parity, risk at the onset of labour and gestation at the time of birth.

‡Also adjusted for augmentation and induction.

§Also adjusted for augmentation and induction. Elective caesarean sections excluded from analysis.

¶Also adjusted for augmentation and induction. All caesarean sections excluded from analysis.

*** One woman from the freestanding midwifery unit group and four women from the tertiary level maternity unit group went into labour spontaneously and proceeded to have an elective caesarean section. They were coded as both spontaneous and elective caesarean.*

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Primary and secondary neonatal outcomes

Table 5 describes the primary and secondary neonatal outcomes for live born babies and shows the unadjusted and adjusted odds ratios of neonatal outcomes by planned place of birth. Babies from the freestanding midwifery unit group were significantly less likely to be admitted to SCN or NICU (AOR 0.61; 95%CI 0.40 to 0.92) (Table 5). The reduction in the odds of babies from the freestanding midwifery unit group having an Apgar score of less than 7 at 5 minutes lost significance when adjusted for confounding factors (AOR 0.55; 95%CI 0.24 to 1.29).

After adjusting for known confounders in the model, babies from the freestanding midwifery unit group were significantly more likely to require no resuscitation at birth compared to babies from the tertiary level maternity unit group (AOR 1.40; 95%CI 1.05 to 1.87). The adjusted odds of being greater than 42 weeks gestation (AOR 4.41; 95%CI 2.22 to 8.76), being breastfed at birth (AOR 2.26; 95%CI 1.51 to 3.37) or being exclusively breastfed on hospital discharge (AOR 1.58; 95%CI 1.13 to 2.22) were significantly higher in babies from the freestanding midwifery unit group compared to those from the tertiary level maternity unit group.

Significantly fewer babies from the freestanding midwifery unit group were less than 37 weeks gestation (AOR 0.53, 95%CI 0.29 to 0.97) or had a birth weight of less than 2500 grams (AOR 0.40, 95%CI 0.17 to 0.92). The adjusted odds of babies requiring suctioning, supplemental oxygen or inspiratory positive pressure (with mask or endotracheal tube), being greater than 2500 grams at birth or being between 37 and 41 weeks gestation at birth showed no significant difference between the two groups (Table 5).

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Table 5. Neonatal outcomes for live births by planned place of birth

Outcome	*Freestanding n = 490 No. (%)*	*Tertiary n =3145 No. (%)*	*Unadjusted OR (95% CI)**	*Adjusted OR (95% CI)*†*	p*
Apgar					
<7 at 5 minutes	6 (1.2)	88 (2.8)	**0.43 (0.19-0.99)**	0.55 (0.24-1.29)‡	0.172
SCN/NICU					
Admitted to SCN/ NICU	33 (6.7)	432 (13.7)	**0.45 (0.31-0.65)**	**0.61 (0.40-0.92)‡**	**0.020**
Need for resuscitation					
Nil	421 (85.9)	2462 (78.3)	**1.69 (1.29-2.21)**	**1.40 (1.05-1.87)§**	**0.020**
Suction	11 (2.2)	134 (4.3)	**0.52 (0.28-0.96)**	0.58 (0.31-1.10)§	0.095
Supplemental oxygen	13 (2.7)	150 (4.8)	**0.54 (0.31-0.97)**	0.69 (0.38-1.25)§	0.226
IPP¶¶ (Mask)	43 (8.8)	371 (11.8)	**0.72 (0.52-1.00)**	0.82 (0.57-1.17)§	0.266
IPP¶¶ (Endotracheal tube)	1 (0.2)	25 (0.8)	0.26 (0.03-1.89)	††	††
Cardiac compression	1 (0.2)	3 (0.1)	2.14 (0.22-20.54)	††	††
Birthweight (g)					
<2500	9 (1.8)	176 (5.6)	**0.32 (0.16-0.62)**	**0.40 (0.17-0.92)‡**	**0.032**
2500-4500	472 (96.3)	2899 (92.2)	**2.26 (1.37-3.63)**	1.66 (0.96-2.89)‡	0.071
>4500	9 (1.8)	70 (2.2)	0.82 (0.41-1.66)	0.79 (0.39-1.63)‡	0.529
Gestational age					
<37	14 (2.9)	202 (6.4)	**0.43 (0.25-0.74)**	**0.53 (0.29-0.97)¶**	**0.039**
37-41	461 (94.1)	2913 (92.6)	1.27 (0.85-1.89)	0.94 (0.61-1.46)¶	0.798
42-43	15 (3.1)	30 (1.0)	**3.28 (1.75-6.14)**	**4.41 (2.22-8.76)¶**	**<0.0001**
Breastfeeding					
Breastfed at birth	460 (93.9)	2604 (82.8)	**3.19 (2.18-4.66)**	**2.26 (1.51-3.37)****	**<0.0001**
Exclusive on discharge§§	447 (91.22)	2586 (82.23)	**2.10 (1.53-2.87)**	**1.58 (1.13-2.22)****	**0.008**

**Statistically significant results in bold. p values reported for adjusted ORs.*

† *All adjusted ORs adjusted for maternal age, smoking status, parity, augmentation, induction and risk at the onset of labour.*

‡*Also adjusted for elective caesarean section and gestation at time of birth.*

§*Also adjusted for elective caesarean section and restricted to 37-41 weeks gestation at birth.*

¶*Also adjusted for caesarean section.*

***Also adjusted for caesarean section and gestation at time of birth.*

††*Numbers too small. Multivariate model cannot converge.*

§§*Exclusively breastfeeding on discharge from hospital.*

¶¶*Inspiratory positive pressure.*

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Severe morbidity affected three babies from the freestanding midwifery unit group and 46 babies from the tertiary level maternity unit group (Figure 2). One of these babies from the tertiary level maternity unit group subsequently died and two were transferred to another hospital.

Tables 6 and 7 describe perinatal mortality by planned place of birth. There were a total of 31 perinatal deaths during the study period. 16 babies were stillborn; four of these infants were born in a tertiary level maternity unit following antenatal transfer from a freestanding midwifery unit, and 12 were in the tertiary level maternity unit group. 15 neonatal deaths occurred in the tertiary level maternity unit group.

Table 8 describes severe maternal morbidity by planned place of birth. One caesarean section (and hysterectomy) was carried out at the nearest general hospital to a freestanding midwifery unit owing to maternal collapse due to a suspected amniotic fluid embolism. The woman and her baby were transferred to a non-referral tertiary hospital immediately postpartum. Five women from the tertiary level maternity unit group had a hysterectomy following postpartum haemorrhage of greater than 1000mls, and one of these women was transferred to another hospital during the postnatal period.

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Table 6. Perinatal mortality: planned freestanding midwifery unit group†

Infants	*Obstetric details/ complications*	*Neonatal details/ complications†*
Stillbirths (20 to 24 weeks gestation)		
n=2	Antenatal transfer to tertiary referral hospital.	Congenital anomaly.
Stillbirths (37 to 41 weeks gestation)		
n=1	Antenatal transfer to tertiary referral hospital.	Fetal death in utero.
n=1	Antenatal transfer to tertiary referral hospital.	Concerns for fetal wellbeing.

† No intrapartum stillbirths recorded

Table 7. Perinatal mortality: planned tertiary level maternity unit group†

Infants	*Obstetric details/ complications*	*Neonatal details/ complications†*
Stillbirths (20 to 24 weeks gestation)		
n=3		Congenital anomaly.
n=1		Chorioamnionitis.
Neonatal deaths (20 to 24 weeks gestation)		
n=6		Congenital anomaly.
n=3	Premature labour.	
n=1	Prolonged pre-term rupture of membranes.	
Stillbirths (25 to 32 weeks gestation)		
n=1	Placental abruption, hypertension.	
n=1	Antepartum haemorrhage.	
n=1		No documented complications.
n=1		Congenital anomaly.
Neonatal death (25 to 32 weeks gestation)		
n=1	Premature labour.	Respiratory distress, NICU.
Neonatal deaths (33 to 36 weeks gestation)		

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n=1		Diaphragmatic hernia, NICU.
n=1	HELLP syndrome.	Respiratory distress, NICU.
n=1	Caesarean section (LSCS) for non-reassuring cardiotocograph (CTG) and fetal blood sampling.	Isoimmunisation, intrauterine transfusion, SCN.
Stillbirths (37 to 41 weeks gestation)		
n=2		No documented complications.
n=1	Anhydamnios.	
n=1	Antepartum haemorrhage.	
Neonatal deaths (37 to 41 weeks gestation)		
n=1	Hypertension, LSCS for delayed second stage and non-reassuring CTG.	Respiratory distress, NICU.

† No intrapartum stillbirths recorded

Table 8. Severe maternal morbidity by planned place of birth*

Women	*Obstetric details/ complications*	*Neonatal details/ complications*†
Planned place of birth: freestanding midwifery unit		
n=1	Maternal **cardiac arrest** and **collapse** during first stage of labour, possible **amniotic fluid embolism**, caesarean section (LSCS) at nearest general hospital, postpartum haemorrhage greater than 1500ml, multiple blood products, **hysterectomy.** Postnatal transfer to non-referral tertiary hospital.	37-41 weeks gestation. Baby transferred to NICU.
Planned place of birth: tertiary level maternity unit		
n=1	Elective lower segment caesarean section (ELSCS) for previous LSCS, cervical suture and antepartum haemorrhage (550mls). PPH greater than 1500mls, ***hysterectomy.***	25 to 32 weeks gestation, respiratory distress, low haemoglobin, NICU.
n=1	Premature labour, ELSCS for breech and previous LSCS. PPH greater than 1500mls, blood transfusion (19 units), ***hysterectomy.***	33 to 36 weeks gestation.
n=1	ELSCS for placenta praevia grade 4 and previous LSCS. PPH between 1000 and 1500mls, ***hysterectomy.***	33 to 36 weeks gestation, respiratory distress, NICU.
n=1	ELSCS for major placenta praevia, isoimmunisation and previous LSCS. PPH greater	33 to 36 weeks gestation, presence of maternal antibodies, special care

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	than 1500mls, ***postnatal transfer to another hospital.***	nursery (SCN).
n=1	ELSCS for placenta accreta and previous LSCS. PPH 1000 to 1500mls, ***hysterectomy.***	37 to 41 weeks gestation.

* Severe maternal morbidity highlighted in bold

DISCUSSION

Women who planned to give birth at freestanding midwifery units were significantly more likely than women who planned to give birth at tertiary level maternity units to have a spontaneous vaginal birth, and significantly less likely to have a caesarean section or an infant admitted to SCN/NICU. Similar rates were observed for Apgar score of less than 7 at 5 minutes.

With regard to secondary outcomes, women who planned to give birth at freestanding midwifery units were significantly more likely than women who planned to give birth at tertiary level maternity units to have a spontaneous onset of labour, estimated postpartum blood loss of less than 500mls or physiological management of third stage of labour. They were significantly less likely to have an induction or augmentation of labour, IM/IV analgesia or have an estimated blood loss of between 500 and 1000mls. The babies of women who planned to give birth at freestanding midwifery units were significantly more likely than the babies of women who planned to give birth at tertiary level maternity units to require no resuscitation at birth, be greater than 42 weeks gestation at the time of birth, be breastfed at birth or exclusively breastfed on hospital discharge. They were significantly less likely to weigh less than 2500 grams at birth or to be less than 37 weeks gestation.

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This is the first prospective cohort study of maternal and neonatal outcomes amongst women who planned to give birth in freestanding midwifery units in Australia. Selection bias was minimised by prospectively identifying women's planned place of birth at booking rather than at the onset of labour. Self-selection bias was eliminated through the use of a population data base of all women who met the inclusion criteria during the study period. All women who planned to give birth at a freestanding midwifery unit were included in the study, regardless of identified risks at booking. In this way the outcomes reflect the current practice and function of freestanding midwifery units in Australia. The study ensured comparability of the cohorts of women by controlling for risk at the onset of labour during analysis.

The study is limited because it was not possible to randomly assign women to one or other maternity unit and system of care, therefore leaving a potential for selection bias. In particular, the subtle differences that may exist between women who plan to give birth where there is no specialised medical support on site and those who choose to go to a tertiary level maternity unit cannot be quantified. These differences in themselves may be factors that have a bearing on some of the outcome measures, including the rate of unassisted vaginal birth in either setting. Selecting a prospective comparative reference cohort from the referral hospitals and analysing the data according to the place where women intended to give birth went some way in addressing the selection bias at the design stage.

A further limitation of the study was the inability to retrieve data on severe morbidity recorded in databases other than the one available for the study. As a result this study could not provide the level of information relating to more complex measures of maternal and perinatal morbidity as employed in other studies [17, 20, 27]. This reflects the fragmented nature of routine maternity information system databases.

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No inferential statistics were applied to some measures because of small numbers, however the crude number of rare outcomes in this study is surprising. Firstly an amniotic fluid embolism that was not preceded by an induction of labour is extremely rare. The reported incidence of amniotic fluid embolism in high-resource countries ranges from between 1.9 to 6.1 cases per 100 000 births [28], with induction of labour being a highly significant risk factor [29]. Given the high fatality rate for this condition, it is notable that the woman survived and was able to be transferred to a tertiary level hospital. Secondly, the incidence of postpartum haemorrhage followed by hysterectomy in this study (1.64 per 1000 births) is relatively high compared to results from a large population-based cohort study in America (0.48 per 1000 births) [30]. Further research into the incidence and prevalence of severe morbidity amongst childbearing women is needed, and is already underway in Australia through the Australasian Maternity Outcomes Surveillance System (AMOSS). AMOSS is a national surveillance mechanism designed to study a variety of rare or serious conditions during the antenatal, intrapartum and postnatal periods [31].

Generalization of these findings should be undertaken with caution given that there are very few freestanding midwifery units in Australia. Due to their rarity in Australia there are no nationally recognised guidelines and referral pathways specific to freestanding midwifery units other than those designed by the Australian College of Midwives [25]. The midwives who provide care in the units in this study are highly skilled and have formally integrated networking relationships with their referral tertiary level maternity units through which they have the support of obstetric teams [13]. The findings may not apply to other maternity units that do not offer the same care, referral pathways and distance to tertiary referral hospitals.

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In addition, giving birth in any maternity setting brings with it a unique set of complexities and relationships which impact on outcomes for women and their infants [32]. Women who plan to give birth outside the conventional tertiary hospital setting may choose to do so for various reasons. The impact these characteristics have on birth outcomes are unknown and outside the scope of this paper. Further analysis of women's self- reported rationale for choosing a freestanding midwifery unit, or not, will add further detail to these findings [33].

