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# Freestanding midwifery-led unit versus obstetric unit: A matched cohort study of outcomes in low-risk women



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**Objective:**

To compare perinatal and maternal morbidity and birth interventions in low-risk women giving birth in two freestanding midwifery units (FMUs) and two obstetric units (OUs).

**Design:**

A cohort study with a matched control group

**Setting:**

The region of North Jutland, Denmark

**Participants:**

839 low-risk women intending FMU birth and a matched control group of 839 low-risk women intending OU birth were included at the start of care in labour. OU women were individually chosen to match selected obstetric/socio-economic characteristics of FMU women. Analysis by intention-to-treat.

**Main outcome measures:**

Perinatal and maternal morbidity and interventions

**Results:**

No significant differences in perinatal morbidity were observed between groups (Ap-gar scores <7/5, <9/5 or <7/1, admittance to neonatal unit, asphyxia, or readmission). Adverse outcomes were rare, and occurred in both groups.

FMU women were significantly less likely to experience abnormal fetal heart rate (RR: 0.3, 95% CI: 0.2 to 0.5), fetal-pelvic complications (0.2, 0.05 to 0.6), shoulder dystocia (0.3, 0.1 to 0.9), occipital-posterior presentation (0.5, 0.3 to 0.9), and postpartum haemorrhage >500ml (0.4, 0.3 to 0.6) compared to OU women.

Significant reductions were found for FMU group's use of epidural analgesia (0.4, 0.3 to 0.6), caesarean section (0.6, 0.3 to 0.9), instrumental delivery (0.4, 0.3 to 0.6), and oxytocin augmentation (0.5, 0.3 to 0.6).

Transfer during or <2 hours after birth occurred in 14.8% of all FMU births but much more frequently in primiparas than in multiparas (36.7% versus 7.2%).

**Conclusion**

Comparing FMU and OU groups, no increase was found in perinatal morbidity, but significantly reduced incidences of maternal morbidity, birth interventions, and in-creased likelihood of spontaneous vaginal birth. FMU care may be considered as an adequate alternative to OU care for low-risk women. Pregnant prospective mothers should be given informed choice of place of birth, including information on transfers.

## Article Summary

Article focus:

The safety of birth in free-standing midwifery-led units (FMUs) is strongly debated as acute complications may arise in a spite of careful risk assessment of women.

Studies of various observational design suggest that FMU care for low risk women is related to low perinatal and maternal morbidity, fewer interventions and a decreased use of medical pain relief compared to OU care but the level of evidence is weak and some studies is limited by e.g. the inclusion of high-risk women, low number of participants, and inadequate control of bias and confounding.

The aim of present study was to compare perinatal and maternal morbidity, birth interventions, and pain relief in low-risk women giving birth in two freestanding midwifery-led units (FMUs) and two obstetric units (OUs) in Denmark.

Key messages:

No increase in perinatal morbidity was found among infants of low-risk women who intended birth in an FMU compared to infants of low-risk women who intended birth in an OU. More studies on rare adverse outcomes are needed.

The results of present study suggest that FMU care has important benefits such as reduced maternal morbidity, reduced use of birth interventions including caesarean sections and increased likelihood of spontaneous vaginal birth compared to OU care. However, more than one in three primiparas and one in fourteen multiparas is in need of transfer.

Care in FMUs may be considered as an adequate alternative to OU care for low-risk women, and women should be given an informed choice of place of birth, including information on transfer.

Strengths and limitations of this study

A major study strength is that it compares processes and outcomes from women who have been prospectively judged to be at low obstetric risk in two well-defined and carefully established settings in the same region. Also the data are complete as all eligible women planning to give birth in the FMU settings were included, and full follow-up on all participants was obtained.

The primary study limitations stem partly from its observational design, partly from the sudden closure of the two FMUs. Although the study groups were very closely matched and adjustment for the matching factors revealed no residual confounding, the risk of confounding by unknown factors related to women's choice of care in labour persists. Neither can any bias linked to the delayed data collection for 289 FMU participants from 2004 be ruled out, but sub group analysis showed that 2004 data were in conformity with the later data.

# Freestanding midwifery-led unit versus obstetric unit:

## A matched cohort study of outcomes in low-risk women

### Introduction

In most industrialised countries, obstetric units (OU) have become the primary setting for birth with the safety of other birth settings strongly debated[1-5]. The primary concern regarding birth outside an OU relates to the anticipation of adverse perinatal outcomes. But steadily increasing birth intervention rates and studies of women's perceptions of childbirth indicate that OUs may not always provide optimal conditions for low-risk childbirth or satisfy women's individual needs[6-14]. In many countries the introduction of midwifery-led units has given women a choice among places of birth[1].

A Cochrane review concerning alongside midwifery-led units (AMU) found no significant differences in perinatal mortality or perinatal and maternal morbidity. In addition, it documented both significantly fewer medical interventions and increased maternal satisfaction[12]. However, this evidence cannot be generalised to freestanding midwifery-led units (FMU) and homebirths. Concern has been expressed that acute intrapartum and postpartum complications may arise in spite of careful assessment of low-risk women and that transfer delays may affect lifesaving medical interventions such as caesarean section or advanced neonatal resuscitation.

The two prospective, controlled cohort studies of FMUs[16;17] undertaken unanimously report low perinatal and maternal morbidity, fewer interventions and decreased use of medical pain relief. The results are supported by a wide range of retrospective, uncontrolled and/or population-based studies[6;10;18-30]. But the evidence is conflicting as two studies also found significantly lower 1-

[1] The terms used were adopted from Birthplace in England Research Programme (Study 1: terms and definitions)[15]

(while not 5-) minute Apgar scores[28] and increased need for neonatal ventilation[10] in FMUs . Because of greatly varying criteria for low-risk categorisation, care standards, midwives' training, cooperation between FMUs and OUs, etc., considerable caution must be observed when generalising previous findings to other settings and countries. Furthermore, the level of evidence was weak[31]. The applicability/validity of many studies is limited by factors such as restricted participation, inclusion of high-risk women, limited control of bias and confounding, and inadequate descriptions of inclusion and exclusion criteria, medical assistance (if any), and transfer criteria.

The need for further research is substantial, but the rarity of adverse outcomes in a low-risk population, the limited number of FMU births, and women's strong preference for choice of birthplace[32;33] converge to form serious barriers for the investigation of perinatal mortality in large, adequately powered, randomised controlled trials (RCTs). This increases the need for evidence from carefully planned cohort studies.

**Objectives**

The present study compared labouring processes, perinatal and maternal morbidity and birth interventions in low-risk women giving birth in FMUs and OUs in Denmark.

The study is reported in accordance with STROBE requirements[34;35].

**Study hypotheses**

We hypothesised that the FMU care concept, with its emphasis on the physiological birth process and socio-physical well-being during childbirth, would entail a number of positive effects for the

women, such as a higher rate of spontaneous vaginal birth, intact perineum, and use of non-pharmacological pain relief. FMU women were expected to experience fewer interventions (including caesarean section) and require less use of pharmacological pain relief compared to OU women. No differences in perinatal or maternal morbidity were predicted.

## Methods

### Design

A matched cohort study

### Setting

The study was conducted in North Jutland, a relatively sparsely populated region of Denmark where the local health authorities in 2001 had decided to transform two of the region's four maternity units into FMUs, opening in 2001 and 2004. The FMUs offered midwifery-led care during pregnancy and intrapartum and postnatal periods to low-risk women.

### Data collection

In a 3.5-year period between 2004 and 2008, data on socio-demographic factors, previous pregnancies and births, current pregnancy and birth, infants, FMU transfers, and maternal/neonatal readmissions 0-28 days postpartum were collected from patient records and the North Jutland Patient Administration System. The data collection was carried out by project staff with comprehensive professional knowledge of the field on basis of written instructions.

### Data security and ethics

The project was approved by the Danish Data Protection Agency (reference number: 2005-41-5352) and the regional health authorities of North Jutland. Data were handled in strict confidentiality and in accordance with Danish law requiring neither approval from an ethics committee nor informed consent from patients for observational studies involving no risk or inconvenience to patients[36].

**Characteristics of the freestanding maternity units**

In Denmark care for low-risk women is midwifery-led in all birth settings. Midwives employed at the FMUs were required to have at least two years of practice experience and adequate training in obstetric emergencies, including ventouse delivery in case of acute second-stage fetal distress. Complications or indications hereof resulted in transferral of the women and/or the infants to the nearest OU. Both FMUs were located in community hospitals with an intensive care unit but without obstetric service. In case of emergencies, an anaesthesiologist/resuscitation-capable specialist nurse was available. The annual number of FMU births were approximately 170 (Hobro) and 130 (Frederikshavn).

**(Supplementary information: Table A: Characteristics of FMUs)**

**Characteristics of the obstetric maternity units**

Aalborg University Hospital is a one of five highly specialised Danish hospitals with a specialist OU who saw approximately 3500 births a year. Vendsyssel Hospital is a provincial hospital with 10 clinical specialities, including an OU providing care for low-risk and most high-risk pregnancies and a generalised paediatric ward. The annual number of births was approximately 1400. Mothers and infants with severe illness were transferred.

**(Supplementary information: Table B: Characteristics of OUs)**

**Participants**

The study population was composed of an intervention group of 839 low-risk women from two freestanding midwifery-led units in Hobro and Frederikshavn, and a control group of 839 low-risk women, matched for key factors, who received routine care from the specialist obstetric unit at Aalborg University Hospital and the obstetric unit at Vendsyssel Hospital, Hjørring.

**Inclusion criteria**

All labouring women admitted to the FMUs by their midwives on the basis of multi-disciplinary, regional admission criteria were included in the study. As informed consent of participation was not required due to Danish legislation, all eligible women were included.

Women in the control group were eligible for inclusion only if they represented an individual match to the obstetric and social characteristics of a woman in the FMU group.

Women in both study groups were thus rigorously judged to be at low-risk and fulfil criteria for FMU birth, and included at the start of care in labour.

**Exclusion criteria**

Excluded for the study were only women admitted to an FMU for emergency treatment without satisfying the criteria for FMU care; an event occurring very rarely.

**The matching process**

Confounding is a main concern in cohort studies. The matched design was chosen because it potentially increases the statistical precision in a cohort study and effectively eliminates the association between the exposure (place of birth) and the matching variables, given a perfect

balance of data is obtained on matched variables between groups[34;37;38]. Matching is especially relevant in situations with non-linearity and inter-correlation between variables or where a substantial difference in the distribution of confounders between groups is expected[39]. This was the case in present study whose participants were recruited from areas characterised by varying degrees of urbanisation and heterogeneity in socio-demographic characteristics[40;41].

Women in the control group were selected from the region's patient administration system which carries detailed information on the region's pregnant women. For each participant included in the FMU group, a control participant from the nearest OU was identified among the admitted low-risk women. The selection of matched control participants was conducted in accordance to strict guidelines by project staff that were blinded to the identity and the birth outcomes of women in the FMU group. The matching result was blinded until the selected control participants had given birth.