The research findings agree with important large studies undertaken recently overseas including the UK [17], Scandinavia [20] and New Zealand [19] which found that planning to give birth in a freestanding midwifery unit was associated with a reduced risk of having a caesarean section and either no difference or a reduction in the odds of neonatal morbidities [17, 19, 20]. The study also found similar rates of intrapartum and postnatal transfers as the two studies that reported on transfer rates [17, 20]. The current study is unique in that it reports rates of antenatal transfer which could not be compared with other studies given the point of entry into those studies was the onset of labour [17, 20]. It also found similar rates of maternal and neonatal outcomes for low risk women reported in a previous Australian population based study to determine disadvantages associated with giving birth in low volume maternity hospitals [16].

As a model, the freestanding midwifery unit is a growing and sustainable phenomenon in many countries, including in rural areas, where they are a valuable feature of the publically funded maternity system [19, 34, 35]. The centralisation of maternity services in Australia has led to the closure of many smaller maternity units, which has left a gap in accessible maternity care. Some freestanding midwifery units have filled this gap in urban and regional areas, however the lack of accessible maternity services in rural and remote regions of

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Australia continues to have widespread implications for women and their families [6, 10, 36, 37]. The challenge facing maternity services today is how to balance the need for safety with the need for equal access to maternity services, including to primary level birth facilities such as freestanding midwifery units.

This study supports the provision of care in freestanding midwifery units as an alternative to tertiary level maternity units for women with low risk pregnancies at the time of booking. Clinicians and policy makers may find these results useful in the planning and preservation of maternity services in areas where midwifery-only care is available in freestanding midwifery units. Further investigation into complex and longer-term measures of perinatal morbidity, transfer, and the viability of freestanding midwifery units in the rural/remote settings is required.

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Contributorship Statement

ST was the chief investigator of the EMU study, and led its design and coordination. ST, AM, CG, MT and MF were involved in the design of the study. AM was responsible for coordinating the Australian arm of the study, including data collection, cleaning of the data, data analyses and interpretation. CG was responsible for coordinating the New Zealand arm of the study. MT conducted data analysis and provided statistical advice. AM, ST and MT were involved in interpreting the data. AM drafted the manuscript and wrote the final version. All authors critically revised the manuscript, provided comment and approved the final version for publication.

Competing interests

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that there has been no support from any organisations for the submitted work. All authors declare that they had no relationships which companies that might have an interest in

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the submitted work in the previous three years, no family members with financial relationships that may be relevant to the submitted work and no non-finaancial interests that may be relevant to the submitted work.

Ethics approval

The study was approved by the Northern Sydney Local Health District Ethics Committee, the Hunter New England Human Research Ethics Committee and The University of Sydney Human Research Ethics Committee (NSW HREC reference number: HREC/09/HNE/78).

Data sharing statement

No additional data available.

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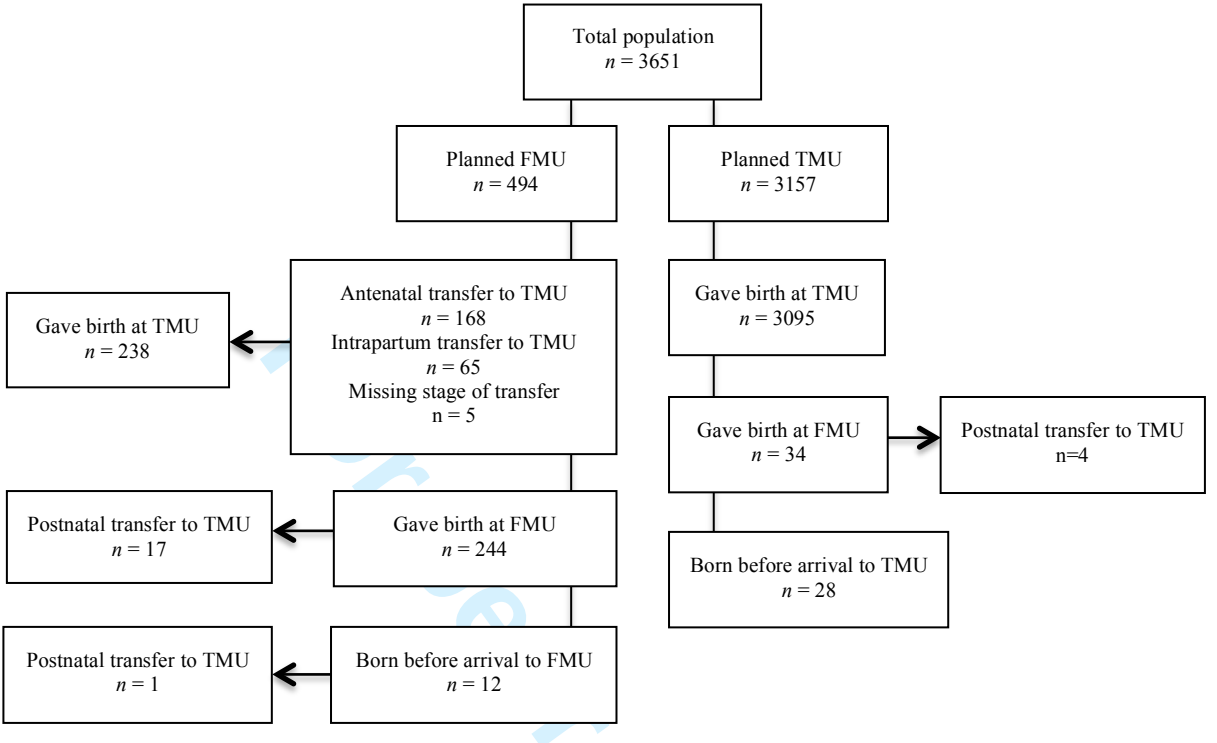
Figure 1. Study population and transfers from freestanding midwifery units (FMU) to tertiary level maternity units (TMU)



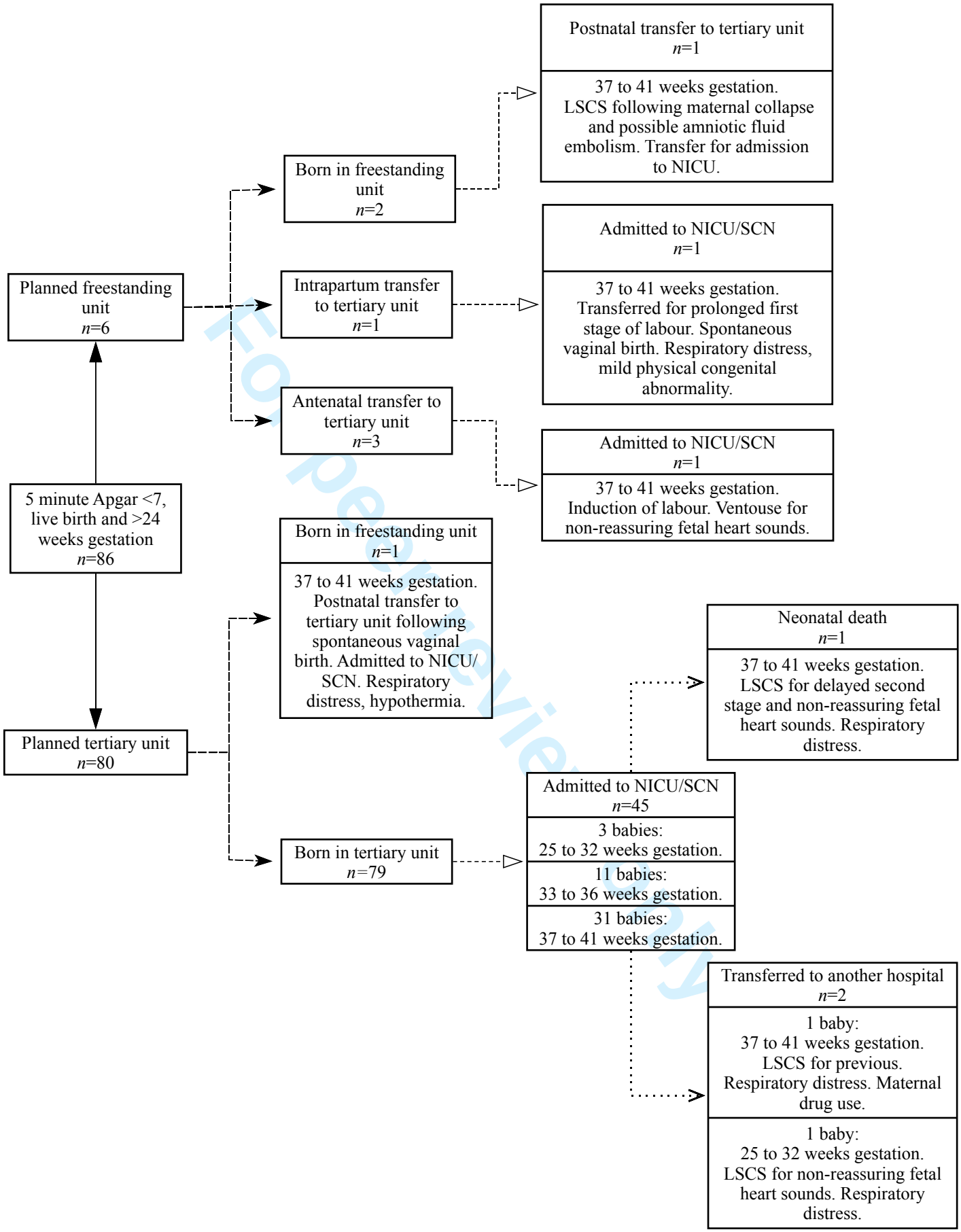


Figure 2. Severe neonatal morbidity: Babies with a 5 minute Apgar score of less than 7 followed by admission to NICU/SCN (restricted to live born babies greater than 24 weeks gestation).

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3, 4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5, 6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6, 7, 8, 9
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	7, 8
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9, 10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9
Bias	9	Describe any efforts to address potential sources of bias	9, 10
Study size	10	Explain how the study size was arrived at	9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9, 10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9, 10
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	10
		(*d*) If applicable, explain how loss to follow-up was addressed	
		(*e*) Describe any sensitivity analyses	
Results			

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Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	10, 11
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11, 12
		(b) Indicate number of participants with missing data for each variable of interest	See Tables
		(c) Summarise follow-up time (eg, average and total amount)	n/a
Outcome data	15*	Report numbers of outcome events or summary measures over time	12-16
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	12-16
		(*b*) Report category boundaries when continuous variables were categorized	See Tables
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9, 10
Discussion			
Key results	18	Summarise key results with reference to study objectives	20
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	20-23
Generalisability	21	Discuss the generalisability (external validity) of the study results	22, 23
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	24

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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BMJ Open

Evaluating Midwifery Units (EMU): A prospective cohort study of freestanding midwifery units in New South Wales, Australia.

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Keywords:	OBSTETRICS, Pregnancy, Cohort studies, Midwifery, Birthing centres, free-standing, Delivery room

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Title: Evaluating Midwifery Units (EMU): A prospective cohort study of freestanding midwifery units in New South Wales, Australia

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ABSTRACT

Objective: To compare maternal and neonatal birth outcomes and morbidities associated with the intention to give birth in two freestanding midwifery units and two tertiary level maternity units in New South Wales, Australia.

Design: Prospective cohort study.

Participants: 494 women who intended to give birth at freestanding midwifery units and 3157 women who intended to give birth at tertiary level maternity units. Participants had low risk, singleton pregnancies and were less than 28^{+0} weeks gestation at the time of booking.

Primary and secondary outcome measures: Primary outcomes were mode of birth, Apgar score of less than 7 at 5 minutes and admission to the neonatal intensive care unit or special care nursery. Secondary outcomes were onset of labour, analgesia, blood loss, management of third stage of labour, perineal trauma, transfer, neonatal resuscitation, breastfeeding, gestational age at birth, birth weight, severe morbidity and mortality.

Results: Women who planned to give birth at a freestanding midwifery unit were significantly more likely to have a spontaneous vaginal birth (AOR 1.57; 95%CI 1.20 to 2.06) and significantly less likely to have a caesarean section (AOR 0.65; 95%CI 0.48 to 0.88). There was no significant difference in the adjusted odds ratio of 5 minute Apgar scores, however babies from the freestanding midwifery unit group were significantly less likely to be admitted to neonatal intensive care or special care nursery (AOR 0.60; 95%CI 0.39 to 0.91). Analysis of secondary outcomes indicated that planning to give birth in a freestanding midwifery unit was associated with similar or reduced odds of intrapartum interventions and similar or improved odds of indicators of neonatal wellbeing.

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Conclusions: The results of this study support the provision of care in freestanding midwifery units as an alternative to tertiary level maternity units for women with low risk pregnancies at the time of booking.

ARTICLE SUMMARY

Strengths and limitations of the study

- This is the first prospective cohort study of maternal and neonatal outcomes of women who planned to give birth in freestanding midwifery units compared to women who planned to give birth in tertiary level maternity units in Australia.
- Selection bias was minimised by prospectively identifying women's planned place of birth at booking and analysing the outcomes according to the place where women intended to give birth. The population database ensured that there was a minimal loss to follow-up and minimal bias introduced due to a non-response rate.
- The study ensured comparability of the cohorts of women by evaluating risk at booking and controlling for confounding factors including risk at the onset of labour. However subtle differences may exist between women who plan to give birth in different settings, and these differences cannot be quantified. Also, socioeconomic status and body mass index could not be controlled and may have had a confounding effect on the outcomes.
- This study was not powered to detect clinically significant differences in perinatal mortality. Meaningful conclusions on longer-term perinatal outcomes could not be drawn from the datasource.

INTRODUCTION

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In New South Wales, the most populous state in Australia, most babies are born in a hospital setting. Of the 96,489 recorded births in 2010, 246 (0.3%) babies were born at home, 468 (0.5%) babies were born before arrival to hospital and 95,775 (99.3%) babies were born in a hospital maternity unit [1]. Contemporary hospital maternity services differ from each other considerably. The two hospital maternity services at opposite ends of the spectrum in terms of context and system of care are freestanding midwifery units and tertiary level maternity units. There are major gaps in the evidence associated with giving birth in these different settings.

Tertiary level maternity units offer care by specialist obstetricians and midwives. They cater for all pregnant women, regardless of risk status, and are the most appropriate place for women with complex and/or rare problems to give birth. Specialist obstetric, anaesthetic and paediatric consultation is available 24 hours a day [2, 3]. Some tertiary level maternity units have integrated alongside birth centres that have a home-like environment and offer a midwifery-managed model of care to women at low risk of obstetric complication [4].

Freestanding midwifery units provide a unique system of care to Australian women who have no identified risk factors and who either choose not to give birth at, or have limited access to other types of maternity care. They are unique in the Australian context because they offer primary level care by a named midwife and have no routine involvement of medical staff. They are also geographically separate from facilities offering onsite obstetric, paediatric or specialised medical consultation and procedures including epidural analgesia and caesarean section [2, 5].