Matching was done prospectively on criteria with an established influence on birth outcomes[42-45]: low risk status, parity, smoking, BMI, age, ethnicity, education, occupation, and cohabitation status. A 100% match was carried out on: low-risk status, parity and smoking status. Body Mass Index (BMI) and age were matched with a range of +/-5; meaning that BMI/age scores of 22 were matchable with scores between 17 and 27. Socio-demographic characteristics such as ethnicity, education level, occupation, and cohabitation status were matched within groups as shown in Table 1.

**Definition of low risk**

Women were judged to be at low risk if they were healthy, presented in spontaneous labour between 37+0 and 41+6 days of gestation, had an uncomplicated pregnancy and no

medical/obstetric history or conditions increasing obstetric risk as outlined in the UK NICE intrapartum care guidelines[46]. However, we considered healthy multiparous women as low-risk regardless of their age and BMI if their previous pregnancies and deliveries had been uncomplicated.

**Variables and data measurement**

The primary outcome variables were the following: Apgar score <7/5 minutes, <9/5 minutes, and <7/1 minutes; admittance to neonatal intensive care unit (NICU); admittance to NICU >48 hours; abnormal fetal heart rate leading to action; spontaneous vaginal birth; no perineal trauma; postpartum haemorrhage >500 ml; caesarean section; instrumental vaginal delivery; episiotomy; epidural analgesia; and water immersion. Unfortunately, we were unable to obtain data on umbilical blood gas. Intended birthplace at the start of care in labour was considered the exposure.

The data were recorded in accordance with the National Birth Register and the North Jutland Birth Register, standards and guidelines applying to all four units and with which all midwives and doctors in the region were familiar. A stop watch was used when measuring Apgar scores. Postpartum haemorrhage was routinely estimated rather than measured.

**Power calculation, sample size and changes in study protocol**

Clinically important differences and power calculations were performed for all the above-mentioned clinical endpoints /primary outcomes. The frequencies used in the calculations originate in the North Jutland Birth Register and the international literature. Estimations of sample sizes were based on power calculation for the two most important outcomes: Apgar score <7/5 minute and caesarean section. The limited number of FMU births, at 300-350 per year, was also taken into

account. The study was originally planned to include data on 1027 FMU participants and 1027 control participants over a period of 3.5 years, starting 1st January 2005, however, in October 2006 the local authorities unexpectedly announced the imminent closure of its two FMUs. The decision was based on criticism of the FMU concept by the National Board of Health. The power to detect differences between our two study groups was consequently reduced and a thorough revision of the study protocol was required. At the time of the FMU closures, 550 FMU participants had been included, and in order to obtain the largest possible sample of FMU participants, we included all of the 289 eligible women who had been admitted to the FMUs since the opening of the second FMU (1 March 2004). These women were prospectively matched with women from the nearest OU, thus ensuring total samples of 839 women in each group.

This sample provided power (5% significance level, 80% power) to detect an increase in Apgar score <7/5 minutes from expected 1.07% in the OU standard care group to 3.1% in the FMU group and a reduction in the incidence rate of caesarean section from 8.8% in the OU group to 5.5% in the FMU group . The study sustained the power to detect clinically relevant differences between groups on all of the other primary outcomes as well.

**Statistical analysis of data**

Analyses were based on the intention-to-treat principle and carried out by use of STATA software, version 11.

The two groups (matched 1:1) were compared by paired tests on all measures, McNemar's test for paired binary data (medical data on the birth process) and Wilcoxon's signed-rank test for paired continuous data (e.g. birth weight). As we were concerned that residual confounding might remain, supplementary regression analysis adjusting for the matching characteristics was performed by use

of both continuous and grouped variables[47;48]. For ease of interpretation (e.g. calculation of confidence bands), ordinal outcomes were dichotomized, but we controlled for conclusive agreement with test results based on the original data.

The analysis for occipital posterior position was performed after excluding caesarean deliveries. For all comparisons, relative risks with 95% confidence intervals were calculated. All reported P-values were two-sided, and the level of statistical significance 5%. To check for bias introduced by the inclusion of FMU women giving birth in 2004, supplementary sub-group analyses were performed (2004-data versus main data).

**Participants**

A low-risk match was prospectively identified for all 839 women admitted to an FMU and full follow-up was obtained for all 1678 women. Of the 839 FMU women, 733 (87.4%) gave birth as planned in the FMU or at home, assisted by a FMU midwife (cf. Figure 1). Transit births were included in the few cases where the woman had consulted a midwife <24 hours before giving birth and had been advised to stay at home longer/return to her home.

Ninety-seven FMU women (11.6%) were transferred intrapartum, among these two gave birth in the ambulance. Eleven, who were in early labour, were transported in their own vehicle. Twenty-seven transfers (3.2%) took place <2 hours after birth, another thirteen (1.5%) during the postnatal stay. The total number of transfers was 137 (16.4%).

**Figure 1: Flow chart**

As shown in Table 1, the matching produced two fully comparable groups in terms of key medical and socio-demographic factors. The FMU women's background details reflected the life conditions

of the local population in general[40;49]. With Aalborg and Hjørring municipalities as exceptions, the educational and income levels in North Jutland rank as the lowest in Denmark. In the FMUs' predominantly rural catchment areas, unemployment rates are high, which is reflected in a slightly higher rate of FMU women without employment outside the home.

## Main results

### Primary outcomes

Table 2 shows no statistically significant differences between the two study groups with regard to perinatal morbidity as measured by: Apgar scores <7/5 minutes, <9/5 minutes, <7/1 minutes; the total number of NICU admittances; NICU admittance >48 hours; neonatal asphyxia; and maternal and neonatal readmission to hospital 0-28 days postpartum.

The women in the FMU group were significantly less likely to experience abnormal fetal heart rate leading to action (relative risk (RR): 0.3; 95% confidence interval (CI): 0.2 to 0.5); caesarean section (0.6,0.3 to 0.9); instrumental delivery (0.4, 0.3 to 0.6); 1-2$^{nd}$ degree tearing (0.9, 0.8 to 0.97); postpartum haemorrhage >500ml (0.4, 0.3 to 0.7), or to have epidural analgesia (0.4, 0.3 to 0.6), and pudendal nerve block (0.1, 0.0 to 0.5) for pain relief compared to women in the OU group. Moreover, the FMU women were significantly more likely to experience spontaneous vaginal birth (1.06, 1.03 to 1.09), intact perineum (1.1, 1.02 to 1.2) and water immersion for pain relief (1.4, 1.2 to 1.6) than were the OU women.

**Table 2: Primary outcomes**

### Secondary outcomes

No significant differences between groups were found for: infant birth weight (mean: 3.636 kg (FMU) and 3.641 kg (OU), the occurrence of meconium-stained amniotic fluid, the use of

uterotonics, and non-recumbent positions for birth, postpartum haemorrhage >1000 ml, 3rd/4th degree tears, cervical dilatation on admission (mean: 4.4 cm (FMU) and 4.3 cm (OU)), or duration of admission for labour care (mean: 5.3 hours (FMU) and 5.6 hours (OU)) .

As shown in table 3, the FMU women were significantly less likely to experience: dystocia (0.4, 0.3 to 0.5); intrapartum fetal-pelvic complications (0.2, 0.05 to 0.6); shoulder dystocia (0.3, 0.1 to 0.9); and occipital posterior presentation (0.5, 0.3 to 0.9) compared to OU women. The same applied for oxytocin augmentation (0.5, 0.3 to 0.6), treatment for shoulder dystocia (0.1, 0.01 to 0.8), perineal suturing (0.8, 0.7 to 0.9), and intrauterine palpation (0.3, 0.1 to 0.9).

**Table 3: Secondary outcomes**

**Other analyses**

A regression analysis adjusting for the matching characteristics showed coinciding results with the match analysis, thus confirming the robustness of our results and matching. A sub-group analysis comparing the late collected data on 2004-FMU participants with the main, prospectively collected data detected no systematic differences or deviation of results between the two bodies of data.

**Transfer**

For the 97 FMU women transferred to an OU during labour, the most common reasons were: failure to progress in labour (56%), meconium-stained amniotic fluid (14.2%), and abnormal fetal heart rate (10.2%). The risk of transfer during or <2 hours after birth was very different for primiparous and multiparous women (36.7% versus 7.2%). All reasons for transfer are tabulated in Table 4. Ambulance transfers from the two FMUs averaged 42/38 minutes (range: 20 to 60). Further information on transfers is under preparation for publication elsewhere.

After transfer, women had shared care between an obstetrician and a midwife (either an OU midwife or a FMU midwife accompanying them to the OU (in 36% of transfers)).

**Table 4: Causes of FMU-OU transfers**

**Adverse outcome**s were defined as severe maternal morbidity, perinatal mortality, Apgar score <7/5 minutes, and >1 week NICU admittance. One incident of severe maternal morbidity (uterine rupture) occurred among the OU women. In the FMU group, one perinatal/neonatal death occurred due to an undetected, severe congenital malformation. Nine infants were born with 5 minute Apgar scores of 4-6; three belonged to the FMU group but were born in an OU following intrapartum transferral. Eight of the nine infants were admitted to NICU; all were later discharged well.

Three infants from the FMU group, who were born in an OU after transfer, had NICU stays exceeding one week. One infant with a 5/5 Apgar score had a stay of 36 days, but this was due primarily to an undetected congenital heart disease.

One adverse perinatal event was dealt with in a FMU shortly after its opening. Due to an umbilical cord prolapse, emergency caesarean section was carried out by a gynaecologist, employed at the unit before its transformation into a FMU and summoned against protocol. Apgar scores were 10/1, 10/5. (**Supplementary information on all adverse events is provided in Table C).**

## Discussion

### Key results

This study aimed to compare maternal and infant outcomes for women at low risk who intended to give birth in FMU or OU settings. We found no significant differences in perinatal morbidity measured by Apgar scores <7/5 minutes, <9/5 minutes, <7/1 minutes; the total number of NICU admittances; neonatal admittance to NICU >48 hours; neonatal asphyxia; or neonatal readmission to hospital.

Moreover, among this population of low-risk women, dystocia, intrapartum fetal-pelvic complications, occipital-posterior position of the infant, shoulder dystocia, oxytocin augmentation, instrumental delivery, caesarean section, and post-partum haemorrhage >500 ml occurred significantly less often in the FMU group compared to the OU group. A comparison of the groups thus showed the FMU women to have a significantly greater likelihood of spontaneous vaginal birth and intact perineum.

**Limitations**

The limitations of our study stem partly from its observational design, partly from the sudden closure of the two FMUs. A non-randomised study design precludes elimination of all potential confounding factors; only known confounders can be adjusted for, and only as far as they can be accurately measured. Despite of our close matching of study groups and adjustment for matching factors, residual confounding and confounding by unknown factors related to women's choice of care in labour may persist. Neither can any bias linked to the delayed data collection for 289 FMU participants from 2004 be ruled out, but we were somewhat reassured to find that the 2004 data were in conformity with the later data. Our contention that such a risk is limited is also supported by the fact that no interventions were performed in the study, participants were included on the same principles, individual and project-specific data collections were performed for all participants,

patient records were of good quality, and all control participants were prospectively included. The obstetric quality indicators, which were compiled annually by the units, were closely followed to detect any changes in practices or technology use; no systematic changes occurred during the study period. No new technology was introduced, nor were any major change in obstetrical practices implemented.

Furthermore, some primary outcomes (Apgar scores, postpartum haemorrhage) were exposed to measurement subjectivity, others were proxies for morbidity, although globally used quality indicators/research outcomes, and the number of events in some analyses was low. It is also uncertain whether the outcomes would have been different for the two FMU infants had 1) a caesarean section not been performed and 2) the infant with severe congenital malformation been born in the alternative setting. Ideally, the results should be confirmed (or refuted) in a large RCT, but as the recruitment of an adequately large number of women willing to be randomised to place of birth would be logistically challenging, the most robust design seems to be a large prospective cohort study.

**Strengths**

We present findings from the second-largest prospectively controlled study of FMU care. A major strength of our study is that it compares processes and outcomes from women who have been prospectively judged to be at low obstetric risk in two well-defined and carefully established settings in the same region. Also, in contrary to some earlier studies[10;16;29], the data are complete as all eligible women planning to give birth in the FMU settings were included, and full follow-up on all participants was obtained.

**Interpretation**

The present study was powered to compare perinatal outcomes estimated by Apgar score <7/5 minutes, neonatal asphyxia and NICU admission >48 hours. No difference was found between the two study groups.

Although the mothers were transferred to the OU without delay (3-23 hours before giving birth), it is concerning that the three NICU stays exceeding one week occurred in the FMU group. Further study of rare adverse outcomes and optimisation of care for transferred women are needed.

The study findings conform with other studies of FMU care[6;10;18;24;26;28;29] that have all reported a reduced incidence of some medical birth interventions while the caesarean section rate is seldom found to be affected, something which may stem from inadequacies in the power or robustness of their design. In this respect, our study forms an important exception.

In addition, the present study is the first to report that FMU women were significantly less likely to experience fetal-pelvic complications, occipital-posterior position of the infant at birth and shoulder dystocia compared to OU women.

Although the study does not enable us to be specific about the individual mechanisms or elements of FMU care leading to decreases in the incidence of caesarean section and birth complications, we would indicate as influencing factors the greater availability of continuous support during labour, the encouragement of women to ambulate and use different position during labour, and the spacious and calm FMU facilities. Continuous support during labour has been proved to reduce birth interventions and the need for pharmaceutical pain relief[50]. Mobilisation and the practice of hand-

knee position have furthermore been shown to support fetal rotation into an occipital anterior position and to reduce the duration of labour[51;52]. In contrast, the use of epidural analgesia and oxytocin augmentation in OU care both require CTG monitoring and are likely to restrict mobility[53] and thus use of different labour positions. Furthermore, oxytocin augmentation can cause uterine hyper-stimulation leading to fetal heart rate abnormality and oxygen desaturation[54].

We suggest that the assessment of the risk of rare adverse outcomes in low-risk FMU births be balanced against our findings that infant morbidity was not affected and the women intending to give birth in a FMU are less likely to suffer complications or undergo caesarean section and other birth interventions when compared to women intending to give birth in an OU.

**Generalisability**

Any generalisation of our findings must consider the full public funding of all maternity services in Denmark. The FMU midwives were skilled in dealing with obstetric emergencies, cooperation between FMUs and OUs was excellent, and the local implementation of multi-disciplinary guidelines for referral and transfer were based on the best evidence available, thus improving the reliability of care provided. Furthermore, the FMUs were located in community hospitals that offered life-supporting assistance in emergencies. Generalising to other countries offering different conditions should be made with caution.

Compared to most other countries, Denmark is culturally less diverse and characterised by less social inequality, with high standards of health and one of the lowest perinatal mortality rates in the world (6.6 per 1000 in 2004)[55]. However, the FMU women in this study had higher-than-average BMIs and lower educational and occupational status than Danish women in general[49;56],

characteristics that reflect the life conditions and health status of women in the FMUs' peripheral catchment area. We take this as an indication that positive outcomes for women choosing FMU care are not necessarily restricted to women privileged by high socio-economic status or excellent health, an assumption that is in line with the findings of the so far largest study of FMU care[16].

The distances between the four units studied were 35-55 kilometres; FMU and OU care was thus not equally accessible to all women. Taking into account the characteristics of women in the study and the finding of convenience/proximity as the most important factor in North Jutland women's choice of birthplace[57], we hypothesise that philosophies/ideas about childbirth play a minor role in our study in comparison to studies involving women whose choices are not affected by geography.

Further work should examine the potential influence of birth expectations and perceptions on women's choice between FMU and OU care to determine any impact of world-views or philosophies on birth outcomes. Additional aims would be to elucidate the underlying elements of FMU care and their influence on outcomes and to explore the potential differences between AMU care and FMU care. Operational efficiency, cost-effectiveness and rare outcomes also present areas for further work, the latter through a rigorous review of controlled studies of FMU.

**Conclusion**

In conclusion, the present study found no increase in perinatal morbidity among infants of low-risk women intending to give birth in an FMU compared to infants of women intending to give birth in an OU. Among the FMU women it found reduced maternal morbidity, fewer caesarean sections and other birth interventions, along with an increased likelihood of spontaneous vaginal birth. Further study of rare adverse outcomes is needed.

Care in FMUs may be considered an adequate alternative to OU care for low-risk women. Pregnant mothers should thus be given an informed basis for their choice of birthing place, with information on the high risk of transfer during or immediately after birth for primiparous women. FMU care seems to offer important qualities that should also be brought to bear on the development of OU care for low-risk women.

| What is already known on this topic |
| --- |
| The safety of birth in free-standing midwifery-led units (FMUs) is strongly debated as acute complications may arise in a spite of careful risk assessment of women.<br><br>Women's strong preferences in choice of birthplace and a low number of out of OU births form serious barriers for the investigation of rare adverse outcomes in large adequately powered randomised controlled trials.<br><br>Studies of various observational design suggest that FMU care for low risk women is related to low perinatal and maternal morbidity, fewer interventions and a decreased use of medical pain relief compared to OU care but the level of evidence is weak and some studies is limited by e.g. the inclusion of high-risk women, low number of participants, and inadequate control of bias and confounding. |
| **What this study adds** |
| No increase in perinatal morbidity was found among infants of low-risk women who intended birth in an FMU compared to infants of low-risk women who intended birth in an OU. More studies on rare adverse outcomes are needed.<br><br>Present study suggest that FMU care has important benefits such as reduced maternal morbidity, reduced use of birth interventions including caesarean sections and increased likelihood of spontaneous vaginal birth compared to OU care. More than one in three primiparas and one in fourteen multiparas is in need of transfer.<br><br>Care in FMUs may be considered as an adequate alternative to OU care for low-risk women, and women should be given an informed choice of place of birth, including information on transfer. |



## Contributors

Charlotte Overgaard is responsible for the study's conceptual design, designed the data collection tools, and monitored all data collection. She also participated in the cleaning, analysis and interpretation of data, the drafting of the article and wrote the final version. She is guarantor. Morten Fenger-Grøn participated in the analysis and interpretation of data and the drafting of the

article. Anna Margrethe Møller participated in the conceptual design of the study, the interpretation of data and the drafting of the article. Lisbeth B Knudsen and Jane Sandall participated in the interpretation of data and the drafting of the article. All of the authors critically reviewed the article and approved the final version that was submitted 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: CO had research grants (paid to her institution) from: the Augustinus Foundation, the Obel Family Foundation, the Oticon Foundation, the University College North Jutland Research and

Development Fund, and the Research Foundation of the Danish Association of Midwives for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years; no other relationships or activities that could appear to have influenced the submitted work.

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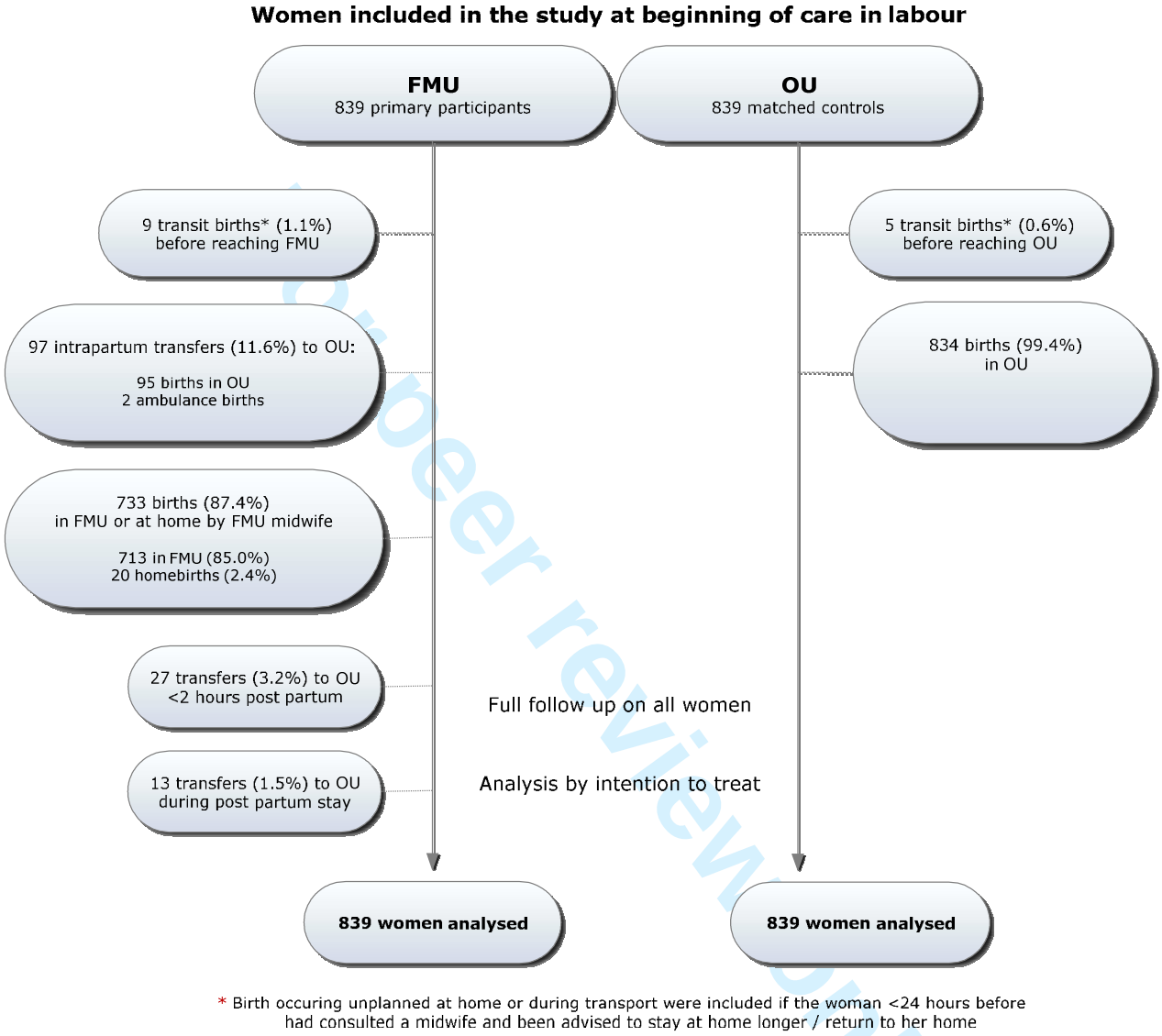
## Tables and figures, chronological order:

### Figure 1: Study flow chart



## Table 1: Matching characteristics

| Characteristics | FMU | (%) | OU | (%) |
|---|---|---|---|---|
| **Complete match retained in all cases** | | | | |
| **Obstetric risk status** | | | | |
| Low risk | 839 | (100) | 839 | (100) |
| **Parity** | | | | |
| Primiparous | 215 | (25.6) | 215 | (25.6) |
| Multiparous | 624 | (74.4) | 624 | (74.4) |
| **Smoking status** | | | | |
| Non-smoker | 684 | (81.5) | 684 | (81.5) |
| 1-9 cigarettes | 59 | (7.0) | 59 | (7.0) |
| 10 or more cigarettes | 96 | (11.5) | 96 | (11.5) |
| **Individuals matched within ranges/groups** | | | | |
| **BMI** | | | | |
| <18 | 17 | (2.1) | 22 | (2.6) |
| 18-24.9 | 528 | (62.9) | 530 | (63.2) |
| 25-29.9 | 226 | (26.9) | 219 | (26.1) |
| >30 | 68 | (8.1) | 68 | (8.1) |
| **Age** | | | | |
| 16-20 | 24 | (2.9) | 25 | (3.0) |
| 21-35 | 731 | (87.1) | 716 | (85.3) |
| >35 | 84 | (10.0) | 98 | (11.7) |
| **Ethnicity** | | | | |
| Nordic or Western European | 805 | (96.0) | 809 | (96.4) |
| Eastern European or Asian | 27 | (3.2) | 22 | (2.6) |
| Arab or African | 7 | (0.8) | 8 | (1.0) |
| **Education level*** | | | | |
| No training/education qualifying for the labour market | 216 | (25.7) | 217 | (25.9) |
| Skilled training | 255 | (30.4) | 255 | (30.4) |

| | | | | |
|---|---|---|---|---|
| 1-2 ½ years of post-secondary education | 84 | (10.0) | 81 | (9.6) |
| 3-4 years of post-secondary education | 254 | (30.3) | 256 | (30.5) |
| 5-6 years of post-secondary education | 30 | (3.6) | 30 | (3.6) |
| **Occupation** | | | | |
| No paid work | 160 | (19.1) | 131 | (15.6) |
| Unskilled work | 107 | (12.7) | 119 | (14.2) |
| Skilled work[±] | 542 | (64.6) | 557 | (66.4) |
| Academic work/manager or senior official: | 30 | (3.6) | 32 | (3.8) |
| **Cohabitation status** | | | | |
| Living with partner | 815 | (97.1) | 819 | (97.6) |
| Not living with partner | 24 | (2.9) | 20 | (2.4) |

* Students and trainees were classified along with the educational level for which they were being trained
[±] All non-academic/non-managerial vocations requiring 1-4 years of post-secondary education/training [61]

## Table 2: Primary outcomes

| | FMU (%) | OU (%) | RR | 95%CI | P-value |
|---|---|---|---|---|---|
| **Perinatal** | | | | | |
| Abnormal fetal heart rate leading to action | 34 (4.1) | 98 (11.7) | 0.3 | 0.2-0.5 | 0.0000 |
| Apgar score <7 after 1 min | 22 (2.6) | 25 (3.0) | 0.9 | 0.5-1.6 | 0.7709 |
| Apgar score <9 after 5 min | 15 (1.8) | 20 (2.4) | 0.8 | 0.4-1.5 | 0.4996 |
| Apgar score <7 after 5 min | 5 (0.6) | 5 (0.6) | 1 | 0.3-3.4 | 1.0000 |
| Neonatal asphyxia | 27 (3.2) | 41 (4.9) | 0.7 | 0.4-1.1 | 0.1143 |
| Neonatal admittance to NICU | 28 (3.3) | 42 (5.0) | 0.7 | 0.4-1.1 | 0.1143 |
| Neonatal stay in NICU >48 hours | 14 (1.7) | 15 (1.8) | 0.9 | 0.5-1.9 | 1.0000 |
| Child readmitted to hospital 0-28 days postpartum | 26 (3.1) | 35 (4.2) | 0.7 | 0.4-1.1 | 0.1480 |
| **Maternal** | | | | | |
| Spontaneous vaginal birth | 796 (94.9) | 751 (89.5) | 1.06 | 1.03-1.09 | 0.0000 |
| Caesarean section | 19 (2.3) | 34 (4.0) | 0.6 | 0.3-0.9 | 0.0400 |
| Instrumental delivery* | 25 (3.0) | 61 (7.8) | 0.4 | 0.3-0.6 | 0.0000 |
| Epidural analgesia | 35 (4.2) | 86 (10.3) | 0.4 | 0.3-0.6 | 0.0000 |
| Emission in water for pain relief | 269 (32.1) | 197 (23.5) | 1.4 | 1.2-1.6 | 0.0001 |
| Pudendal nerve block | 3 (0.4) | 21 (2.5) | 0.1 | 0.0-0.5 | 0.0000 |
| Postpartum haemorrhage >500 ml | 29 (3.5) | 68 (8.1) | 0.4 | 0.3-0.7 | 0.0001 |
| Intact perineum | 514 (61.3) | 466 (55.5) | 1.1 | 1.02-1.2 | 0.0142 |
| 1st-2nd degree tear | 290 (34.6) | 337 (40.2) | 0.9 | 0.8-0.97 | 0.0154 |
| Readmission /outpatient visit 0-28 days postpartum | 24 (2.9) | 40(4.8) | 0.6 | 0.4-1.0 | 0.0599 |

*FMU midwives had extended authorisation to perform ventouse deliveries in case of acute fetal distress in the second stage of labour. This was used only once, in a case of acute bradycardia. Apgar score 2/1, 8/5, 10/10.

## Table 3: Secondary outcomes

| Outcome | FMU (n) | OU (n) | RR | 95%CI | P-value |
|---|---|---|---|---|---|
| **Perinatal** | | | | | |
| Child live born | 839 | 839 | | | |
| Perinatal and neonatal death | 1* | 0 | | | |
| **Maternal** | | | | | |
| Severe maternal morbidity | 0 | 1[±] | | | |
| Dystocia in labour | 88 (10.5) | 234 (27.9) | 0.4 | 0.3-0.5 | 0.0000 |
| Intrapartum fetal-pelvic complications[‡] | 3 (0.4) | 16 (1.9) | 0.2 | 0.05-0.6 | 0.0044 |
| Shoulder dystocia | 3 (0.4) | 12 (1.4) | 0.3 | 0.1-0.9 | 0.0352 |
| Meconium-stained amniotic fluid | 136 (16.2) | 148 (17.6) | 0.9 | 0.7-1.1 | 0.4004 |
| Occipital posterior presentation at birth[π] | 13 (1.6) | 28 (3.3) | 0.5 | 0.3-0.9 | 0.0201 |
| Postpartum haemorrhage > 1000 ml | 11 (1.3) | 14 (1.7) | 0.8 | 0.4-1.7 | 0.6900 |
| 3rd and 4th degree tears | 19 (2.3) | 24 (2.9) | 0.8 | 0.4-1.4 | 0.5224 |
| **Birth interventions** | | | | | |
| Oxytocin augmentation of labour | 69 (8.2) | 154 (18.6) | 0.5 | 0.3-0.6 | 0.0000 |
| Treatment for shoulder dystocia | 1 (0.1) | 10 (1.2) | 0.1 | 0.01-0.8 | 0.0117 |
| One or more uterotonics | 675 (80.5) | 672 (80.1) | 1.0 | 0.9-1.0 | 0.9070 |
| Perineal suturing | 294 (35.0) | 366 (43.6) | 0.8 | 0.7-0.9 | 0.0002 |
| Intrauterine palpation | 5 (0.6) | 16 (1.9) | 0.3 | 0.1-0.9 | 0.0266 |
| **Other** | | | | | |
| Non recumbent position for birth | 188 (22.4) | 158 (18.3) | 1.2 | 0.98-1.4 | 0.0964 |
| Discharge <6 hours postpartum | 106 (12.6) | 191 (22.8) | 0.6 | 0.5-0.7 | 0.0000 |
| Transfers intrapartum or <2 hours after birth | 124 (14.8) | | | | |
| *Of these primiparas* | *79 (36.7)* | | | | |
| *Of these multiparas* | *45 (7.2)* | | | | |

*The infant was born with severe diaphramic hernia, not detected by ultrasound screening at 19.4 weeks.
[±] Uterine rupture followed by peripartum hysterectomy in a multipara having epidural analgesia and oxytocin augmentation
[‡] Including diagnosis for: abnormal maternal pelvis, cephalopelvic disproportion and failed ventouse delivery
$\pi$ Deliveries by caesarean section excluded from this analysis

| Table 4: Causes of FMU to OU transfer | Number | % |
|---|---|---|
| **Before birth** | | |
| Failure to progress | 55 | (40.1) |
| Meconium-stained amniotic fluid | 14 | (10.2) |
| Fetal heart rate abnormality | 10 | (7.2) |
| Prolonged latent phase | 7 | (5.1) |
| Request for epidural analgesia | 6 | (4.3) |
| Abnormal fetal presentation (including caudal presentation) | 5 | (3.6) |
| **Between birth and 2 hours postpartum** | | |
| Perineal trauma (complicated/3$^{rd}$-4$^{th}$ degree tear) | 16 | (11.7) |
| Retained placenta/postpartum haemorrhage | 9 | (6.6) |
| Minor respiratory problem (infant) | 2 | (1.5) |
| **More than 2 hours postpartum** | | |
| Neonatal cause (light for date, minor respiratory problem, hypoglycaemia, jaundice) | 11 | (5.2) |
| Maternal cause (post partum bleeding, infection) | 2 | (1.5) |
| **Total number of transfers from FMU** | **137** | **(100)** |