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New South Wales' maternity policy strongly supports tertiary level maternity care for all women [6-11]. Planning to give birth at a facility without on-site specialist medical support is largely perceived as hazardous and unsafe for women and their unborn babies [6, 12]. Consequently there were only two freestanding midwifery units in New South Wales (and in Australia) in 2005, recording a combined total of approximately 300 births [13, 14], compared to 7 tertiary level maternity units with 25,637 births [15, 16]. It is unknown whether the actual gains match the expected gains of concentrating all low risk births in large tertiary hospitals [5, 17, 18].

Robust international evidence has recently been published to evaluate the safety and cost effectiveness of planning to give birth at freestanding midwifery units for women with low risk pregnancies [19-23]. A landmark prospective cohort study by the Birthplace in England Collaborative Group [19] found that there was no significant difference in rates of perinatal mortality or morbidities relating to intrapartum events between women who planned to give birth in freestanding midwifery units compared to those who planned to give birth in tertiary obstetric units (adjusted odds ratio (AOR) 0.92; 95% CI 0.58 to 1.46). Furthermore, women who planned to give birth in the freestanding units were less likely to have a ventouse delivery (AOR 0.32; 95% CI 0.22 to 0.47), forceps delivery (AOR 0.45, 95% CI 0.32 to 0.63), intrapartum caesarean section (AOR 0.32, 95% CI 0.24 to 0.42) or syntocinon augmentation (AOR 0.26; 95% CI 0.20 to 0.33) than women who planned to give birth at a tertiary obstetric hospital.

Despite these findings, freestanding midwifery units remain a scarce model of maternity care in Australia. This is likely to remain the case without robust Australian research that evaluates their safety.

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Objectives

The Evaluation of Midwifery Units study was a prospective cohort study that aimed to fill in some of the gaps in current research evidence on giving birth in freestanding midwifery units compared to tertiary level maternity units. It was undertaken in two Area Health Services in New South Wales, Australia and in one District Health Board in New Zealand. The aim was to compare the maternal and neonatal birth outcomes and morbidities associated with the 'intention to give birth' or 'booking at' the freestanding midwifery units in each health district compared with a reference cohort booked at the tertiary referral maternity hospitals integrated with the freestanding midwifery units. This paper reports the findings from the Australian arm of the study.

The researchers have adhered to the STROBE statement for improving the quality of the reporting of observational studies [24].

METHODS

Setting

Two freestanding midwifery units in regional and urban areas of New South Wales participated in the study. The most recent published data on the volume of births in the participating units (which were the only FMUs in Australia at the time) is from 2005/2006, when 326 births were recorded over a 12-month period [13, 14]. Women receive antenatal, intrapartum and postnatal care from their midwifery group practice midwives. These

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midwives work in small groups and provide 24-hour on-call midwifery care. If the need for transfer to the referral tertiary level maternity unit arises, the midwifery group practice midwife often, but not always, transfers with the woman and continues to provide midwifery care in the tertiary unit [25]. The referral tertiary level maternity units are approximately 15 to 20 kilometers away from the freestanding midwifery units; and transfer time may take between 15 minutes and 65 minutes depending on traffic conditions. Intrapartum and postnatal transfers occur via car or ambulance depending on the urgency of the transfer.

The two tertiary level maternity units used as comparators in this study were the tertiary referral hospitals formally recognized as the referral hospitals for the freestanding midwifery units described above. They recorded a combined total of 6072 births in 2010 [1]. They have a very wide catchment area, spanning 75 hospitals in New South Wales [26] and receive women and babies transferred from all other maternity units in the catchment areas. Women receive antenatal, intrapartum and postnatal care from a number of models of care, including obstetric and midwifery antenatal clinics, general practitioner shared care, birth centre and midwifery group practice [25].

Participants

Women with low risk singleton pregnancies were eligible to participate in the study if they were less than 28+0 weeks pregnant at the time of booking and planned to give birth at a participating maternity unit during the study period.

The Australian College of Midwives (ACM) Guidelines for Consultation and Referral were used to identify low risk women from the tertiary level maternity unit cohort (Table 1).

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Women were defined as low risk if they did not identify an ACM B/C or C risk factor at booking (Table 2) [27]. Previous caesarean sections are not classed as an ACM category B/C or C risk factor. Therefore women who had experienced a previous caesarean section were included in the study and 'previous caesarean section' was controlled in the analysis.

All women booked to give birth at the freestanding midwifery units were considered low risk and were included in the study, regardless of their specific ACM risk classification. This was a pragmatic a-priori decision taken at the beginning of the study. The rationale for this was that the midwifery and obstetric teams from the freestanding midwifery units in this study work collaboratively with women to ensure their suitability to give birth at the freestanding midwifery units. They use the ACM guidelines in conjunction with other information (such as detailed medical records and physical assessment) to determine with the women themselves whether they would be advised to proceed to give birth in a freestanding midwifery unit and, if necessary, when to transfer.

The two sample cohorts were further scrutinised to identify women with a risk at the onset of labour. Women were defined as having a risk at the onset of labour if they developed any ACM B/C or C risk conditions during pregnancy that may have led to a higher risk of requiring medical or obstetric care during labour and birth (Table 2). This enabled 'risk at the onset of labour' to be controlled in the analysis.

Table 1. ACM three levels of consultation and referral*

ACM A- Discuss	*ACM B - Consult*	*ACM C- Refer*
The woman's condition or situation requires discussion with another midwife or member of the health care team to plan for optimal care. Responsibility of care stays with the midwife.	The woman's condition or situation requires consultation with the medical practitioner, ideally in a 'face to face' consultation. Responsibility of care will either stay with the midwife or transfer to	The woman's condition or situation requires temporary or ongoing medical care at a tertiary or secondary level. Responsibility of care is transferred to a medical practitioner.

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a medical practitioner.

**ACM occasionally uses levels interchangeably by categorizing some conditions as A/B or B/C. Level of referral is left to the discretion of the midwife, in consultation with the woman, and a medical practitioner if required.*

Table 2. ACM B/C and C conditions constituting a risk at booking or at the onset of labour.

Type of risk	*Description of ACM B/C and C conditions constituting a risk*
Booking	Essential hypertension, renal disease, diabetes (not including gestational diabetes), adrenal disease, pituitary disease, asthma, cardiomyopathy, congenital heart disease, heart murmur, myocardial infarction, congenital renal disease, glomerulonephritis, antiphospholoid antibodies, rheumatoid antibodies, SLE, connective tissue disease, epilepsy, benign intracranial hypertension, thromboembolism, platelet disorder, clotting disorder, thalassaemia, organ transplant, neurological/spinal surgery*, classical caesarean section*, spina bifida*, fibromyalgia*, spinal cord disease* or any cardiac condition*, myomectomy, bicornate uterus, eclampsia or HELLP syndrome (hemolysis, elevated liver enzymes and low platelet count).
Onset of labour	Abnormal placental site, placenta praevia, placental abruption, eclampsia, preeclampsia, essential hypertension, renal hypertension, insulin dependent gestational diabetes, pre-existing diabetes, any new cardiac, endocrine, GIT, liver, gastrobiliary, haematological or infectious condition, pyelonephritis, uterine anomaly*, any new renal/neurological conditions*, any fetal anomaly, threatened premature labour, admission for cervical shortening/dilatation, antenatal steroid course, isoimmunisation, antibodies, cervical suture, feticide, intrauterine transfusion, breech/transverse/oblique lie or pre-term rupture of membranes.

**These condition were not listed in ACM guidelines, however they were considered to be equivalent to ACM B/C and C conditions.*

Data collection

Data custodians from each maternity unit used the ObstetriX database to identify eligible women who booked to give birth at the participating maternity units during the study period 1st April 2010 and 31st August 2011. ObstetriX is a statewide surveillance system used across New South Wales to provide point-of-care maternity data collection across the antenatal, intrapartum and immediate postnatal periods. Midwives contribute the data on each woman and her baby as soon after birth as is possible.

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The primary outcome measures were mode of birth, 5 minute Apgar score of less than 7 and admission to the neonatal intensive care unit (NICU) or special care nursery (SCN) from the time of birth to discharge. Secondary maternal outcomes included type of onset of labour, use of analgesia, rates of postpartum haemorrhage, management of third stage of labour, rates of perineal trauma, stage of transfer and severe morbidity. Secondary neonatal outcomes included the need to resuscitate, breastfeeding at birth and upon hospital discharge, gestational age, birth weight, severe morbidity (defined as 5 minute Apgar score of less than 7 followed by admission to NICU/SCN, restricted to live born babies greater than 24 weeks gestation) and neonatal mortality.

Data were collected from the ObstetriX database, except for a limited amount of transfer data which were collected from maternal medical records. Neonatal data on reason for NICU/SCN admission, treatment details and perinatal mortality and morbidity recorded in data bases other than the ObstetriX data base were not available for this study.

Statistical analysis

The study was powered to detect a clinically relevant fall of 21% in the rate of women requiring a caesarean section from 29.0% to 23.0%, with 90% power and a significance level of p=0.05. These numbers were also sufficient to detect a clinically significant reduction of 4.0 percentage points in the rate of instrumental birth (forceps/ventouse) from 11.0% to 7.0% with 90% power and a significance level of p=0.05. These differences were based on data available from the first report of birth outcomes at both freestanding midwifery units in the years preceding the study compared to statewide maternity data [13, 14, 16].

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Analyses were by 'intention to treat' with outcomes attributed to planned place of birth at the time of booking. Odds ratios with 95% confidence intervals were calculated for the primary and secondary outcomes. Measures of categorical data were analysed with chi-square tests and continuous data were analysed using the t-test. Multivariate logistic regression was used for dichotomous outcomes to adjust for relevant known confounders. Adjustment was made for maternal age, smoking status, parity, risk at the onset of labour, previous caesarean section, gestation at the time of birth, induction and augmentation of labour where relevant. Socioeconomic status and body mass index (BMI) were unable to be controlled using the available data sources. Adjusting for ethnicity was complex due to the diverse ethnic groups represented in the sample; the individual ethnic groups were not found to have a confounding effect so were not included in the final analysis. Women who had an elective caesarean section were excluded when calculating the adjusted odds ratios for analgesia during labour. Women who had a caesarean section were excluded when calculating the odds ratios for perineal trauma. Neonatal outcomes for live born babies were adjusted for maternal age, smoking status, parity, augmentation, induction, previous caesarean section and risk at the onset of labour. Caesarean section and gestation at birth were adjusted where relevant. Adjustments for all outcomes are outlined below the tables. Multivariate regression models were restricted to subjects with no missing values. No inferential statistics were carried out on severe maternal or neonatal morbidity and mortality outcomes due to the small numbers involved. Stata version 12 was used for all analyses.

RESULTS

Data were obtained for all 3,651 eligible women identified. 494 planned to give birth at a

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freestanding midwifery unit and 3157 planned to give birth at a tertiary level maternity unit (Figure 1). Of the 494 women who planned to give birth at the freestanding midwifery unit 238 women (48.2%) gave birth at a tertiary level maternity unit, 244 women (49.4%) gave birth at the freestanding midwifery unit as planned, and a further 12 (2.4%) gave birth before admission to the freestanding midwifery unit. Of the 494 women who planned to give birth in a freestanding midwifery unit, 256 (51.8%) transferred to a tertiary level maternity unit (34% antenatal, 13.2% intrapartum, 3.6% postnatal and 1% unknown stage of transfer). The majority of women who planned to give birth at a tertiary level maternity unit actually gave birth there (98%), with 28 women (0.9%) giving birth before arriving. 34 women (1.1%) who intended to give birth at a tertiary level maternity unit actually gave birth at a freestanding midwifery unit, and four of these women transferred to a tertiary level maternity unit postnatally.

Table 3 shows the mean age, mean parity, proportion of nulliparous women, ethnicity, smoking status, risk status at booking, risk status at the onset of labour and rates of previous caesarean section by planned place of birth. There was no significant difference in mean parity and proportion of nulliparous women in each group. Women who planned to give birth at a freestanding midwifery unit had a significantly higher mean age, and significantly fewer women from this group smoked, had a risk factor at the onset of labour or had experienced a previous caesarean section compared to women from the tertiary level maternity unit. There were 27 women from the freestanding midwifery unit group who had a risk factor at the time of booking. Women who identified as an Oceanic ethnicity (representing women born in Australia, New Zealand, Papua New Guinea, Fiji and Western Samoa) made up most of the tertiary level maternity unit group (90.5%), while this ethnicity only represented 70.9% of the freestanding midwifery unit group.

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Table 3. Maternal characteristics by planned place of birth

Characteristics	*Freestanding n=494 No. (%)*	*Tertiary n=3157 No. (%)*	p*
Mean age	29.6	28.5[†]	**<0.001**
Median (mean) parity	1 (0.9)	1 (1.0)	0.8
Proportion of nulliparae	208 (42.1)	1364 (43.2)	0.6
Ethnicity			
African	5 (1.0)	40 (1.3)	
Asian	100 (20.2)	140 (4.4)	
European	27 (5.5)	92 (2.9)	
Oceania	350 (70.9)	2856 (90.5)	
Aboriginal/TSI	12 (3.4)[‡]	165 (5.8)[‡]	
South American	4 (0.8)	5 (0.2)	
North American	7 (1.4)	20 (0.6)	
Missing data	1 (0.2)	4 (0.1)	**<0.001**
Smoking status			
Smoker	27 (5.5)	546 (17.3)	**<0.001**
Risk at booking			
Category B/C or C	27 (5.5)	0	[§]
Risk at onset of labour			
Category B/C or C	65 (13.2)	598 (18.9)	**0.002**
Previous caesarean section	2 (0.4)	430 (13.6)	**<0.0001**

**Statistically significant results in bold.*
[†]*From n=3156 women. Missing data from one woman.*
[‡]*Expressed as a percentage of the Oceania population in the corresponding cohort.*
[§]*Numbers too small, multivariate model cannot converge.*

Primary and secondary maternal outcomes

Table 4 describes the primary and secondary maternal outcomes and shows the unadjusted and adjusted odds ratios of maternal outcomes by planned place of birth. After adjusting for maternal age, smoking status, parity, risk at the onset of labour, gestation at the time of birth and previous caesarean section, compared to the tertiary cohort, freestanding midwifery unit

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women were significantly more likely to have a spontaneous vaginal birth (AOR 1.57; 95%CI 1.20 to 2.06) and significantly less likely to have a caesarean section (AOR 0.65; 95%CI 0.48 to 0.88), including elective caesarean section (AOR 0.50; 95%CI 0.29 to 0.88). The reduction in the odds of women from the freestanding midwifery unit group having an instrumental delivery or intrapartum caesarean section lost significance when adjusted for confounding factors (AOR 0.79; 95%CI 0.53 to 1.17 and AOR 0.76; 95%CI 0.53 to 1.10 respectively) (Table 4).