**The following 3 tables is provided for supplementary information (electronic supplement)**

## Supplementary information:

### Table A: Characteristics of freestanding midwifery-led units

| | Hobro FMU | Frederikshavn FMU |
|---|---|---|
| **Geographical setting** | District/community hospital, southern town in region (11 000 inhabitants) | District/community hospital, northern town in region (24 000 inhabitants) |
| **Obstetrical assistance** | Not available<br>No epidurals or argumentation | Not available<br>No epidurals or argumentation |
| **Assistance for maternal and neonatal emergencies *** | 24-hour emergency assistance on site from anaesthesiologist (day) / resuscitation-capable specialist nurse (evening + night). | 24-hour emergency assistance on site from anaesthesiologist (day) / resuscitation-capable specialist nurse (evening + night). |
| **Midwifery staff and training** | Experienced local midwives whose employment predated unit's conversion into FMU, working in 24 hour shifts<br>Mannequin training in obstetrical emergencies, including ventouse delivery± | Experienced local midwives whose employment predated unit's conversion into FMU, working in 24 hour shifts.<br>Mannequin training in obstetrical emergencies, including ventouse delivery± |
| **Minimum transfer time** | 35 minutes | 25 minutes |
| **Women transferred to** | OU, Aalborg Hospital | OU, Vendsyssel Hospital |
| **Some women may choose transfer to:** | OU, Randers Hospital or OU, Viborg Hospital (out-of-region hospitals) | OU, Aalborg Hospital |
| **Number of birthing rooms** | 2 | 2 |
| **Birthing facilities** | Conventional birthing rooms with easy access to birthing pool and shower. Other facilities such as resting room, living room, corridor and kitchen were also used | Large birthing rooms with birthing pool, shower and both double bed and obstetric bed. Other facilities such as living room, corridor and kitchen were also used |
| **Care characteristics** | One-to-one care and continuous support in labour most often available<br>Mobility and use of different labour positions supported. Music used for relaxation | One-to-one care and continuous support in labour most often available<br>Mobility and use of different labour positions supported. Music used for relaxation |

| | | |
|---|---|---|
| **Cardiotocography (CTG)** | Admission CTG offered to all women<br>Transfer performed if CTG indicated | Admission CTG offered to all women<br>Transfer performed if CTG indicated |
| **Early labour assessment** | Home visits occasionally offered | Home visits occasionally offered (10-20%) |
| **Homebirth**‡ | Offered as part of service | Offered as part of service |
| **Postnatal care** | 3-4 days in family rooms, family friendly environment, always possible for partner to stay. No postnatal staff during night<br>Full 'baby-friendly' WHO/UNICEF accreditation | 3-4 days in 2-bed postnatal rooms, family friendly environment, always possible for partner to stay. No postnatal staff during night.<br>Full 'baby-friendly' WHO/UNICEF accreditation |
| **Antenatal care** | The region's 'standard package' of antenatal care offered by FMU midwives | The region's 'standard package' of antenatal care offered by FMU midwives |

** Only for emergencies such as maternal collapse, severe postpartum haemorrhage or need for neonatal resuscitation.*

*±Ventouse delivery is included in the ICM Essential Competencies for Midwifery Practice and midwives in many different settings and countries (including FMUs in e.g. the UK, Norway and Denmark) have acquired the necessary skills*

*‡ As selection criteria for home birth and FMU were identical, both home birth and FMU birth were offered to all low-risk women by FMU midwives. Decision about place of birth could be changed at any time, also during labour.*

## Supplementary information:

### Table B: Characteristics of obstetric units

| Characteristics | Aalborg OU | Vendsyssel OU |
|---|---|---|
| **Geographical setting** | Specialist, university hospital, located in main city of the region (120.000 inhabitants) | Provincial hospital, centrally placed in the North of the region (25.000 inhabitants) |
| **Facilities** | Neonatal intensive care unit<br>Neonatal surgical<br>Adult intensive care | Generalised paediatric unit with neonatal beds<br>Adult intensive care unit |
| **Consultant obstetrician** | 24-hour service on site | On site during daytime |
| **Consultant paediatrician** | 24-hour service on site | On site during daytime |
| **Consultant anaesthesiologist** | 24-hour service on site | On site during daytime ( resuscitation-capable specialist nurse on site during night) |
| **Midwifery staff** | Mixed level of experience<br>24-hour consultant midwife on site | Mixed level of experience<br>Consultant midwife on site during daytime |
| **Number of labour rooms** | 12 | 5 |
| **Birthing facilities** | Conventional birthing rooms. 1 room with birthing pool, access to two labour pools<br>Most women stay in birthing room during labour | Conventional birthing rooms, two rooms with birthing pool<br>Most women stay in birthing room during labour |
| **Care characteristics** | One-to-one care and continuous support in labour typically not available | One-to-one care and continuous support in labour typically not available |
| **CTG** | No admission CTG<br>Auscultation used in low-risk labour<br>(continuous CTG used in case of oxytocin augmentation and epidural analgesia) | No admission CTG<br>Auscultation used in low-risk labour<br>(continuous CTG used in case of oxytocin augmentation and epidural analgesia) |
| **Early labour assessment** | Home visits not offered | Home visits not offered |
| **Postnatal care**<br>(complicated birth) | Conventional postnatal ward (nurse staff)<br>2-4 postnatal beds per room | Conventional postnatal ward (nurse staff)<br>2-4 postnatal beds per room |

| | | |
|---|---|---|
| **Postnatal care**<br><br>(uncomplicated birth) | 3-4 days on midwifery-led ward<br>2-4 postnatal beds per room<br>Rarely possible for partner to stay<br>Postnatal staff on ward 24 hours a day | 3-4 days in same conventional postnatal ward<br>as women with complicated birth<br>Rarely possible for partner to stay<br>Postnatal staff on ward 24 hours a day |
| **Antenatal care** | The region's 'standard package' of antenatal care offered by OU midwives | The region's 'standard package' of antenatal care offered by OU midwives |



## Supplementary information

**Table C: Adverse outcomes:** maternal morbidity, perinatal death, 5 min Apgar score<7, >1 week NICU stay

| Cases | Apgar score | Birth characteristics | Place of birth | Days in NICU | Neonatal events |
|---|---|---|---|---|---|
| **Freestanding Midwifery-led Unit** | | | | | |
| Case 1 | **3/5** | **The only case of perinatal/neonatal mortality in the study**<br>Multipara<br>FMU in active labour, normal admission CTG, clear amniotic fluid, spontaneous vaginal birth. Respiratory failure 2-3 minutes after birth. Anaesthesiological assistance called, immediate **advanced resuscitation attempted but the infant did not response**.<br><br>The rare and severe condition of the infant was not detected by antenatal ultrasound screening at 19.4 weeks. Had the mother not chosen FMU care, this infant would most likely have been born in the nearest OU, here located in a provincial hospital with a generalised paediatric unit (consultant paediatrician, obstetrician and anaesthesiologist on call outside daytime). Transfer required to specialised unit (305 km away). | FMU | 0 | **Infant dead**<br><br>**Severe congenital malformation** (diaphragmatic hernia).<br><br>Occurrence 1:2500-1:5000, approx. 40% of infants have additional malformations. Total mortality (Danish population): 43%<br><br>Advanced resuscitation on site |
| Case 2 | **4/5** | Primipara<br>Primary rupture of membranes, FMU 20 hours later, 1 cm cervical dilatation, normal admission CTG. Transferred to OU 6 hours later (3 cm dilatation) due to slow progress of labour and request for epidural.<br>In OU: shared care (OU midwife and obstetrician). Epidural, augmentation of labour, pathological CTG pattern. Pyrexia, | OU | **36 *** | Ventilation<br>Admitted to NICU shortly after birth, treated for sepsis and asphyxia. Continuous positive airway pressure (CPAP) and antibiotics. **Severe congenital heart disease,** surgery at 6 |

| | | | | | |
|---|---|---|---|---|---|
| | | meconium-stained fluid, fetal blood sampling, episiotomy, instrumental delivery of infant 7 hours after transfer | | | months<br>Discharged well |
| Case 3 | **5/5** | Primipara<br>Primary rupture of membranes, presents at FMU 10 hours later, clear amniotic fluid, latent phase. Returns home after 6 hours, transferred to OU 24 hours after rupture of membranes.<br>In OU: shared care (OU midwife and obstetrician). Cervical dilatation 1 cm, augmentation of labour, no antibiotics, meconium-stained fluid. Spontaneous vaginal birth 6.5 hours after transfer. | OU | 5.7 | No ventilation, short intubation for trachea suction. Admitted to NICU shortly after birth due to asphyxia and meconium aspiration CPAP, antibiotics<br>Discharged well |
| Case 4 | **5/5** | Primipara<br>FMU during latent phase, 1 cm cervical dilatation. Normal admission CTG. After 9 hours, cervix dilated 3 cm, transferred to OU due to protracted latent phase<br>In OU: shared care (OU midwife and obstetrician). Amniotomy, augmentation of labour, epidural, CTG. Occipital posterior position, clear amniotic fluid. After 23 hours in OU, spontaneous vaginal birth | OU | 0 | No ventilation<br>Child not admitted to NICU<br>Discharged well |
| Case 5 | **6/5** | Multipara<br>FMU at 2 cm cervical dilatation. Normal admission CTG. Transferred to OU 8 hours later because of no progress<br>In OU: shared care (FMU midwife and obstetrician). Augmentation of labour, epidural. Pyrexia, antibiotics. Clear amniotic fluid. Caesarean section 5 hours after transfer because of pathological CTG | OU | 0.6 | Ventilation, no chest compressions.<br>Birth weight low for gestational age (2554 g). Child admitted to NICU for 14 hours, observation only<br>Discharged well |
| Case 6 | (7/5) | Multipara<br>FMU at 2 cm cervical dilatation, frequent painful contractions. **Admission CTG with pathological pattern**, **emergency transferred to OU** 1 hour after admittance. Tocolytic given for transfer, CTG pattern improves<br>In OU: shared care (FMU midwife and obstetrician). CTG, Caesarean section 4 hours after transfer due to fetal distress. Abruptio placentae | OU | **12.5 **** | Ventilation, no chest compressions.<br>Admitted to NICU shortly after birth. CPAP and antibiotics. 2 days later, acute apnoea: Intubation, ventilation and transfer<br>Discharged well |
| Case 7 | (7/5) | Primipara<br>FMU at 1 cm cervical dilatation. Normal admission CTG. Transferred to OU 10 hours later at 7 cm cervical dilatation because of slow progress of labour<br>In OU: shared care (OU midwife and obstetrician). Augmentation of labour, CTG, spontaneous vaginal birth 3 hours after transfer | OU | **11 ***** | No ventilation<br>Admitted to NICU shortly after birth for respiratory problems. CPAP<br>Discharged well |
| Case 8 | 10/5 | **Adverse event with potential adverse outcome**<br>Multipara: Umbilical cord prolapse in multipara after spontaneous rupture of membranes. Local gynaecologist is summoned against protocol and an emergency caesarean section performed.<br>Had guidelines been followed, the woman would have had a tocolytic, pelvic elevation, and the infant would have been pushed up vaginally while an emergency transfer was | FMU | **0** | The event happened less than two months after the maternity unit had been turned into a FMU.<br>The staff involved had previously worked closely together and chose not to follow the regional guidelines |

| | | | | | |
|---|---|---|---|---|---|
| | | carried out (minimum duration 20 min.). The women would have been taken directly to the operating theatre where an obstetrician would decide on the further action. | | | for emergency transfer from FMUs.<br>Apgar score 10/1, 10/5. Infant and mother discharged well |
| **Obstetric Unit** | | | | | |
| Case 9 | **4/5** | Multipara<br>OU at 10 cm cervical dilatation, fast labour. No CTG.<br>Meconium-stained amniotic fluid just before spontaneous vaginal birth | OU | 0.4 | Ventilation, chest compression.<br>Admitted to NICU for 9 hours, CPAP<br>Discharged well |
| Case 10 | **6/5** | **The only case of severe maternal morbidity in the study (also leading to neonatal morbidity).**<br>Multipara<br>OU at 5 cm cervical dilatation. Epidural, augmentation of labour, continuous CTG. Meconium-stained amniotic fluid, fetal distress leading to caesarean section.<br>**Uterine rupture** discovered. Postpartum haemorrhage>2500 ml. **Peripartum hysterectomy**. | OU | 5 | Oxygen mask, no ventilation<br><br>Admitted to NICU shortly after birth, hypertonia and respiratory problems. CPAP<br>Discharged well |
| Case 11 | **6/5** | Primipara<br>OU at 5 cm dilatation. No dilatation for two hours: Augmentation of labour, CTG, meconium-stained fluid. Spinal analgesia (saddle block), followed by short fetal bradycardia. Ventouse delivery 7.5 hours after admission | OU | 4.6 | No ventilation<br>Admitted to NICU shortly after birth for respiratory problems. CPAP, antibiotics<br>Discharged well |
| Case 12 | **6/5** | Multipara<br>OU at 5 cm cervical dilation.<br>Augmentation of labour, meconium-stained labour, continuous CTG, spontaneous vaginal birth | OU | 3.7 | No ventilation<br>Admitted to NICU, hypertonia and respiratory problems. CPAP, treatment for seizures.<br>Discharged well |
| Case 13 | **6/5** | Multipara<br>OU at 10 cm cervical dilation. No CTG, fast labour, clear amniotic fluid, spontaneous vaginal birth | OU | 1.5 | No ventilation<br>Admitted to NICU for respiratory problems CPAP.<br>Discharged well |