After adjusting for confounding factors, women who planned to give birth in a freestanding midwifery unit were twice as likely to have a spontaneous onset of labour (AOR 2.01; 95%CI 1.60 to 2.54) and significantly less likely to experience: induction (AOR 0.50; 95% CI 0.39 to 0.63), augmentation of labour (AOR 0.51; 95%CI 0.38 to 0.67) or intramuscular (IM) or intravenous (IV) narcotic analgesia (AOR 0.26; 95%CI 0.18 to 0.36).

Despite the significantly higher odds of physiological management of the third stage of labour amongst women from the freestanding midwifery unit group (AOR 15.03; 95%CI11.05 to 20.43), they were significantly more likely to experience blood loss of less than 500mls (AOR 1.37; 95%CI 1.03 to 1.82) and significantly less likely to experience blood loss of 500 to 999mls (AOR 0.70; 95%CI, 0.51 to 0.97). There was no significant difference in major postpartum haemorrhage of greater than 1000mls (AOR 0.88; 95%CI, 0.52 to 1.47) (Table 4).

The adjusted odds of having epidural/spinal analgesia, no analgesia or any type of perineal trauma (including episiotomy extending to third or fourth degree tear) did not differ significantly between settings.

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Table 4. Maternal outcomes by planned place of birth

Outcome	*Freestanding n=494 No. (%)*	*Tertiary n=3157 No. (%)*	*Unadjusted OR (95% CI)* [*]	*Adjusted OR (95% CI)* [*†]	p*
Mode of birth					
Spontaneous vaginal	400 (81.0)	2044 (64.7)	**2.32 (1.83-2.93)**	**1.57 (1.20-2.06)**[‡]	**=0.001**
Instrumental	34 (6.9)	331 (10.5)	**0.63 (0.44-0.91)**	0.79 (0.53-1.17)[‡]	0.237
Caesarean section	60 (12.1)	782 (24.8)	**0.42 (0.32-0.56)**	**0.65 (0.48-0.88)**[‡]	**=0.006**
Intrapartum	40 (8.1)	413 (13.1)	**0.53 (0.38-0.74)**	0.76 (0.53-1.10)[‡]	=0.151
Elective	20 (4.0)	369 (11.7)	**0.32 (0.20-0.51)**	**0.50 (0.29-0.88)**[‡]	**=0.02**
Labour onset[**]					
Spontaneous	378 (76.5)	1782 (56.4)	**2.51 (2.02-3.13)**	**2.01 (1.60-2.54)**	**<0.0001**
Induction	97 (19.6)	1010 (32.0)	**0.52 (0.41-0.66)**	**0.50 (0.39-0.63)**	**<0.0001**
Labour intervention					
Augmentation	66 (13.4)	690 (21.9)	**0.55 (0.42-0.72)**	**0.51 (0.38-0.67)**	**<0.0001**
Analgesia					
Epidural/ spinal	62 (12.6)	577 (18.3)	**0.64 (0.48-0.85)**	0.87 (0.63-1.19)[§]	0.388
IM/IV narcotic	38 (7.7)	856 (27.1)	**0.22 (0.16-0.31)**	**0.26 (0.18-0.36)**[§]	**<0.0001**
No analgesia	115 (23.3)	556 (17.6)	**1.42 (1.13-1.78)**	0.92 (0.72-1.18)[§]	0.512
Blood loss					
<500mls	428 (86.6)	2533 (80.2)	**1.60 (1.22-2.10)**	**1.37 (1.03-1.82)**[‡]	**0.029**
500-999mls	48 (9.7)	485 (15.4)	**0.59 (0.43-0.81)**	**0.70 (0.51-0.97)**[‡]	**0.031**
>1000mls	18 (3.6)	139 (4.4)	0.82 (0.50-1.35)	0.88 (0.52-1.47)[‡]	0.618
Third stage					
Physiological	185 (37.4)	93 (2.9)	**19.7 (15.0-26.0)**	**15.03 (11.05-20.43)**[‡]	**<0.0001**
Perineal trauma					
None/graze	241 (48.8)	1752 (55.5)	**0.76 (0.63-0.92)**	0.88 (0.71-1.10)[¶]	0.275
1st/2nd degree tear	229 (46.4)	1273 (40.3)	**1.28 (1.06-1.55)**	1.15 (0.93-1.42)[¶]	0.210
3rd/4th degree tear	24 (4.9)	132 (4.2)	1.17 (0.75-1.83)	0.90 (0.56-1.45)[¶]	0.671
Episiotomy					
Episiotomy	38 (7.7)	315 (10.0)	0.75 (0.53-1.07)	0.81 (0.55-1.19)[¶]	0.275
Extended to 3rd/4th	7 (1.4)	37 (1.2)	1.2 (0.53-2.71)	1.59 (0.67-3.77)[¶]	0.292

[*] *Statistically significant results in bold. p values reported for adjusted ORs.*

[†] *All adjusted ORs adjusted for maternal age, smoking status, parity, risk at the onset of labour, previous caesarean section and gestation at the time of birth.*

[‡] *Also adjusted for augmentation and induction.*

[§] *Also adjusted for augmentation and induction. Elective caesarean sections excluded from analysis.*

[¶] *Also adjusted for augmentation and induction. All caesarean sections excluded from analysis.*

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** *One woman from the freestanding midwifery unit group and four women from the tertiary level maternity unit group went into labour spontaneously and proceeded to have an elective caesarean section. They were coded as both spontaneous and elective caesarean.*

Primary and secondary neonatal outcomes

Table 5 describes the primary and secondary neonatal outcomes for live born babies and shows the unadjusted and adjusted odds ratios of neonatal outcomes by planned place of birth. Babies from the freestanding midwifery unit group were significantly less likely to be admitted to SCN or NICU (AOR 0.60; 95%CI 0.39 to 0.91) (Table 5). The reduction in the odds of babies from the freestanding midwifery unit group having an Apgar score of less than 7 at 5 minutes lost significance when adjusted for confounding factors (AOR 0.57; 95%CI 0.25 to 1.35).

After adjusting for known confounders, babies from the freestanding midwifery unit group were significantly more likely to require no resuscitation at birth compared to babies from the tertiary level maternity unit group (AOR 1.39; 95%CI 1.04 to 1.85). The significance of the higher odds of babies from the freestanding midwifery unit group weighing between 2500 and 4500 grams at birth was borderline (AOR 1.74; 95% CI 1.00 to 3.03) The adjusted odds of being greater than 42 weeks gestation (AOR 4.62; 95%CI 2.31 to 9.31), being breastfed at birth (AOR 2.38; 95%CI 1.59 to 3.57) or being exclusively breastfed on hospital discharge (AOR 1.59; 95%CI 1.14 to 2.24) were significantly higher in babies from the freestanding midwifery unit group compared to those from the tertiary level maternity unit group.

Significantly fewer babies from the freestanding midwifery unit group were less than 37

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weeks gestation (AOR 0.53, 95%CI 0.29 to 0.96) or had a birth weight of less than 2500 grams (AOR 0.38, 95%CI 0.16 to 0.89). The adjusted odds of babies requiring resuscitation at birth in the form of suction, supplemental oxygen or inspiratory positive pressure (with mask or endotracheal tube), or being between 37 and 41 weeks gestation at birth showed no significant difference between the two groups (Table 5).

Table 5. Neonatal outcomes for live births by planned place of birth

Outcome	*Freestanding n = 490 No. (%)*	*Tertiary n =3145 No. (%)*	*Unadjusted OR (95% CI)**	*Adjusted OR (95% CI)*†*	p*
Apgar					
<7 at 5 minutes	6 (1.2)	88 (2.8)	**0.43 (0.19-0.99)**	0.57 (0.25-1.35)‡	0.203
SCN/NICU					
Admitted to SCN/ NICU	33 (6.7)	432 (13.7)	**0.45 (0.31-0.65)**	**0.60 (0.39-0.91)‡**	**0.017**
Need for resuscitation					
Nil	421 (85.9)	2462 (78.3)	**1.69 (1.29-2.21)**	**1.39 (1.04-1.85)§**	**0.027**
Suction	11 (2.2)	134 (4.3)	**0.52 (0.28-0.96)**	0.62 (0.33-1.17)§	0.139
Supplemental oxygen	13 (2.7)	150 (4.8)	**0.54 (0.31-0.97)**	0.73 (0.40-1.32)§	0.291
IPP¶¶ (Mask)	43 (8.8)	371 (11.8)	**0.72 (0.52-1.00)**	0.80 (0.56-1.15)§	0.231
IPP¶¶ (Endotracheal tube)	1 (0.2)	25 (0.8)	0.26 (0.03-1.89)	††	††
Cardiac compression	1 (0.2)	3 (0.1)	2.14 (0.22-20.54)	††	††
Birthweight (g)					
<2500	9 (1.8)	176 (5.6)	**0.32 (0.16-0.62)**	**0.38 (0.16-0.89)‡**	**0.026**
2500-4500	472 (96.3)	2899 (92.2)	**2.26 (1.37-3.63)**	**1.74 (1.00-3.03)‡**	**0.050**
>4500	9 (1.8)	70 (2.2)	0.82 (0.41-1.66)	0.77 (0.37-1.58)‡	0.473
Gestational age					
<37	14 (2.9)	202 (6.4)	**0.43 (0.25-0.74)**	**0.53 (0.29-0.96)¶**	**0.035**
37-41	461 (94.1)	2913 (92.6)	1.27 (0.85-1.89)	0.95 (0.61-1.47)¶	0.810
42-43	15 (3.1)	30 (1.0)	**3.28 (1.75-6.14)**	**4.62 (2.31-9.31)¶**	**<0.0001**
Breastfeeding					
Breastfed at birth	460 (93.9)	2604 (82.8)	**3.19 (2.18-4.66)**	**2.38 (1.59-3.57)****	**<0.0001**
Exclusive on discharge§§	447 (91.22)	2586 (82.23)	**2.10 (1.53-2.87)**	**1.59 (1.14-2.24)****	**0.007**

**Statistically significant results in bold. p values reported for adjusted ORs.*
† All adjusted ORs adjusted for maternal age, smoking status, parity, augmentation, induction, previous caesarean section and risk at the onset of labour.
‡Also adjusted for elective caesarean section and gestation at time of birth.
§Also adjusted for elective caesarean section and restricted to 37-41 weeks gestation at birth.
¶Also adjusted for caesarean section.

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[**] *Also adjusted for caesarean section and gestation at time of birth.*
[††] *Numbers too small. Multivariate model cannot converge.*
[§§] *Exclusively breastfeeding on discharge from hospital.*
[¶¶] *Inspiratory positive pressure.*

Severe neonatal morbidity was defined as 5 minute Apgar score of less than 7 followed by admission to NICU/SCN. This affected three babies from the freestanding midwifery unit group and 46 babies from the tertiary level maternity unit group (Figure 2 online). One of these babies from the tertiary level maternity unit group subsequently died and two were transferred to another hospital.

There were a total of 31 perinatal deaths during the study period. 16 (0.44%) babies were stillborn; four of these infants were born in a tertiary level maternity unit following antenatal transfer from a freestanding midwifery unit, and 12 were in the tertiary level maternity unit group. 15 (0.41%) neonatal deaths occurred in the tertiary level maternity unit group. Supplementary information on perinatal mortality by planned place of birth is provided in Table A and Table B online.

Table C online describes severe maternal morbidity by planned place of birth. One caesarean section (and hysterectomy) was carried out at the nearest general hospital to a freestanding midwifery unit owing to maternal collapse due to a suspected amniotic fluid embolism. The woman and her baby were transferred to a non-referral tertiary hospital immediately postpartum. Five women from the tertiary level maternity unit group had a hysterectomy following postpartum haemorrhage of greater than 1000mls, and one of these women was transferred to another hospital during the postnatal period.

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DISCUSSION

Women who planned to give birth at freestanding midwifery units were significantly more likely than women who planned to give birth at tertiary level maternity units to have a spontaneous vaginal birth and significantly less likely to have a caesarean section. The subgroups of caesarean section produced different results. Women from the freestanding midwifery unit group were significantly less likely to have an elective caesarean section, and the adjusted odds of requiring an intrapartum caesarean section were not significant. Not surprisingly, the most predictive variable for caesarean section (including intrapartum and elective caesarean section) was having a 'previous caesarean section'. Infants of women from the freestanding midwifery unit group were significantly less likely to be admitted to SCN/NICU. Similar rates were observed for Apgar score of less than 7 at 5 minutes.

With regard to secondary outcomes, women who planned to give birth at freestanding midwifery units were significantly more likely than women who planned to give birth at tertiary level maternity units to have a spontaneous onset of labour, estimated postpartum blood loss of less than 500mls or physiological management of third stage of labour. They were significantly less likely to have an induction or augmentation of labour, IM/IV analgesia or have an estimated blood loss of between 500 and 1000mls. The babies of women who planned to give birth at freestanding midwifery units were significantly more likely than the babies of women who planned to give birth at tertiary level maternity units to require no resuscitation at birth, weigh between 2500 and 4500 grams at birth, be greater than 42 weeks gestation at the time of birth, be breastfed at birth or exclusively breastfed on hospital discharge. They were significantly less likely to weigh less than 2500 grams at birth or to be less than 37 weeks gestation.

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This is the first prospective cohort study of maternal and neonatal outcomes amongst women who planned to give birth in freestanding midwifery units in Australia. Selection bias was minimised by prospectively identifying women's planned place of birth at booking and analysing the outcomes according to the place where women intended to give birth. The use of a population database ensured that there was a minimal loss to follow-up and minimal bias introduced due to a non-response rate. All women who planned to give birth at a freestanding midwifery unit were included in the study, regardless of identified risks at booking. In this way the outcomes reflect the current practice and function of freestanding midwifery units in Australia. The study ensured comparability of the cohorts of women by rigorously judging the tertiary level maternity unit group at booking to be at low risk of developing obstetric complications, and also by controlling for risk at the onset of labour during analysis.

The study is limited because it was not possible to randomly assign women to one or other maternity unit and system of care, therefore leaving a potential for selection bias. In particular, the subtle differences that may exist between women who plan to give birth where there is no specialised medical support on site and those who choose to go to a tertiary level maternity unit cannot be quantified. 34 women from the tertiary unit group crossed over to give birth in the freestanding midwifery unit group, although these women represented less than 1% of the study population. These factors, along with not controlling for BMI and socioeconomic status, may have had a bearing on some of the outcome measures. Selecting a prospective comparative reference cohort from the referral hospitals and analysing the data according to the place where women intended to give birth went some way in addressing the selection bias at the design stage.