*Longest NICU stay in study **Second longest NICU stay ***Third longest NICU stay

**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 | 2 + 4 |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | 3 |
| **Introduction** | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 4 + 5 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 5 + (6) |
| **Methods** | | | |
| Study design | 4 | Present key elements of study design early in the paper | 6 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 6-8 + supplementary information in table A + B |
| Participants | 6 | (*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up | 8-9 |
| | | (*b*) For matched studies, give matching criteria and number of exposed and unexposed | 8-9 + table 1 |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 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 | *10* |
| Bias | 9 | Describe any efforts to address potential sources of bias | 14-15 |
| Study size | 10 | Explain how the study size was arrived at | 10-11 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 10 |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding | 11-12 |
| | | (*b*) Describe any methods used to examine subgroups and interactions | 12 |
| | | (*c*) Explain how missing data were addressed | |
| | | (*d*) If applicable, explain how loss to follow-up was addressed | No loss |
| | | (*e*) Describe any sensitivity analyses | |

| | | | |
|---|---|---|---|
| **Results** | | | |
| 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 | 12 |
| | | (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 | 12-13 + table 1 |
| | | (b) Indicate number of participants with missing data for each variable of interest | Table 2 +3 |
| | | (c) Summarise follow-up time (eg, average and total amount) | |
| Outcome data | 15* | Report numbers of outcome events or summary measures over time | |
| 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 | 13-14 + table 2+3 |
| | | (*b*) Report category boundaries when continuous variables were categorized | 14 |
| | | (*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 | 14-15 + table 4 + supplementary information, table C |
| **Discussion** | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 16 |
| **Limitations** | | | |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 16-19 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 19-20 |
| **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 | 23 |

*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.

BMJ open

# Freestanding midwifery unit versus obstetric unit: A matched cohort study of outcomes in low-risk women



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|---|---|
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| | |

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**Objective:**

To compare perinatal and maternal morbidity and birth interventions in low-risk women giving birth in two freestanding midwifery units (FMUs) and two obstetric units (OUs).

**Design:**

A cohort study with a matched control group

**Setting:**

The region of North Jutland, Denmark

**Participants:**

839 low-risk women intending FMU birth and a matched control group of 839 low-risk women intending OU birth were included at the start of care in labour. OU women were individually chosen to match selected obstetric/socio-economic characteristics of FMU women. Analysis by intention-to-treat.

**Main outcome measures:**

Perinatal and maternal morbidity and interventions

**Results:**

No significant differences in perinatal morbidity were observed between groups (Apgar scores <7/5, <9/5 or <7/1, admittance to neonatal unit, asphyxia, or readmission). Adverse outcomes were rare, and occurred in both groups.

FMU women were significantly less likely to experience abnormal fetal heart rate (RR: 0.3, 95% CI: 0.2 to 0.5), fetal-pelvic complications (0.2, 0.05 to 0.6), shoulder dystocia (0.3, 0.1 to 0.9), occipital-posterior presentation (0.5, 0.3 to 0.9), and postpartum haemorrhage >500ml (0.4, 0.3 to 0.6) compared to OU women.

Significant reductions were found for FMU group's use of caesarean section (0.6, 0.3 to 0.9), instrumental delivery (0.4, 0.3 to 0.6), and oxytocin augmentation (0.5, 0.3 to 0.6) and epidural analgesia (0.4, 0.3 to 0.6).

Transfer during or <2 hours after birth occurred in 14.8% of all FMU births but more frequently in primiparas than in multiparas (36.7% versus 7.2%).

**Conclusion**

Comparing FMU and OU groups, no increase was found in perinatal morbidity, but significantly reduced incidences of maternal morbidity, birth interventions including caesarean section, and increased likelihood of spontaneous vaginal birth. FMU care may be considered as an adequate alternative to OU care for low-risk women. Pregnant prospective mothers should be given informed choice of place of birth, including information on transfer.

**Article summary:**

Article focus:

- The safety of birth in free-standing midwifery units (FMUs) is strongly debated as acute complications may arise in a spite of careful risk assessment of women.

- Prior studies suggest that FMU care for low risk women is related to low perinatal and maternal morbidity, fewer interventions and a decreased use of medical pain relief compared to care from obstetric units (OUs) care but some are limited by e.g. the inclusion of high-risk women, low number of participants, and inadequate control of bias and confounding.

- The present study aim to compare perinatal and maternal morbidity, birth interventions, and pain relief in low-risk women giving birth in two freestanding midwifery-led units and two obstetric units (OUs) in Denmark.

Key messages:

- No difference in perinatal morbidity was found among infants of low-risk women who intended birth in an FMU compared to infants of low-risk women who intended birth in an OU. More studies on rare adverse outcomes are needed.

- FMU care had important benefits such as reduced maternal morbidity, reduced use of birth interventions including caesarean sections and increased likelihood of spontaneous vaginal birth compared to OU care. However 37% of primiparas and 7% of multiparas transferred during or <2 hours after birth.

- Care in FMUs may be considered as an adequate alternative to OU care for low-risk women, and women should be given an informed choice of place of birth, including information on transfer.

Strengths and limitations of this study

- The study compares processes and outcomes from women who have been rigorously and prospectively judged to be at low obstetric risk in two well-defined and carefully established settings in the same region.

- Data are complete as all eligible women planning to give birth in the FMU settings were included, and full follow-up on all participants was obtained.

- Although the study groups were matched and adjustment for the matching factors revealed no residual confounding, the risk of confounding by unknown factors related to women's choice of care in labour persists.

# Freestanding midwifery unit versus obstetric unit:

## A matched cohort study of outcomes in low-risk women

### Introduction

In most industrialised countries, obstetric units (OU) have become the primary setting for birth with the safety of other birth settings strongly debated[1-5]. The primary concern regarding birth outside an OU relates to the anticipation of adverse perinatal outcomes. But steadily increasing birth intervention rates and studies of women's perceptions of childbirth indicate that OUs may not always provide optimal conditions for low-risk childbirth or satisfy women's individual needs[6-14]. In many countries the introduction of midwifery units[1] has given women more choice of place of birth.

A Cochrane review concerning alongside midwifery units (AMU) found no significant differences in perinatal mortality or perinatal and maternal morbidity. It also documented significantly fewer medical interventions and increased maternal satisfaction[12]. However, this evidence cannot be generalised to freestanding midwifery units (FMU). Concern has been expressed that acute intrapartum and postpartum complications may arise in spite of careful assessment of low-risk women and that transfer delays may affect lifesaving medical interventions such as caesarean section or advanced neonatal resuscitation.

Two prospective, controlled cohort studies of FMUs[16;17] both report low perinatal and maternal morbidity, fewer interventions and decreased use of medical pain relief. The results are supported by a wide range of retrospective, uncontrolled and/or population-based studies[6;10;18-30]. But the

[1] A midwifery unit is a clinical location offering care to women with straightforward pregnancies during labour and birth in which midwives take primary professional responsibility for care. It may be in the site of a hospital with an obstetric unit, hence termed an "alongside" midwifery unit (AMU) or be a physically separated, freestanding unit (FMU) where obstetric, neonatal and anaesthetic care requires ambulance transfer[15].

evidence is conflicting as two of these studies found significantly lower 1-minute Apgar scores[28] and increased need for neonatal ventilation[10] in FMUs. Because of greatly varying criteria for low-risk categorisation, care standards, midwives' training, cooperation between FMUs and OUs, etc., considerable caution must be observed when generalising findings to other settings and countries. Furthermore, the level of evidence was weak[31]. The applicability/validity of many studies is limited by factors such as small sample size, inclusion of high-risk women, limited control of bias and confounding, and inadequate descriptions of inclusion and exclusion criteria, medical assistance (if any), and transfer criteria.

There is a need for further research, but the rarity of adverse outcomes in a low-risk population, the limited number of FMU births, and women's strong preference for choice of birthplace[32;33] converge to form serious barriers for the investigation of perinatal mortality in large, adequately powered, randomised controlled trials (RCTs). This increases the need for evidence from carefully planned cohort studies.

**Objectives**

The present study compared labouring processes, perinatal and maternal morbidity and birth interventions in low-risk women intending to give birth in two FMUs and two OUs in Denmark. The study is reported in accordance with STROBE requirements[34;35].

**Study hypotheses**

On basis on of previous research, we hypothesised that FMU care, with its emphasis on the physiological birth process and psycho-social well-being during childbirth, would entail a number of positive effects for the women, such as a higher rate of spontaneous vaginal birth, intact

perineum, and use of non-pharmacological pain relief. FMU women were hypothesised to experience fewer interventions (including caesarean section) and require less use of pharmacological pain relief compared to OU women. No differences in perinatal or maternal morbidity were predicted.

## Methods

### Design

A matched cohort study

### Setting

The study was conducted in North Jutland, a relatively sparsely populated region of Denmark where the local health authorities in 2001 had decided to transform two of the region's four maternity units into FMUs, opening in 2001 and 2004. The FMUs offered midwifery-led care during pregnancy and intrapartum and postnatal periods to low-risk women.

### Data collection

In a 3.5-year period between 2004 and 2008, data on socio-demographic factors, previous pregnancies and births, current pregnancy and birth, infants, FMU transfers, and maternal/neonatal readmissions 0-28 days postpartum were collected from patient records and the North Jutland Patient Administration System. The data collection was carried out by project staff with comprehensive professional knowledge of the field on basis of written instructions.

### Data security and ethics

The project was approved by the Danish Data Protection Agency (reference number: 2005-41-5352) and the regional health authorities of North Jutland. Data were handled in strict confidentiality and in accordance with Danish law requiring neither approval from an ethics committee nor informed consent from patients for observational studies involving no risk or inconvenience to patients[36].

**Characteristics of the freestanding midwifery units**

In Denmark care for low-risk women is midwifery-led in all birth settings. Both FMUs were located in community hospitals with an intensive care unit but without an obstetric service. The annual number of births in the FMUs were approximately 170 (Hobro) and 130 (Frederikshavn). Women transferred to OUs by ambulance using multidisciplinary regional criteria and continued care with an FMU or OU midwife under the supervision of an obstetrician. FMU midwives had at least two years experience and training in obstetric emergencies, including ventouse delivery. FMU midwives provided antenatal care and out-of-hours post-partum care for all women in the area booked for both OU and FMU birth. FMU midwives also assisted at the nearest OU, if FMU not busy, and had 40-70 births a year. Additional contextual information is available in Table A.