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A further limitation of the study was the inability to retrieve data on severe morbidity recorded in databases other than the one available for the study. As a result this study could not provide the level of information relating to more complex measures of maternal and perinatal morbidity as employed in other studies [19, 22, 28]. This reflects the fragmented nature of routine maternity information system databases.

No inferential statistics were applied to some measures because of small numbers, however the detailed reporting of adverse and rare events strengthened the study. The crude number of rare outcomes in this study is surprising. Firstly an amniotic fluid embolism that was not preceded by an induction of labour is extremely rare. The reported incidence of amniotic fluid embolism in high-resource countries ranges from between 1.9 to 6.1 cases per 100 000 births [29], with induction of labour being a highly significant risk factor [30]. Given the high fatality rate for this condition, it is notable that the woman survived and was able to be transferred to a tertiary level hospital.

Secondly, the incidence of postpartum haemorrhage followed by hysterectomy in this study (1.64 per 1000 births) is relatively high compared to results from a large population-based cohort study in America (0.48 per 1000 births) [31]. Five of the six cases of postpartum haemorrhage followed by hysterectomy were in women who had a repeat caesarean section, and three of these women had placenta praevia or accreta. There is conflicting evidence on the association between repeat caesarean section and postpartum haemorrhage [32], with evidence pointing towards no association between the two [33, 34]. A causative link has been established between repeat caesarean sections and placenta accreta and hysterectomy [35-37], however there is the possibility of other causative influences for placenta accreta such as surgical technique [36, 38]. Further research into the incidence and prevalence of severe

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morbidity amongst childbearing women is needed, and is already underway in Australia through the Australasian Maternity Outcomes Surveillance System (AMOSS). AMOSS is a national surveillance mechanism designed to study a variety of rare or serious conditions during the antenatal, intrapartum and postnatal periods [39].

Generalization of these findings should be undertaken with caution given that there are very few freestanding midwifery units in Australia. Due to their rarity in Australia there are no nationally recognised guidelines and referral pathways specific to freestanding midwifery units other than the general guidelines designed by the Australian College of Midwives [27]. The midwives who provide care in the units in this study are highly skilled and have formally integrated networking relationships with their referral tertiary level maternity units through which they have the support of obstetric teams [13]. The findings may not apply to other maternity units that do not offer the same care, referral pathways and distance to tertiary referral hospitals.

In addition, giving birth in any maternity setting brings with it a unique set of complexities and relationships which impact on outcomes for women and their infants [40]. Women who plan to give birth outside the conventional tertiary hospital setting may choose to do so for various reasons. The impact these characteristics have on birth outcomes are unknown and outside the scope of this paper. Further analysis of women's self- reported rationale for choosing a freestanding midwifery unit, or not, will add further detail to these findings [41].

The research findings agree with important large studies undertaken recently overseas including the UK [19], Scandinavia [22] and New Zealand [21] which found that planning to give birth in a freestanding midwifery unit was associated with a reduced risk of having a

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caesarean section and either no difference or a reduction in the odds of neonatal morbidities [19, 21, 22]. This study found similar rates of maternal and neonatal outcomes for low risk women reported in a previous Australian population based study to determine disadvantages associated with giving birth in low volume maternity hospitals [18]. Looking at neonatal mortality, the overall rates of stillbirth in this study (0.44%) were lower than all maternity units in Tracy, Sullivan and Dahlen et al's study (2006), which reported rates of stillbirth between 0.49% for hospitals with less than 100 births per annum and 0.94% for hospitals with greater than 2000 births per annum [18]. The rate of neonatal deaths in this study (0.41%) were lower than those reported for hospitals of comparable size (0.56%) [18]. The proportion of low birthweight babies in both cohorts in this study (1.8% in the freestanding group and 5.6% in the tertiary group) was relatively low compared to the incidence of low birthweight babies in Australian maternity units with between 100 and 500 births birth year (4.04%) and in maternity units with greater than 2000 births per year (9.77%) [18].

The overall rate of transfer in this study (51.8%) appears high when compared to the two recent cohort studies on freestanding midwifery units [19, 22]. However the current study is unique in that it reports rates of antenatal transfer (34%). Both freestanding units studied have a strong collaborative relationship with their tertiary referral units and women and midwives are encouraged to err on the side of caution and transfer antenatally whenever there is a possibility that medical intervention may be required during the birth process. Comparable rates of antenatal transfer were reported in randomised controlled trials on alongside midwife-led units in Ireland [42] (45%) and Scotland [43] (38%). The rates of intrapartum/postnatal transfer from this study (16.8%) sit between the intrapartum/postnatal transfer rates from freestanding midwifery units reported by Overgaard, Mollerm Fenger-Gron, Knudsen and Sandall [22] (16.3%) and the Birthplace in England Collaborative Group

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[19] (21.9%).

As a model, the freestanding midwifery unit is a growing and sustainable phenomenon in many countries, including in rural areas, where they are a valuable feature of the publically funded maternity system [21, 44, 45]. The centralisation of maternity services in Australia has led to the closure of many smaller maternity units, which has left a gap in accessible maternity care. Some freestanding midwifery units have filled this gap in urban and regional areas, however the lack of accessible maternity services in rural and remote regions of Australia continues to have widespread implications for women and their families [6, 10, 46, 47]. The challenge facing maternity services today is how to balance the need for safety with the need for equal access to maternity services, including to primary level birth facilities such as freestanding midwifery units.

This study supports the provision of care in freestanding midwifery units as an alternative to tertiary level maternity units for women with low risk pregnancies at the time of booking. Clinicians and policy makers may find these results useful in the planning and preservation of maternity services in areas where midwifery-only care is available in freestanding midwifery units. There is also scope for the development of standardized national protocols on freestanding midwifery units to improve the transparency of transfers and support the processes of development and evaluation. Further investigation into complex and longer-term measures of perinatal morbidity, transfer, and the viability of freestanding midwifery units in the rural/remote settings is required.

Contributorship

ST was the chief investigator of the EMU study, and led its design and coordination. ST, AM, CG, MT and MF were involved in the design of the study. AM was responsible for

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coordinating the Australian arm of the study, including data collection, cleaning of the data, data analyses and interpretation. CG was responsible for coordinating the New Zealand arm of the study. MT conducted data analysis and provided statistical advice. AM, ST and MT were involved in interpreting the data. AM drafted the manuscript and wrote the final version. All authors critically revised the manuscript, provided comment and approved the final version for publication.

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Competing interests

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that there has been no support from any organisations for the submitted work. All

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authors declare that they had no relationships which companies that might have an interest in the submitted work in the previous three years, no family members with financial relationships that may be relevant to the submitted work and no non-finaancial interests that may be relevant to the submitted work.

Ethics approval

The study was approved by the Northern Sydney Local Health District Ethics Committee, the Hunter New England Human Research Ethics Committee and The University of Sydney Human Research Ethics Committee (NSW HREC reference number: HREC/09/HNE/78).

Data sharing statement

No additional data available.

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EVALUATING MIDWIFERY UNITS ~~(EMU)~~: A PROSPECTIVE COHORT STUDY OF FREESTANDING MIDWIFERY UNITS IN NEW SOUTH WALES, AUSTRALIA.

ABSTRACT

Objective: To compare maternal and neonatal birth outcomes and morbidities associated with the intention to give birth in two freestanding midwifery units and two tertiary level maternity units in New South Wales, Australia. ~~different settings.~~

Design: Prospective cohort study.

~~**Setting:** Two freestanding midwifery units and two tertiary level maternity units in New South Wales, Australia.~~

Participants: ~~3651~~ 494 women who intended to give birth at freestanding midwifery units and 3157 women who intended to give birth at tertiary level maternity units. Participants had low risk, ~~women with~~ singleton pregnancies ~~who~~ and were less than 28^{+0} weeks gestation ~~and who intended to give birth at a participating maternity unit~~ at the time of booking.

Primary and secondary outcome measures: Primary outcomes were mode of birth, Apgar score of less than 7 at 5 minutes and admission to the neonatal intensive care unit or special care nursery. Secondary outcomes were onset of labour, analgesia, blood loss, management of third stage of labour, perineal trauma, transfer, neonatal resuscitation, breastfeeding, gestational age at birth, birth weight, severe morbidity and mortality.

Results: ~~After adjusting for relevant confounders~~ W~~w~~omen who planned to give birth at a freestanding midwifery unit were significantly more likely to have a spontaneous vaginal birth (AOR 1.57; 95%CI 1.20 to 2.06) and significantly less likely to have a caesarean section (AOR 0.65; 95%CI 0.48 to 0.88). There was no significant difference in the adjusted odds ratio of 5 minute Apgar scores, however babies from the freestanding midwifery unit group

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were significantly less likely to be admitted to neonatal intensive care or special care nursery (AOR 0.60; 95%CI 0.39 to 0.91). Analysis of secondary outcomes indicated that planning to give birth in a freestanding midwifery unit was associated with similar or reduced odds of intrapartum interventions and similar or improved odds of indicators of neonatal wellbeing.

Conclusions: The results of this study support the provision of care in freestanding midwifery units as an alternative to tertiary level maternity units for women with low risk pregnancies at the time of booking.

ARTICLE SUMMARY

Strengths and limitations of the study

- This is the first prospective cohort study of maternal and neonatal outcomes of women who planned to give birth in freestanding midwifery units compared to women who planned to give birth in tertiary level maternity units in Australia.
- Selection bias was minimised by prospectively identifying women's planned place of birth at booking ~~rather than at the onset of labour~~ and analysing the ~~data~~ outcomes according to the place where women intended to give birth. The population database ensured that there was a minimal loss to follow-up and minimal bias introduced due to a non-response rate. ~~Self-selection bias was eliminated through the use of a population database of all pregnant women who met the inclusion criteria during the study period.~~
- The study ensured comparability of the cohorts of women by evaluating risk at booking and controlling for confounding factors including risk at the onset of labour. However subtle differences may exist between women who plan to give birth in different settings, and these differences cannot be quantified. Also, socioeconomic status and body mass index could not

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be controlled and may have had a confounding effect on the outcomes.

- This study was not powered to detect clinically significant differences in perinatal mortality. Meaningful conclusions on longer-term perinatal outcomes could not be drawn from the datasource.

INTRODUCTION

In New South Wales, the most populous state in Australia, most babies are born in a hospital setting. Of the 96,489 recorded births in 2010, 246 (0.3%) babies were born at home, 468 (0.5%) babies were born before arrival to hospital and 95,775 (99.3%) babies were born in a hospital maternity unit [1]. Contemporary hospital maternity services differ from each other considerably. The two hospital maternity services at opposite ends of the spectrum in terms of context and system of care are freestanding midwifery units and tertiary level maternity units. There are major gaps in the evidence associated with giving birth in these different settings.

Tertiary level maternity units offer care by specialist obstetricians and midwives. They cater for all pregnant women, regardless of risk status, and are the most appropriate place for women with complex and/or rare problems to give birth. Specialist obstetric, anaesthetic and paediatric consultation is available 24 hours a day [2, 3]. Some tertiary level maternity units have integrated alongside birth centres that have a home-like environment and offer a midwifery-managed model of care to women at low risk of obstetric complication [4].

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Freestanding midwifery units provide a unique system of care to Australian women who have no identified risk factors and who either choose not to give birth at, or have limited access to other types of maternity care. They are unique in the Australian context because they offer primary level care by a named midwife and have no routine involvement of medical staff. They are also geographically separate from facilities offering onsite obstetric, paediatric or specialised medical consultation and procedures including epidural analgesia and caesarean section [2, 5].

New South Wales' maternity policy strongly supports tertiary level maternity care for all women [6-11]. Planning to give birth at a facility without on-site specialist medical support is largely perceived as hazardous and unsafe for women and their unborn babies [6, 12]. Consequently there were only two freestanding midwifery units in New South Wales (and in Australia) in 2005, recording a combined total of approximately 300 births [13, 14], compared to 7 tertiary level maternity units with 25,637 births [15, 16]. It is unknown whether the actual gains match the expected gains of concentrating all low risk births in large tertiary hospitals [5, 17, 18].

Robust international evidence has recently been published to evaluate the safety and cost effectiveness of planning to give birth at freestanding midwifery units for women with low risk pregnancies [19-23]. A landmark prospective cohort study by the Birthplace in England Collaborative Group [19] found that there was no significant difference in rates of perinatal mortality or morbidities relating to intrapartum events between women who planned to give birth in freestanding midwifery units compared to those who planned to give birth in tertiary obstetric units (adjusted odds ratio (AOR) 0.92; 95% CI 0.58 to 1.46). Furthermore, women who planned to give birth in the freestanding units were less likely to have a ventouse

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delivery (AOR 0.32; 95% CI 0.22 to 0.47), forceps delivery (AOR 0.45, 95% CI 0.32 to 0.63), intrapartum caesarean section (AOR 0.32, 95% CI 0.24 to 0.42) or syntocinon augmentation (AOR 0.26; 95% CI 0.20 to 0.33) than women who planned to give birth at a tertiary obstetric hospital.

Despite these findings, freestanding midwifery units remain a ~~underutilised~~ scarce model of maternity care in Australia. This is likely to remain the case without robust Australian research that evaluates their safety.

Objectives

The Evaluation of Midwifery Units ~~(EMU)~~ study was a prospective cohort study that aimed to fill in some of the gaps in current research evidence on giving birth in freestanding midwifery units compared to tertiary level maternity units. It was undertaken in two Area Health Services in New South Wales, Australia and in one District Health Board in New Zealand. The aim was to compare the maternal and neonatal birth outcomes and morbidities associated with the 'intention to give birth' or 'booking at' the freestanding midwifery units in each health district compared with a reference cohort booked at the tertiary referral maternity hospitals integrated with the freestanding midwifery units. This paper reports the findings from the Australian arm of the study.

The researchers have adhered to the STROBE statement for improving the quality of the reporting of observational studies [24].

METHODS

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Setting

Two freestanding midwifery units in regional and urban areas of New South Wales participated in the study. The most recent published data on the volume of births in ~~these~~ the participating units (which were the only FMUs in Australia at the time) is from 2005/2006, when 326 births were recorded over a 12-month period [13, 14]. Women receive antenatal, intrapartum and postnatal care from their midwifery group practice midwives. These midwives work in small groups and provide 24-hour on-call midwifery care. If the need for transfer to the referral tertiary level maternity unit arises, the midwifery group practice midwife often, but not always, transfers with the woman and continues to provide midwifery care in the tertiary unit [25]. The referral tertiary level maternity units are approximately 15 to 20 kilometers away from the freestanding midwifery units; and transfer time may take between 15 minutes and 65 minutes depending on traffic conditions. Intrapartum and postnatal transfers occur via car or ambulance depending on the urgency of the transfer.

The two tertiary level maternity units used as comparators in this study were the tertiary referral hospitals formally recognized as the referral hospitals for the freestanding midwifery units described above. They recorded a combined total of 6072 births in 2010 [1]. They have a very wide catchment area, spanning 75 hospitals in New South Wales [26] and receive women and babies transferred from all other maternity units in the catchment areas. Women receive antenatal, intrapartum and postnatal care from a number of models of care, including obstetric and midwifery antenatal clinics, general practitioner shared care, birth centre and midwifery group practice [25].

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Participants ~~and data collection~~

Women with low risk singleton pregnancies were eligible to participate in the study if they were less than 28+0 weeks pregnant at the time of booking and planned to give birth at a participating maternity unit during the study period. ~~Eligible participants were less than 28+0 weeks pregnant at the time of commencement of antenatal care at their chosen maternity unit.~~

~~Only women considered to be at low risk of requiring ongoing obstetric and medical care were included in the tertiary level maternity unit cohort, as per~~ The Australian College of Midwives (ACM) Guidelines for Consultation and Referral were used to identify low risk women from the tertiary level maternity unit cohort (Table 1). Women were defined as low risk if they did not identify an ACM B/C or C risk factor at booking (Table 2) [27]. Previous caesarean sections are not classed as an ACM category B/C or C risk factor. Therefore women who had experienced a previous caesarean section were included in the study and 'previous caesarean section' was controlled in the analysis.

All women booked to give birth at the freestanding midwifery units were considered low risk and were included in the study, regardless of their specific ACM risk classification. This was a pragmatic a-priori decision taken at the beginning of the study. The rationale for this was that the midwifery and obstetric teams from the freestanding midwifery units in this study work collaboratively with women to ensure their suitability to give birth at the freestanding midwifery units. They use the ACM guidelines in conjunction with other information (such as detailed medical records and physical assessment) to determine with the women themselves whether they would be advised to proceed to give birth in a freestanding midwifery unit and, if necessary, when to transfer.

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The two sample cohorts were further scrutinised to identify women with a risk at the onset of labour. Women were defined as having a risk at the onset of labour if they developed any ACM B/C or C risk conditions during pregnancy that may have led to a higher risk of requiring medical or obstetric care during labour and birth (Table 2). This enabled 'risk at the onset of labour' to be controlled in the analysis.

Table 1. ACM three levels of consultation and referral*

ACM A- Discuss	*ACM B - Consult*	*ACM C- Refer*
The woman's condition or situation requires discussion with another midwife or member of the health care team to plan for optimal care. Responsibility of care stays with the midwife.	The woman's condition or situation requires consultation with the medical practitioner, ideally in a 'face to face' consultation. Responsibility of care will either stay with the midwife or transfer to a medical practitioner.	The woman's condition or situation requires temporary or ongoing medical care at a tertiary or secondary level. Responsibility of care is transferred to a medical practitioner.

**ACM occasionally uses levels interchangeably by categorizing some conditions as A/B or B/C. Level of referral is left to the discretion of the midwife, in consultation with the woman, and a medical practitioner if required.*

Table 2. ACM B/C and C conditions ~~identified at booking~~constituting a risk at booking or at the onset of labour. ~~and during pregnancy~~

~~*Identification of risk*~~*Type of risk*	*Description of ACM B/C and C conditions constituting a risk*
~~At booking~~Booking	Essential hypertension, renal disease, diabetes (not including gestational diabetes), adrenal disease, pituitary disease, asthma, cardiomyopathy, congenital heart disease, heart murmur, myocardial infarction, congenital renal disease, glomerulonephritis, antiphospholoid antibodies, rheumatoid antibodies, SLE, connective tissue disease, epilepsy, benign intracranial hypertension, thromboembolism, platelet disorder, clotting disorder, thalassaemia, organ transplant, neurological/spinal surgery*, classical caesarean section*, spina bifida*, fibromyalgia*, spinal cord disease* or any cardiac condition*, myomectomy, bicornate uterus, eclampsia or HELLP syndrome (hemolysis, elevated liver enzymes and low platelet count).

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~~During pregnancy~~Onset of labour	Abnormal placental site, placenta praevia, placental abruption, eclampsia, preeclampsia, essential hypertension, renal hypertension, insulin dependent gestational diabetes, pre-existing diabetes, any new cardiac, endocrine, GIT, liver, gastrobiliary, haematological or infectious condition, pyelonephritis, uterine anomaly*, any new renal/neurological conditions*, any fetal anomaly, threatened premature labour, admission for cervical shortening/dilatation, antenatal steroid course, isoimmunisation, antibodies, cervical suture, feticide, intrauterine transfusion, breech/transverse/oblique lie or pre-term rupture of membranes.

**These condition were not listed in ACM guidelines, however they were considered to be equivalent to ACM B/C and C conditions.*

Data collection

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Data custodians from each maternity unit used the ObstetriX database to identify eligible women who booked to give birth at the participating maternity units during the study period 1st April 2010 and 31st August 2011. ObstetriX is a statewide surveillance system used across New South Wales to provide point-of-care maternity data collection across the antenatal, intrapartum and immediate postnatal periods. Midwives contribute the data on each woman and her baby as soon after birth as is possible.

The primary outcome measures were mode of birth, 5 minute Apgar score of less than 7 and admission to the neonatal intensive care unit (NICU) or special care nursery (SCN) from the time of birth to discharge. Secondary maternal outcomes included type of onset of labour, use of analgesia, rates of postpartum haemorrhage, management of third stage of labour, rates of perineal trauma, stage of transfer and severe morbidity. Secondary neonatal outcomes included the need to resuscitate, breastfeeding at birth and upon hospital discharge, gestational age, birth weight, severe morbidity (defined as 5 minute Apgar score of less than 7 followed by admission to NICU/SCN, restricted to live born babies greater than 24 weeks gestation) and neonatal mortality.

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Data were collected from the ObstetriX database, except for a limited amount of transfer data which were collected from maternal medical records. Neonatal data on reason for NICU/SCN admission, treatment details and perinatal mortality and morbidity recorded in data bases other than the ObstetriX data base were not available for this study.

Statistical analysis

The study was powered to detect a clinically relevant fall of ~~6.0 %~~21% in the rate of women requiring a caesarean section from 29.0% to 23.0%, with 90% power and a significance level of p=0.05. These numbers were also sufficient to detect a clinically significant reduction of 4.0~~%~~ percentage points in the rate of instrumental birth (forceps/ventouse) from 11.0% to 7.0% with 90% power and a significance level of p=0.05. These differences were based on data available from the first report of birth outcomes at both freestanding midwifery units in the years preceding the study compared to statewide maternity data [13, 14, 16].

Analyses were by 'intention to treat' with outcomes attributed to planned place of birth at the time of booking. Odds ratios with 95% confidence intervals were calculated for the primary and secondary outcomes. Measures of categorical data were analysed with chi-square tests and continuous data were analysed using the t-test. Multivariate logistic regression was used for dichotomous outcomes to adjust for relevant known confounders. Adjustment was made for maternal age, smoking status, parity, risk at the onset of labour, previous caesarean section, gestation at the time of birth, induction and augmentation of labour where relevant. Socioeconomic status and body mass index (BMI) were unable to be controlled using the available data sources. Adjusting for ethnicity was complex due to the diverse ethnic groups

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represented in the sample; the individual ethnic groups were not found to have a confounding effect so were not included in the final analysis. Women who had an elective caesarean section were excluded when calculating the adjusted odds ratios for analgesia during labour. Women who had a caesarean section were excluded when calculating the odds ratios for perineal trauma. Neonatal outcomes for live born babies were adjusted for maternal age, smoking status, parity, augmentation, induction, previous caesarean section and risk at the onset of labour. Caesarean section and gestation at birth were adjusted where relevant. Adjustments for all outcomes are outlined below the tables. Multivariate regression models were restricted to subjects with no missing values. No inferential statistics were carried out on severe maternal or neonatal morbidity and mortality outcomes due to the small numbers involved. Stata version 12 was used for all analyses.

RESULTS

Data were obtained for all ~~Data were obtained for~~ 3,651 eligible women identified. ~~who met the inclusion criteria, of whom~~ 494 planned to give birth at a freestanding midwifery unit and 3157 planned to give birth at a tertiary level maternity unit (Figure 1). Of the 494 women who planned to give birth at the freestanding midwifery unit 238 women (48.2%) gave birth at a tertiary level maternity unit, 244 women (49.4%) gave birth at the freestanding midwifery unit as planned, and a further 12 (2.4%) gave birth before admission to the freestanding midwifery unit. Of the 494 women who planned to give birth in a freestanding midwifery unit, 256 (51.8%) transferred to a tertiary level maternity unit (34% antenatal, 13.2% intrapartum, 3.6% postnatal and 1% unknown stage of transfer). The majority of women who planned to give birth at a tertiary level maternity unit actually gave birth there (98%), with 28 women (0.9%) giving birth before arriving. 34 women (1.1%) who intended

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to give birth at a tertiary level maternity unit actually gave birth at a freestanding midwifery unit, and four of these women transferred to a tertiary level maternity unit postnatally.

Table 3 shows the mean age, mean parity, proportion of nulliparous women, ethnicity, smoking status, risk status at booking, risk status at the onset of labour and rates of previous caesarean section by planned place of birth. There was no significant difference in mean parity and proportion of nulliparous women in each group. Women who planned to give birth at a freestanding midwifery unit had a significantly higher mean age, and significantly fewer women from this group smoked, had a risk factor at the onset of labour or had experienced a previous caesarean section compared to women from the tertiary level maternity unit. ~~(this is despite no women from the tertiary level maternity unit group having an identified risk factor at booking).~~ There were 27 women from the freestanding midwifery unit group who had a risk factor at the time of booking. Women who identified as an Oceanic ethnicity (representing women born in Australia, New Zealand, Papua New Guinea, Fiji and Western Samoa) made up most of the tertiary level maternity unit group (90.5%), while this ethnicity only represented 70.9% of the freestanding midwifery unit group.

Table 3. Maternal characteristics by planned place of birth

Characteristics	*Freestanding n=494 No. (%)*	*Tertiary n=3157 No. (%)*	p*
Mean age	29.6	28.5†	**<0.001**
Median (mean) parity	1 (0.9)	1 (1.0)	0.8
Proportion of nulliparae	208 (42.1)	1364 (43.2)	0.6
Ethnicity			
African	5 (1.0)	40 (1.3)	
Asian	100 (20.2)	140 (4.4)	
European	27 (5.5)	92 (2.9)	
Oceania	350 (70.9)	2856 (90.5)	

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Aboriginal/TSI	12 (3.4)‡	165 (5.8)‡	
South American	4 (0.8)	5 (0.2)	
North American	7 (1.4)	20 (0.6)	
Missing data	1 (0.2)	4 (0.1)	**<0.001**
Smoking status			
Smoker	27 (5.5)	546 (17.3)	**<0.001**
Risk at booking			
Category B/C or C	27 (5.5)	0	§
Risk at onset of labour			
Category B/C or C	65 (13.2)	598 (18.9)	**0.002**
Previous caesarean section	2 (0.4)	430 (13.6)	**<0.0001**

**Statistically significant results in bold.*
†From n=3156 women. Missing data from one woman.
‡Expressed as a percentage of the Oceania population in the corresponding cohort.
§Numbers too small, multivariate model cannot converge.

Primary and secondary maternal outcomes

Table 4 describes the primary and secondary maternal outcomes and shows the unadjusted and adjusted odds ratios of maternal outcomes by planned place of birth. After adjusting for maternal age, smoking status, parity, risk at the onset of labour, gestation at the time of birth and previous caesarean section, compared to the tertiary cohort, freestanding midwifery unit women were significantly more likely to have a spontaneous vaginal birth (AOR 1.57; 95%CI 1.20 to 2.06) and significantly less likely to have a caesarean section (AOR 0.65; 95%CI 0.48 to 0.88), including elective caesarean section (AOR 0.50; 95%CI 0.29 to 0.88). The reduction in the odds of women from the freestanding midwifery unit group having an instrumental delivery or intrapartum caesarean section lost significance when adjusted for confounding factors (AOR 0.79; 95%CI 0.53 to 1.17 and AOR 0.76; 95%CI 0.53 to 1.10 respectively) (Table 4).

After adjusting for confounding factors, women who planned to give birth in a freestanding

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midwifery unit were twice as likely to have a spontaneous onset of labour (AOR 2.01; 95%CI 1.60 to 2.54) and significantly less likely to experience: induction (AOR 0.50; 95% CI 0.39 to 0.63), augmentation of labour (AOR 0.51; 95%CI 0.38 to 0.67) or intramuscular (IM) or intravenous (IV) narcotic analgesia (AOR 0.26; 95%CI 0.18 to 0.36).

Despite the significantly higher odds of physiological management of the third stage of labour amongst women from the freestanding midwifery unit group (AOR 15.03; 95%CI11.05 to 20.43), they were significantly more likely to experience blood loss of less than 500mls (AOR 1.37; 95%CI 1.03 to 1.82) and significantly less likely to experience blood loss of 500 to 999mls (AOR 0.70; 95%CI, 0.51 to 0.97). There was no significant difference in major postpartum haemorrhage of greater than 1000mls (AOR 0.88; 95%CI, 0.52 to 1.47) (Table 4).

The adjusted odds of having epidural/spinal analgesia, no analgesia or any type of perineal trauma (including episiotomy extending to third or fourth degree tear) did not differ significantly between settings.