**Web only information: Table A: Characteristics of FMUs**

**Characteristics of the obstetric maternity units**

Aalborg University Hospital is a one of five highly specialised Danish hospitals with a specialist OU who saw approximately 3500 births a year. Vendsyssel Hospital is a provincial hospital with 10 clinical specialities, including an OU providing care for low-risk and most high-risk pregnancies and a generalised paediatric ward. The annual number of births was approximately 1400. Mothers

and infants with severe illness were transferred to Aalborg University Hospital or one of the other four, highly specialised hospitals in Denmark, depending on the condition.

**Web only information: Table B: Characteristics of OUs**

**Participants**

The study population was composed of an intervention group of 839 low-risk women from two freestanding midwifery units in Hobro and Frederikshavn, and a control group of 839 low-risk women, matched for key factors, who received routine care from the specialist obstetric unit at Aalborg University Hospital and the obstetric unit at Vendsyssel Hospital, Hjørring.

**Inclusion criteria**

All labouring women admitted to the FMUs by their midwives on the basis of multi-disciplinary, regional admission criteria were included in the study. As informed consent of participation was not required due to Danish legislation, all eligible women were included.

Women in the control group were eligible for inclusion only if they represented an individual match to the obstetric and social characteristics of a woman in the FMU group.

Women in both study groups were thus rigorously judged to be at low-risk and fulfil criteria for FMU birth, and included at the start of care in labour.

**Exclusion criteria**

Excluded from the study were three women admitted to an FMU for emergency treatment without satisfying the criteria for FMU care; an event occurring very rarely.

**The matching process**

Confounding is a main concern in cohort studies. The matched design was chosen because it potentially increases the statistical precision in a cohort study and effectively eliminates the association between the exposure (place of birth) and the matching variables, given a perfect balance of data is obtained on matched variables between groups[34;37;38]. Matching is especially relevant in situations with non-linearity and inter-correlation between variables or where a substantial difference in the distribution of confounders between groups is expected[39]. This was the case in present study whose participants were recruited from areas characterised by varying degrees of urbanisation and heterogeneity in socio-demographic characteristics[40;41].

Women in the control group were selected from the region's patient administration system which carries detailed information on the region's pregnant women. For each participant included in the FMU group, a control participant from the nearest OU was identified among the admitted low-risk women. The selection of matched control participants was conducted in accordance to strict guidelines by project staff that were blinded to the identity and the birth outcomes of women in the FMU group. The matching result was blinded until the selected control participants had given birth.

Matching was done prospectively on criteria with an established influence on birth outcomes[42-45]: low risk status, parity, smoking, BMI, age, ethnicity, education, occupation, and cohabitation status. A 100% match was carried out on: low-risk status, parity and smoking status. Body Mass Index (BMI) and age were matched with a range of +/-5; meaning that BMI/age scores of 22 were

matchable with scores between 17 and 27. Socio-demographic characteristics such as ethnicity, education level, occupation, and cohabitation status were matched within groups as shown in Table 1.

**Definition of low risk**

Women were judged to be at low risk if they were healthy, presented in spontaneous labour between 37+0 and 41+6 days of gestation, had an uncomplicated pregnancy and no medical/obstetric history or conditions increasing obstetric risk as outlined in the UK NICE intrapartum care guidelines[46]. However, we considered healthy multiparous women as low-risk regardless of their age and BMI if their previous pregnancies and deliveries had been uncomplicated.

**Variables and data measurement**

The primary outcomes were: Apgar score <7/5 minutes, and caesarean section.

Secondary outcomes were the following: Infant: Apgar score <9/5 minutes, <7/1 minutes; neonatal asphyxia; admittance to neonatal intensive care unit (NICU); admittance to NICU >48 hours; neonatal readmission 0-28 days postpartum. Maternal: spontaneous vaginal birth; intact perineum; epidural analgesia; use of water tub for pain relief; abnormal fetal heart rate leading to action; dystocia; shoulder dystocia; instrumental vaginal delivery; postpartum haemorrhage >500 ml; 1$^{st}$-2$^{nd}$ degree tear; 3$^{rd}$/4$^{th}$ degree tear; maternal re-admission 0-28 days postpartum. These outcomes were, along with a range of additional outcomes, defined prior to the initiation of the study, and reported as well as all cases of perinatal mortality and severe perinatal and maternal morbidity. Unfortunately, data on umbilical blood gas was not obtainable.

Intended birthplace at the start of care in labour was considered the exposure. The study did not aim to examine differences in maternal or perinatal mortality since their low occurrence in the Danish low risk population (0.065‰ and 3‰, respectively) would require an extremely large and therefore unrealistic number of participants.

The data were recorded in accordance with the National Birth Register and the North Jutland Birth Register, standards and guidelines applying to all four units and with which all midwives and doctors in the region were familiar. A stop watch was used when measuring Apgar scores. Postpartum haemorrhage was routinely estimated rather than measured.

**Power calculation, sample size and changes in study protocol**

Clinically important differences were defined and power calculations performed for all the above-mentioned clinical endpoints. The frequencies used in the calculations originate in the North Jutland Birth Register and the international literature. Estimations of sample sizes were based on power calculation for the primary outcomes: Apgar score <7/5 minute and caesarean section. The limited number of FMU births, at 300-350 per year, was also taken into account. The study was originally planned to include data on 1027 FMU participants and 1027 control participants over a period of 3.5 years, starting 1st January 2005, however, in October 2006 the local authorities unexpectedly announced the closure of its two FMUs. The National Board of Health expressed concern that the local authorities had introduced a new model of care that had not been subjected to adequate evaluation. The power to detect differences between our two study groups was consequently reduced and a thorough revision of the study protocol was required. At the time of the FMU closures in date, 550 FMU participants had been included, and in order to obtain the largest possible sample of FMU participants, we included all of the 289 eligible women who had been admitted to

the FMUs since the opening of the second FMU (1 March 2004). These women were prospectively matched with women from the nearest OU, thus ensuring total samples of 839 women in each group.

After the FMU closures, power calculations were re-run. The results showed that with a sample of 839 women in each group, the study sustained the power to detect clinically relevant differences between groups on all primary and secondary outcomes. For the two primary outcomes, the revised sample provided power (5% significance level, 80% power) to detect an increase in Apgar score <7/5 minutes from expected 1.07% in the OU group to 3.1% in the FMU group and a reduction in the incidence rate of caesarean section from 8.8% in the OU group to 5.5% in the FMU group.

**Statistical analysis of data**

Analyses were based on the intention-to-treat principle and carried out by use of STATA software, version 11.

The two groups (matched 1:1) were compared by paired tests on all measures, McNemar's test for paired binary data (medical data on the birth process) and Wilcoxon's signed-rank test for paired continuous data (e.g. birth weight). As we were concerned that residual confounding might remain, supplementary regression analysis adjusting for the matching characteristics was performed by use of both continuous and grouped variables[47;48]. For ease of interpretation (e.g. calculation of confidence bands), ordinal outcomes were dichotomized, but we controlled for conclusive agreement with test results based on the original data.

The analysis for occipital posterior position was performed after excluding caesarean deliveries. For all comparisons, relative risks with 95% confidence intervals were calculated. All reported P-values were two-sided, and the level of statistical significance 5%. To check for bias introduced by the

inclusion of FMU women giving birth in 2004, supplementary sub-group analyses were performed on 2004-data and main data, respectively.

**Participants**

A low-risk match was prospectively identified for all 839 women admitted to an FMU and full follow-up was obtained for all 1678 women. Of the 839 FMU women, 733 (87.4%) gave birth as planned in the FMU or at home, assisted by a FMU midwife (cf. Figure 1). Transit births were included in the few cases where the woman had consulted a midwife <24 hours before giving birth and had been advised to stay at home longer/return to her home.

Ninety-seven FMU women (11.6%) were transferred intrapartum, among these two gave birth in the ambulance. Eleven, who were in early labour, were transported in their own vehicle. Twenty-seven transfers (3.2%) took place <2 hours after birth, another thirteen (1.5%) during the postnatal stay. The total number of transfers was 137 (16.4%).

**Figure 1: Flow chart**

As shown in Table 1, the matching produced two fully comparable groups in terms of key medical and socio-demographic factors. The FMU women's background details reflected the life conditions of the local population in general[40;49]. With Aalborg and Hjørring municipalities as exceptions, the educational and income levels in North Jutland rank as the lowest in Denmark. In the FMUs' predominantly rural catchment areas, unemployment rates are high, which is reflected in a slightly higher rate of FMU women without employment outside the home.

**Main results**

**Primary outcomes**

No statistically significant differences between the two study groups in the rate of infants with an Apgar score <7/5 was found (relative risk (RR):1; 95% confidence interval (CI):0.3-3.4). The use of caesarean section (0.6, 0.3 to 0.9) was significantly reduced among FMU women compared to OU women (See Table 2).

**Table 2 on outcomes**

**Secondary perinatal outcomes**

No significant differences were found in perinatal outcome such as Apgar score <7/1 at 1 minute and < 9 at 5 minutes; neonatal asphyxia; neonatal admittance to NICU; neonatal stay in NICU >48 hours or neonatal readmission to hospital 0-28 days postpartum (See Table 2).

One infant was delivered by caesarean section due to umbilical cord prolapse in the hospital where an FMU was co-located. As a result, sensitivity analysis was conducted on the hypothesis that had the women been transferred, the infant would have had an Apgar score <7/5 minutes. Analysis showed no difference between groups (1.25;0.3 to 4.6) and did not affect overall findings. Full case details are given in Table C on adverse outcomes.

**Secondary maternal outcomes**

As shown in Table 2, compared to OU women, FMU women were significantly less likely to experience: abnormal fetal heart rate leading to action (0.3, 0.2 to 0.5); dystocia in labour (0.4, 0.3 to 0.5); intrapartum fetal-pelvic complications (0.2, 0.05 to 0.6); shoulder dystocia (0.3, 0.1 to 0.9);

occipital posterior presentation at birth (0.5, 0.3 to 0.9); postpartum haemorrhage >500ml (0.4, 0.3 to 0.7) and 1st/2nd degree tear (0.9, 0.8 to 0.97).

Moreover compared to OU women, FMU women were significantly more likely to experience: intact perineum (1.1, 1.02 to 1.2) and discharge <6 hours postpartum (0.6, 0.5-0.7).

No significant differences were found in meconium-stained amniotic fluid; postpartum haemorrhage > 1000 ml; 3rd and 4th degree tear; maternal re-admission/outpatient visit 0-28 days postpartum and severe maternal morbidity.

Neither was infant birth weight (mean: 3.636 kg (FMU) and 3.641 kg (OU), cervical dilatation on admission (mean: 4.4 cm (FMU) and 4.3 cm (OU)), or duration of admission for labour care (mean: 5.3 hours (FMU) and 5.6 hours (OU)) different between the two study groups.