Table 4. Maternal outcomes by planned place of birth

Outcome	*Freestanding n=494 No. (%)*	*Tertiary n=3157 No. (%)*	*Unadjusted OR (95% CI)* [*]	*Adjusted OR (95% CI)* [*†]	p*
Mode of birth					
Spontaneous vaginal	400 (81.0)	2044 (64.7)	**2.32 (1.83-2.93)**	**1.57 (1.20-2.06)**[‡]	**=0.001**
Instrumental	34 (6.9)	331 (10.5)	**0.63 (0.44-0.91)**	0.79 (0.53-1.17)[‡]	0.237
Caesarean section	60 (12.1)	782 (24.8)	**0.42 (0.32-0.56)**	**0.65 (0.48-0.88)**[‡]	**=0.006**
Intrapartum	40 (8.1)	413 (13.1)	**0.53 (0.38-0.74)**	0.76 (0.53-1.10)[‡]	=0.151
Elective	20 (4.0)	369 (11.7)	**0.32 (0.20-0.51)**	**0.50 (0.29-0.88)**[‡]	**=0.02**

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Labour onset[**]					
Spontaneous	378 (76.5)	1782 (56.4)	**2.51 (2.02-3.13)**	**2.01 (1.60-2.54)**	**<0.0001**
Induction	97 (19.6)	1010 (32.0)	**0.52 (0.41-0.66)**	**0.50 (0.39-0.63)**	**<0.0001**
Labour intervention					
Augmentation	66 (13.4)	690 (21.9)	**0.55 (0.42-0.72)**	**0.51 (0.38-0.67)**	**<0.0001**
Analgesia					
Epidural/ spinal	62 (12.6)	577 (18.3)	**0.64 (0.48-0.85)**	0.87 (0.63-1.19)[§]	0.388
IM/IV narcotic	38 (7.7)	856 (27.1)	**0.22 (0.16-0.31)**	**0.26 (0.18-0.36)**[§]	**<0.0001**
No analgesia	115 (23.3)	556 (17.6)	**1.42 (1.13-1.78)**	0.92 (0.72-1.18)[§]	0.512
Blood loss					
<500mls	428 (86.6)	2533 (80.2)	**1.60 (1.22-2.10)**	**1.37 (1.03-1.82)**[‡]	**0.029**
500-999mls	48 (9.7)	485 (15.4)	**0.59 (0.43-0.81)**	**0.70 (0.51-0.97)**[‡]	**0.031**
>1000mls	18 (3.6)	139 (4.4)	0.82 (0.50-1.35)	0.88 (0.52-1.47)[‡]	0.618
Third stage					
Physiological	185 (37.4)	93 (2.9)	**19.7 (15.0-26.0)**	**15.03 (11.05-20.43)**[‡]	**<0.0001**
Perineal trauma					
None/graze	241 (48.8)	1752 (55.5)	**0.76 (0.63-0.92)**	0.88 (0.71-1.10)[¶]	0.275
1st/2nd degree tear	229 (46.4)	1273 (40.3)	**1.28 (1.06-1.55)**	1.15 (0.93-1.42)[¶]	0.210
3rd/4th degree tear	24 (4.9)	132 (4.2)	1.17 (0.75-1.83)	0.90 (0.56-1.45)[¶]	0.671
Episiotomy					
Episiotomy	38 (7.7)	315 (10.0)	0.75 (0.53-1.07)	0.81 (0.55-1.19)[¶]	0.275
Extended to 3rd/4th	7 (1.4)	37 (1.2)	1.2 (0.53-2.71)	1.59 (0.67-3.77)[¶]	0.292

[*] *Statistically significant results in bold. p values reported for adjusted ORs.*

[†] *All adjusted ORs adjusted for maternal age, smoking status, parity, risk at the onset of labour, previous caesarean section and gestation at the time of birth.*

[‡] *Also adjusted for augmentation and induction.*

[§] *Also adjusted for augmentation and induction. Elective caesarean sections excluded from analysis.*

[¶] *Also adjusted for augmentation and induction. All caesarean sections excluded from analysis.*

[**] *One woman from the freestanding midwifery unit group and four women from the tertiary level maternity unit group went into labour spontaneously and proceeded to have an elective caesarean section. They were coded as both spontaneous and elective caesarean.*

Primary and secondary neonatal outcomes

Table 5 describes the primary and secondary neonatal outcomes for live born babies and shows the unadjusted and adjusted odds ratios of neonatal outcomes by planned place of birth. Babies from the freestanding midwifery unit group were significantly less likely to be admitted to SCN or NICU (AOR 0.60; 95%CI 0.39 to 0.91) (Table 5). The reduction in the

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odds of babies from the freestanding midwifery unit group having an Apgar score of less than 7 at 5 minutes lost significance when adjusted for confounding factors (AOR 0.57; 95%CI 0.25 to 1.35).

After adjusting for known confounders, babies from the freestanding midwifery unit group were significantly more likely to require no resuscitation at birth compared to babies from the tertiary level maternity unit group (AOR 1.39; 95%CI 1.04 to 1.85). The significance of the higher odds of babies from the freestanding midwifery unit group weighing between 2500 and 4500 grams at birth was borderline (AOR 1.74; 95% CI 1.00 to 3.03) The adjusted odds of being greater than 42 weeks gestation (AOR 4.62; 95%CI 2.31 to 9.31), being breastfed at birth (AOR 2.38; 95%CI 1.59 to 3.57) or being exclusively breastfed on hospital discharge (AOR 1.59; 95%CI 1.14 to 2.24) were significantly higher in babies from the freestanding midwifery unit group compared to those from the tertiary level maternity unit group.

Significantly fewer babies from the freestanding midwifery unit group were less than 37 weeks gestation (AOR 0.53, 95%CI 0.29 to 0.96) or had a birth weight of less than 2500 grams (AOR 0.38, 95%CI 0.16 to 0.89). The adjusted odds of babies requiring resuscitation at birth in the form of suction, supplemental oxygen or inspiratory positive pressure (with mask or endotracheal tube), ~~, being greater than 2500 grams at birth~~ or being between 37 and 41 weeks gestation at birth showed no significant difference between the two groups (Table 5).

Table 5. Neonatal outcomes for live births by planned place of birth

Outcome	*Freestanding*	*Tertiary*	*Unadjusted OR*	*Adjusted OR*

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	n = 490 *No. (%)*	*n =3145* *No. (%)*	*(95% CI)*[*]	*(95% CI)*[*†]	p*
Apgar					
<7 at 5 minutes	6 (1.2)	88 (2.8)	**0.43 (0.19-0.99)**	0.57 (0.25-1.35)[‡]	0.203
SCN/NICU					
Admitted to SCN/ NICU	33 (6.7)	432 (13.7)	**0.45 (0.31-0.65)**	**0.60 (0.39-0.91)**[‡]	**0.017**
Need for resuscitation					
Nil	421 (85.9)	2462 (78.3)	**1.69 (1.29-2.21)**	**1.39 (1.04-1.85)**[§]	**0.027**
Suction	11 (2.2)	134 (4.3)	**0.52 (0.28-0.96)**	0.62 (0.33-1.17)[§]	0.139
Supplemental oxygen	13 (2.7)	150 (4.8)	**0.54 (0.31-0.97)**	0.73 (0.40-1.32)[§]	0.291
IPP[¶¶] (Mask)	43 (8.8)	371 (11.8)	**0.72 (0.52-1.00)**	0.80 (0.56-1.15)[§]	0.231
IPP[¶¶] (Endotracheal tube)	1 (0.2)	25 (0.8)	0.26 (0.03-1.89)	[††]	[††]
Cardiac compression	1 (0.2)	3 (0.1)	2.14 (0.22-20.54)	[††]	[††]
Birthweight (g)					
<2500	9 (1.8)	176 (5.6)	**0.32 (0.16-0.62)**	**0.38 (0.16-0.89)**[‡]	**0.026**
2500-4500	472 (96.3)	2899 (92.2)	**2.26 (1.37-3.63)**	**1.74 (1.00-3.03)**[‡]	**0.050**
>4500	9 (1.8)	70 (2.2)	0.82 (0.41-1.66)	0.77 (0.37-1.58)[‡]	0.473
Gestational age					
<37	14 (2.9)	202 (6.4)	**0.43 (0.25-0.74)**	**0.53 (0.29-0.96)**[¶]	**0.035**
37-41	461 (94.1)	2913 (92.6)	1.27 (0.85-1.89)	0.95 (0.61-1.47)[¶]	0.810
42-43	15 (3.1)	30 (1.0)	**3.28 (1.75-6.14)**	**4.62 (2.31-9.31)**[¶]	**<0.0001**
Breastfeeding					
Breastfed at birth	460 (93.9)	2604 (82.8)	**3.19 (2.18-4.66)**	**2.38 (1.59-3.57)**[**]	**<0.0001**
Exclusive on discharge[§§]	447 (91.22)	2586 (82.23)	**2.10 (1.53-2.87)**	**1.59 (1.14-2.24)**[**]	**0.007**

[*] *Statistically significant results in bold. p values reported for adjusted ORs.*

[†] *All adjusted ORs adjusted for maternal age, smoking status, parity, augmentation, induction, previous caesarean section and risk at the onset of labour.*

[‡] *Also adjusted for elective caesarean section and gestation at time of birth.*

[§] *Also adjusted for elective caesarean section and restricted to 37-41 weeks gestation at birth.*

[¶] *Also adjusted for caesarean section.*

[**] *Also adjusted for caesarean section and gestation at time of birth.*

[††] *Numbers too small. Multivariate model cannot converge.*

[§§] *Exclusively breastfeeding on discharge from hospital.*

[¶¶] *Inspiratory positive pressure.*

Severe neonatal morbidity was defined as 5 minute Apgar score of less than 7 followed by admission to NICU/SCN. This affected three babies from the freestanding midwifery unit group and 46 babies from the tertiary level maternity unit group (Figure 2 online). One of

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these babies from the tertiary level maternity unit group subsequently died and two were transferred to another hospital.

~~Tables 6 and 7 describe perinatal mortality by planned place of birth.~~ There were a total of 31 perinatal deaths during the study period. 16 (0.44%) babies were stillborn; four of these infants were born in a tertiary level maternity unit following antenatal transfer from a freestanding midwifery unit, and 12 were in the tertiary level maternity unit group. 15 (0.41%) neonatal deaths occurred in the tertiary level maternity unit group. Supplementary information on perinatal mortality by planned place of birth is provided in Table A and Table B online.

Table C online~~8~~ describes severe maternal morbidity by planned place of birth. One caesarean section (and hysterectomy) was carried out at the nearest general hospital to a freestanding midwifery unit owing to maternal collapse due to a suspected amniotic fluid embolism. The woman and her baby were transferred to a non-referral tertiary hospital immediately postpartum. Five women from the tertiary level maternity unit group had a hysterectomy following postpartum haemorrhage of greater than 1000mls, and one of these women was transferred to another hospital during the postnatal period.

DISCUSSION

Women who planned to give birth at freestanding midwifery units were significantly more likely than women who planned to give birth at tertiary level maternity units to have a spontaneous vaginal birth and significantly less likely to have a caesarean section. The subgroups of caesarean section produced different results. Women from the freestanding

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midwifery unit group were significantly less likely to have an elective caesarean section, and the adjusted odds of requiring an intrapartum caesarean section were not significant. Not surprisingly, the most predictive variable for caesarean section (including intrapartum and elective caesarean section) was having a 'previous caesarean section'. Infants of women from the freestanding midwifery unit group were significantly less likely to be admitted to SCN/NICU. Similar rates were observed for Apgar score of less than 7 at 5 minutes.

With regard to secondary outcomes, women who planned to give birth at freestanding midwifery units were significantly more likely than women who planned to give birth at tertiary level maternity units to have a spontaneous onset of labour, estimated postpartum blood loss of less than 500mls or physiological management of third stage of labour. They were significantly less likely to have an induction or augmentation of labour, IM/IV analgesia or have an estimated blood loss of between 500 and 1000mls. The babies of women who planned to give birth at freestanding midwifery units were significantly more likely than the babies of women who planned to give birth at tertiary level maternity units to require no resuscitation at birth, weigh between 2500 and 4500 grams at birth, be greater than 42 weeks gestation at the time of birth, be breastfed at birth or exclusively breastfed on hospital discharge. They were significantly less likely to weigh less than 2500 grams at birth or to be less than 37 weeks gestation.

This is the first prospective cohort study of maternal and neonatal outcomes amongst women who planned to give birth in freestanding midwifery units in Australia. Selection bias was minimised by prospectively identifying women's planned place of birth at booking ~~rather than at the onset of labour~~and analysing the outcomes according to the place where women intended to give birth. ~~Self selection bias was eliminated through the use of a population data~~

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base of all women who met the inclusion criteria during the study period.The use of a population database ensured that there was a minimal loss to follow-up and minimal bias introduced due to a non-response rate. All women who planned to give birth at a freestanding midwifery unit were included in the study, regardless of identified risks at booking. In this way the outcomes reflect the current practice and function of freestanding midwifery units in Australia. The study ensured comparability of the cohorts of women by rigorously judging the tertiary level maternity unit group at booking to be at low risk of developing obstetric complications, and also by controlling for risk at the onset of labour during analysis.

The study is limited because it was not possible to randomly assign women to one or other maternity unit and system of care, therefore leaving a potential for selection bias. In particular, the subtle differences that may exist between women who plan to give birth where there is no specialised medical support on site and those who choose to go to a tertiary level maternity unit cannot be quantified. 34 women from the tertiary unit group crossed over to give birth in the freestanding midwifery unit group, although these women represented less than 1% of the study population. These factors, along with not controlling for BMI and socioeconomic status, may have had a bearing on some of the outcome measures. Selecting a prospective comparative reference cohort from the referral hospitals and analysing the data according to the place where women intended to give birth went some way in addressing the selection bias at the design stage.

A further limitation of the study was the inability to retrieve data on severe morbidity recorded in databases other than the one available for the study. As a result this study could not provide the level of information relating to more complex measures of maternal and perinatal morbidity as employed in other studies [19, 22, 28]. This reflects the fragmented

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nature of routine maternity information system databases.

No inferential statistics were applied to some measures because of small numbers, however the detailed reporting of adverse and rare events strengthened the study. The crude number of rare outcomes in this study is surprising. Firstly an amniotic fluid embolism that was not preceded by an induction of labour is extremely rare. The reported incidence of amniotic fluid embolism in high-resource countries ranges from between 1.9 to 6.1 cases per 100 000 births [29], with induction of labour being a highly significant risk factor [30]. Given the high fatality rate for this condition, it is notable that the woman survived and was able to be transferred to a tertiary level hospital.

Secondly, the incidence of postpartum haemorrhage followed by hysterectomy in this study (1.64 per 1000 births) is relatively high compared to results from a large population-based cohort study in America (0.48 per 1000 births) [31]. Five of the six cases of postpartum haemorrhage followed by hysterectomy were in women who had a repeat caesarean section, and three of these women had placenta praevia or accreta. There is conflicting evidence on the association between repeat caesarean section and postpartum haemorrhage [32], with evidence pointing towards no association between the two [33, 34]. A causative link has been established between repeat caesarean sections and placenta accreta and hysterectomy [35-37], however there is the possibility of other causative influences for placenta accreta such as surgical technique [36, 38]. Further research into the incidence and prevalence of severe morbidity amongst childbearing women is needed, and is already underway in Australia through the Australasian Maternity Outcomes Surveillance System (AMOSS). AMOSS is a national surveillance mechanism designed to study a variety of rare or serious conditions during the antenatal, intrapartum and postnatal periods [39].

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Generalization of these findings should be undertaken with caution given that there are very few freestanding midwifery units in Australia. Due to their rarity in Australia there are no nationally recognised guidelines and referral pathways specific to freestanding midwifery units other than the general guidelines designed by the Australian College of Midwives [27]. The midwives who provide care in the units in this study are highly skilled and have formally integrated networking relationships with their referral tertiary level maternity units through which they have the support of obstetric teams [13]. The findings may not apply to other maternity units that do not offer the same care, referral pathways and distance to tertiary referral hospitals.

In addition, giving birth in any maternity setting brings with it a unique set of complexities and relationships which impact on outcomes for women and their infants [40]. Women who plan to give birth outside the conventional tertiary hospital setting may choose to do so for various reasons. The impact these characteristics have on birth outcomes are unknown and outside the scope of this paper. Further analysis of women's self- reported rationale for choosing a freestanding midwifery unit, or not, will add further detail to these findings [41].

The research findings agree with important large studies undertaken recently overseas including the UK [19], Scandinavia [22] and New Zealand [21] which found that planning to give birth in a freestanding midwifery unit was associated with a reduced risk of having a caesarean section and either no difference or a reduction in the odds of neonatal morbidities [19, 21, 22]. This study found similar rates of maternal and neonatal outcomes for low risk women reported in a previous Australian population based study to determine disadvantages associated with giving birth in low volume maternity hospitals [18]. Looking at neonatal

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mortality, the overall rates of stillbirth in this study (0.44%) were lower than all maternity units in Tracy, Sullivan and Dahlen et al's study (2006), which reported rates of stillbirth between 0.49% for hospitals with less than 100 births per annum and 0.94% for hospitals with greater than 2000 births per annum [18]. The rate of neonatal deaths in this study (0.41%) were lower than those reported for hospitals of comparable size (0.56%) [18]. The proportion of low birthweight babies in both cohorts in this study (1.8% in the freestanding group and 5.6% in the tertiary group) was relatively low compared to the incidence of low birthweight babies in Australian maternity units with between 100 and 500 births birth year (4.04%) and in maternity units with greater than 2000 births per year (9.77%) [18].

The overall rate of transfer in this study (51.8%) appears high when compared to the two recent cohort studies on freestanding midwifery units [19, 22]. However the current study is unique in that it reports rates of antenatal transfer (34%). Both freestanding units studied have a strong collaborative relationship with their tertiary referral units and women and midwives are encouraged to err on the side of caution and transfer antenatally whenever there is a possibility that medical intervention may be required during the birth process. Comparable rates of antenatal transfer were reported in randomised controlled trials on alongside midwife-led units in Ireland [42] (45%) and Scotland [43] (38%). The rates of intrapartum/postnatal transfer from this study (16.8%) sit between the intrapartum/postnatal transfer rates from freestanding midwifery units reported by Overgaard, Mollerm Fenger-Gron, Knudsen and Sandall [22] (16.3%) and the Birthplace in England Collaborative Group [19] (21.9%).

As a model, the freestanding midwifery unit is a growing and sustainable phenomenon in many countries, including in rural areas, where they are a valuable feature of the publically

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funded maternity system [21, 44, 45]. The centralisation of maternity services in Australia has led to the closure of many smaller maternity units, which has left a gap in accessible maternity care. Some freestanding midwifery units have filled this gap in urban and regional areas, however the lack of accessible maternity services in rural and remote regions of Australia continues to have widespread implications for women and their families [6, 10, 46, 47]. The challenge facing maternity services today is how to balance the need for safety with the need for equal access to maternity services, including to primary level birth facilities such as freestanding midwifery units.

This study supports the provision of care in freestanding midwifery units as an alternative to tertiary level maternity units for women with low risk pregnancies at the time of booking. Clinicians and policy makers may find these results useful in the planning and preservation of maternity services in areas where midwifery-only care is available in freestanding midwifery units. There is also scope for the development of standardized national protocols on freestanding midwifery units to improve the transparency of transfers and support the processes of development and evaluation. Further investigation into complex and longer-term measures of perinatal morbidity, transfer, and the viability of freestanding midwifery units in the rural/remote settings is required.

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Competing interests

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that there has been no support from any organisations for the submitted work. All authors declare that they had no relationships which companies that might have an interest in the submitted work in the previous three years, no family members with financial relationships that may be relevant to the submitted work and no non-finaancial interests that may be relevant to the submitted work.

Ethics approval

The study was approved by the Northern Sydney Local Health District Ethics Committee, the Hunter New England Human Research Ethics Committee and The University of Sydney Human Research Ethics Committee (NSW HREC reference number: HREC/09/HNE/78).

Data sharing statement

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No additional data available.

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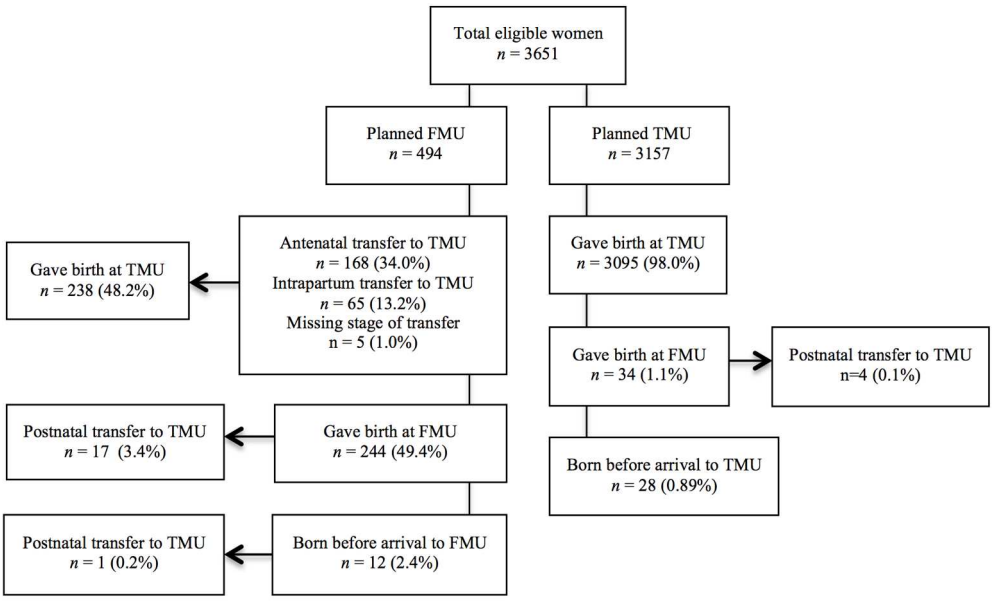
Figure 1. Study population and transfers from freestanding midwifery units (FMU) to tertiary level maternity units (TMU). Percentages expressed by planned place of birth.



161x108mm (300 x 300 DPI)

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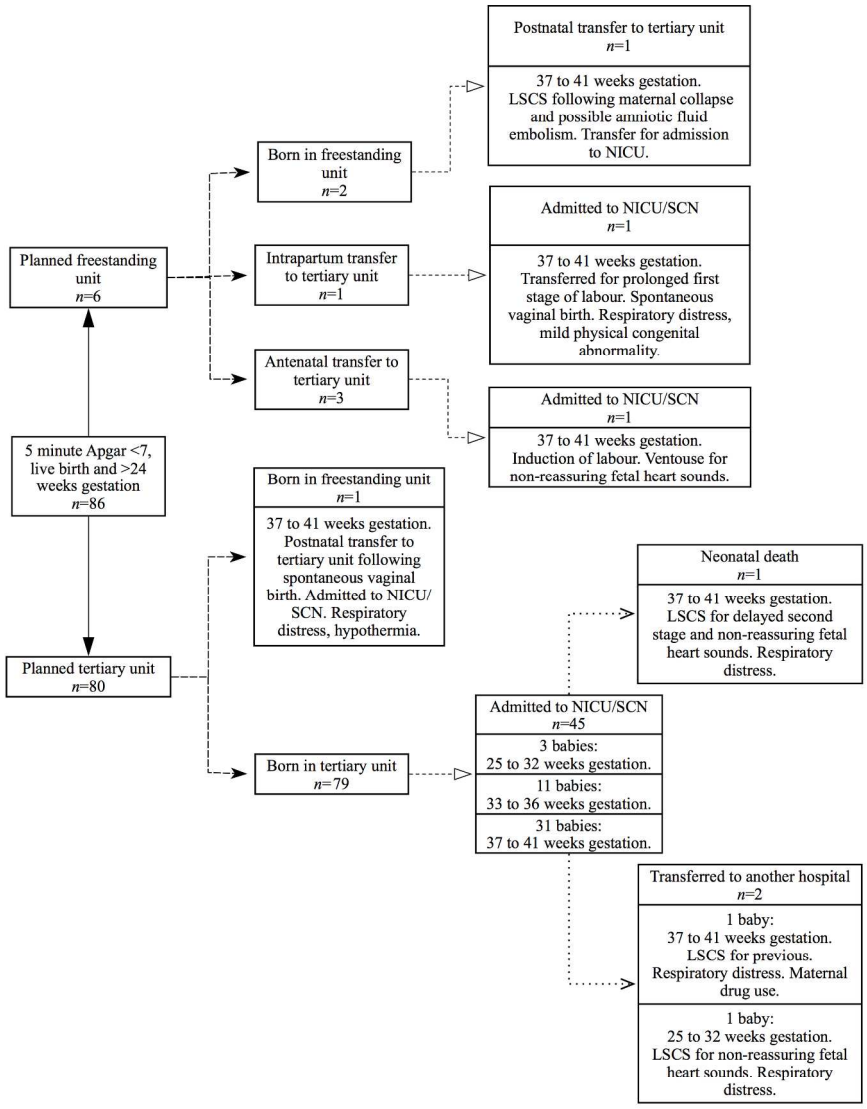

Figure 2. Severe neonatal morbidity: Babies with a 5 minute Apgar score of less than 7 followed by admission to NICU/SCN (restricted to live born babies greater than 24 weeks gestation).

189x260mm (300 x 300 DPI)

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SUPPLEMENTARY INFORMATION

Table A. Perinatal mortality: planned freestanding midwifery unit group†

Infants	*Obstetric details/ complications*	*Neonatal details/ complications*†
Stillbirths (20 to 24 weeks gestation)		
n=2	Antenatal transfer to tertiary referral hospital.	Congenital anomaly.
Stillbirths (37 to 41 weeks gestation)		
n=1	Antenatal transfer to tertiary referral hospital.	Fetal death in utero.
n=1	Antenatal transfer to tertiary referral hospital.	Concerns for fetal wellbeing.

† No intrapartum stillbirths recorded

Table B. Perinatal mortality: planned tertiary level maternity unit group†

Infants	*Obstetric details/ complications*	*Neonatal details/ complications*†
Stillbirths (20 to 24 weeks gestation)		
n=3		Congenital anomaly.
n=1		Chorioamnionitis.
Neonatal deaths (20 to 24 weeks gestation)		
n=6		Congenital anomaly.
n=3	Premature labour.	
n=1	Prolonged pre-term rupture of membranes.	
Stillbirths (25 to 32 weeks gestation)		
n=1	Placental abruption, hypertension.	
n=1	Antepartum haemorrhage.	
n=1		No documented complications.
n=1		Congenital anomaly.
Neonatal death (25 to 32 weeks gestation)		
n=1	Premature labour.	Respiratory distress, NICU.
Neonatal deaths (33 to 36 weeks gestation)		
n=1		Diaphragmatic hernia, NICU.
n=1	HELLP syndrome.	Respiratory distress, NICU.

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n=1	Caesarean section (LSCS) for non-reassuring cardiotocograph (CTG) and fetal blood sampling.	Isoimmunisation, intrauterine transfusion, SCN.
Stillbirths (37 to 41 weeks gestation)		
n=2		No documented complications.
n=1	Anhydamnios.	
n=1	Antepartum haemorrhage.	
Neonatal deaths (37 to 41 weeks gestation)		
n=1	Hypertension, LSCS for delayed second stage and non-reassuring CTG.	Respiratory distress, NICU.

† No intrapartum stillbirths recorded

Table C. Severe maternal morbidity by planned place of birth*

Women	*Obstetric details/ complications*	*Neonatal details/ complications*†
Planned place of birth: freestanding midwifery unit		
n=1	Maternal **cardiac arrest** and **collapse** during first stage of labour, possible **amniotic fluid embolism**, caesarean section (LSCS) at nearest general hospital, postpartum haemorrhage greater than 1500ml, multiple blood products, **hysterectomy.** Postnatal transfer to non-referral tertiary hospital.	37-41 weeks gestation. Baby transferred to NICU.
Planned place of birth: tertiary level maternity unit		
n=1	Elective lower segment caesarean section (ELSCS) for previous LSCS, cervical suture and antepartum haemorrhage (550mls). PPH greater than 1500mls, ***hysterectomy.***	25 to 32 weeks gestation, respiratory distress, low haemoglobin, NICU.
n=1	Premature labour, ELSCS for breech and previous LSCS. PPH greater than 1500mls, blood transfusion (19 units), ***hysterectomy.***	33 to 36 weeks gestation.
n=1	ELSCS for placenta praevia grade 4 and previous LSCS. PPH between 1000 and 1500mls, ***hysterectomy.***	33 to 36 weeks gestation, respiratory distress, NICU.
n=1	ELSCS for major placenta praevia, isoimmunisation and previous LSCS. PPH greater than 1500mls, ***postnatal transfer to another hospital.***	33 to 36 weeks gestation, presence of maternal antibodies, special care nursery (SCN).
n=1	ELSCS for placenta accreta and previous LSCS. PPH 1000 to 1500mls, ***hysterectomy.***	37 to 41 weeks gestation.

* Severe maternal morbidity highlighted in bold

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3, 4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5, 6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6, 7, 8, 9
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	7, 8
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9, 10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9
Bias	9	Describe any efforts to address potential sources of bias	9, 10
Study size	10	Explain how the study size was arrived at	9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9, 10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9, 10
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	10
		(*d*) If applicable, explain how loss to follow-up was addressed	
		(*e*) Describe any sensitivity analyses	
Results			

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Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	10, 11
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11, 12
		(b) Indicate number of participants with missing data for each variable of interest	See Tables
		(c) Summarise follow-up time (eg, average and total amount)	n/a
Outcome data	15*	Report numbers of outcome events or summary measures over time	12-16
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	12-16
		(*b*) Report category boundaries when continuous variables were categorized	See Tables
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9, 10
Discussion			
Key results	18	Summarise key results with reference to study objectives	20
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	20-23
Generalisability	21	Discuss the generalisability (external validity) of the study results	22, 23
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	24

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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