**Birth interventions**

As shown in Table 3, compared to OU women, FMU women were significantly less likely to experience: instrumental delivery (0.4, 0.3 to 0.6); oxytocin augmentation in labour (0.5, 0.3 to 0.6), treatment for shoulder dystocia (0.1, 0.01 to 0.8), perineal suturing (0.8, 0.7 to 0.9), intrauterine palpation (0.3, 0.1 to 0.9) and epidural analgesia (0.4, 0.3 to 0.6).

Moreover, compared to OU women, FMU women were significantly more likely to experience spontaneous vaginal birth (1.06, 1.03 to 1.09), and use of water tub for pain relief (1.4, 1.2 to 1.6).

No significant differences between groups were found for one or more uterotonics, and non-recumbent position for birth.

**Table 3 on interventions and pain relief**

**Other analyses**

A regression analysis adjusting for the matching characteristics showed coinciding results with the match analysis, thus confirming the robustness of our results and matching. A sub-group analysis comparing the late collected data on 2004-FMU participants with the main, prospectively collected data detected no systematic differences or deviation of results between the two bodies of data.

**Transfer**

All reasons for transfer are tabulated in Table 4. Overall intrapartum transfer rates (up to 2 hours post partum) were 14.8% but different for primiparous and multiparous women (36.7 versus 7.2%) The most common reason for transfer for all women was slow progress of labour. Ambulance transfers from the two FMUs averaged 42/38 minutes (range: 20 to 60).

After transfer, women had shared care between an obstetrician and a midwife, and thirty-six percent of transferred women continued to be cared for by the FMU midwife under supervision of an obstetrician.

**Table 4: Causes of FMU-OU transfers**

Adverse outcomes were defined as severe maternal morbidity, perinatal mortality, Apgar score <7/5 minutes, and >1 week NICU admittance. One incident of severe maternal morbidity (uterine

rupture) occurred among the OU women. In the FMU group, one perinatal/neonatal death occurred due to an undetected, severe congenital malformation. Nine infants were born with 5 minute Apgar scores of 4-6; three belonged to the FMU group but were born in an OU following intrapartum transferral. Eight of the nine infants were admitted to NICU; all were later discharged well.

Three infants from the FMU group, who were born in an OU after transfer, had NICU stays exceeding one week. One infant with a 5/5 Apgar score had a stay of 36 days, but this was due primarily to an undetected congenital heart disease.

One adverse perinatal event was dealt with in a FMU shortly after its opening. Due to an umbilical cord prolapse, emergency caesarean section was carried out by a gynaecologist, employed at the unit before its transformation into a FMU and summoned against protocol. Apgar scores were 10/1, 10/5. Supplementary information on all adverse events is provided in Table C

## Discussion

### Key results

This study was powered to compare two primary maternal and infant outcomes for women at low risk who intended to give birth in FMU or OU settings. We found no significant differences in Apgar score <7/5 minutes, and women in the FMU group were less likely to experience caesarean section.

Looking at secondary outcomes, there were no significant differences between Apgar scores <9/5, <7/1 minutes; total number of NICU admittances; NICU admittance >48 hours; neonatal asphyxia; or neonatal readmission to hospital. Among this population of low-risk women, women in the FMU

group compared to the OU group were significantly less likely to experience dystocia, intrapartum fetal-pelvic complications, occipital-posterior position of the infant at birth, shoulder dystocia, oxytocin augmentation, instrumental delivery, and post-partum haemorrhage >500 ml . Moreover, women in the FMU group were significantly more likely to experience spontaneous vaginal birth and intact perineum.

**Limitations**

The limitations of our study stem partly from its observational design, partly from the sudden closure of the two FMUs. A non-randomised study design precludes elimination of all potential confounding factors; only known confounders can be adjusted for, and only as far as they can be accurately measured. Despite of our close matching of study groups and adjustment for matching factors, residual confounding and confounding by unknown factors related to women's choice of care in labour may persist. Neither can any bias linked to the delayed data collection for 289 FMU participants from 2004 be ruled out, but we were somewhat reassured to find that the 2004 data were in conformity with the later data. Our contention that such a risk is limited is also supported by the fact that no interventions were performed in the study, participants were included on the same principles, individual and project-specific data collections were performed for all participants, patient records were of good quality, and all control participants were prospectively included. The obstetric quality indicators, which were compiled annually by the units, were closely followed to detect any changes in practices or technology use; no systematic changes occurred during the study period. No new technology was introduced, nor were any major change in obstetrical practices implemented.

Furthermore, some outcomes (Apgar scores, postpartum haemorrhage) were exposed to measurement subjectivity, others were proxies for morbidity, although globally used quality indicators/research outcomes, and the number of events in some analyses was low. It is also uncertain whether the outcomes would have been different for the two FMU infants had 1) a caesarean section not been performed and 2) the infant with severe congenital malformation been born in the alternative setting. Ideally, the results should be confirmed (or refuted) in a large RCT, but as the recruitment of an adequately large number of women willing to be randomised to place of birth would be logistically challenging, the most robust design seems to be a large prospective cohort study.

**Strengths**

We present findings from the second-largest prospectively controlled study of FMU care so far. A major strength of our study is that it compares processes and outcomes from women who have been prospectively judged to be at low obstetric risk in two well-defined and carefully established settings in the same region and that care for women in both groups is provided by midwives. Also, in contrary to some earlier studies[10;16;29], the data are complete as all eligible women planning to give birth in the FMU settings were included, and full follow-up on all participants was obtained.

**Interpretation**

We found no difference in perinatal morbidity between groups and our results agree with the results of most studies of FMU versus OU care[6;11;18-30.] Although women were transferred to the OU without delay (3-23 hours before giving birth), it is a concern that the three NICU stays exceeding one week occurred in the FMU group. Further study of rare adverse outcomes and optimisation of care for transferred women are needed.

The study findings also agree with other studies of FMU care[6;10;18;24;26;28;29] that have all reported a reduced incidence of birth interventions while the caesarean section rate is seldom found to be affected, something which may stem from inadequacies in the power or robustness of their design. In this respect, our study forms an important exception in finding a significant reduction in caesarean section in women in the FMU group. In addition, the present study is the first to report that FMU women were significantly less likely to experience fetal-pelvic complications, occipital-posterior position of the infant at birth and shoulder dystocia compared to OU women.

FMU care is a complex intervention and although the study does not enable us to be specific about the individual mechanisms or elements of FMU care leading to decreases in the incidence of birth complications and birth interventions, including caesarean section, we would indicate as influencing factors the greater availability of continuous support during labour, the encouragement of women to ambulate and use different position during labour, and the spacious and calm FMU facilities. Continuous support during labour has been proved to reduce birth interventions and the need for pharmaceutical pain relief[50]. Mobilisation and the practice of hand-knee position have furthermore been shown to support fetal rotation into an occipital anterior position and to reduce the duration of labour[51;52]. In contrast, the use of epidural analgesia and oxytocin augmentation in OU care both require CTG monitoring and are likely to restrict mobility[53] and thus use of different labour positions. Furthermore, oxytocin augmentation can cause uterine hyper-stimulation leading to fetal heart rate abnormality and oxygen desaturation[54].

The overall rate of transfers intrapartum and <2hours after birth at 14.8 % is comparable[18] or slightly lower than found in some studies of FMU care [21;22;24;26] (18-24%), though one study [6]

reported a slightly lower rate of 12%. Few studies report transfer rates for primiparas and multiparas separately, but a large American study also finds a transfer rate of 7% for multiparas but a lower rate of 29% for primiparas[24]. In all studies, slow progress of labour was one of the most common reasons for transfer, depending on the strictness of transfer guidelines. These findings provide information upon which women, professionals and policy makers can make decisions. However, these will vary depending upon individual preferences and trade-offs.

We suggest that the assessment of the risk of rare adverse outcomes in low-risk FMU births be balanced against our findings that infant morbidity was not affected and women intending to give birth in a FMU are less likely to suffer complications or undergo caesarean section and other birth interventions when compared to women intending to give birth in an OU.

**Generalisability**

Data was collected between 2004 and 2006, but there has been no change in the background characteristics of participants at that time compared to latest national data in Denmark[41;56].

Any generalisation of our findings must consider the full public funding of all maternity services in Denmark. The FMU midwives were skilled in dealing with obstetric emergencies, cooperation between FMUs and OUs was excellent, and the local implementation of multi-disciplinary guidelines for referral and transfer were based on the best evidence available, thus improving the reliability of care provided. Furthermore, the FMUs were located in community hospitals that offered life-supporting assistance in emergencies. Generalising to other countries offering different conditions should be made with caution.

Compared to most other countries, Denmark is culturally less diverse and characterised by less social inequality, with high standards of health and one of the lowest perinatal mortality rates in the world (6.6 per 1000 in 2004)[55]. However, the FMU women in this study had higher-than-average BMIs and lower educational and occupational status than Danish women in general[49;56], characteristics that reflect the life conditions and health status of women in the FMUs' peripheral catchment area. We take this as an indication that positive outcomes for women choosing FMU care are not necessarily restricted to women privileged by high socio-economic status or excellent health, an assumption that is in line with the findings of the so far largest study of FMU care[16].

The distances between the four units studied were 35-55 kilometres; FMU and OU care was thus not equally accessible to all women. Taking into account the characteristics of women in the study and the finding of convenience/proximity as the most important factor in North Jutland women's choice of birthplace[57], we hypothesise that philosophies/ideas about childbirth play a minor role in our study in comparison to studies involving women whose choices are not affected by geography.

Further work should examine the potential influence of birth expectations and perceptions on women's choice between FMU and OU care to determine any impact of world-views or philosophies on birth outcomes. Additional aims would be to elucidate the underlying elements of FMU care and their influence on outcomes and to explore the potential differences between AMU care and FMU care. Operational efficiency, cost-effectiveness and rare outcomes also present areas for further work, the latter through a rigorous review of controlled studies of FMU.

**Conclusion**

In conclusion, the present study found no increase in perinatal morbidity among infants of low-risk women intending to give birth in an FMU compared to infants of women intending to give birth in an OU. Among the FMU women it found reduced maternal morbidity, fewer caesarean sections and other birth interventions, along with an increased likelihood of spontaneous vaginal birth. Further study of rare adverse outcomes is needed.

Care in FMUs may be considered an adequate alternative to OU care for low-risk women within a network of supporting OUs. Pregnant women should thus be given an informed basis for their choice of birthing place, with information on key maternal and infant outcomes and transfer rates for multiparous and primiparous women. FMU care seems to offer important lessons that should also be brought to bear on the development of OU care for low-risk women.

**Contributors**

Charlotte Overgaard is responsible for the study's conceptual design, designed the data collection tools, monitored all data collection, cleaned the data and participated in the analysis and interpretation of data. She also drafted the article and wrote the final version. She is guarantor. Anna Margrethe Møller participated in the conceptual design of the study and the interpretation of data. Morten Fenger-Grøn participated in the analysis of data. Lisbeth B Knudsen and Jane Sandall participated in the interpretation of data. All of the authors critically revised the manuscript for important intellectual content, read and approved the final version that was submitted for publication.

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**Competing interests**

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf**Error! Hyperlink reference not valid.** (available on request from the corresponding author) and declare: CO had research grants (paid to her institution) from: the Augustinus Foundation, the Obel Family Foundation, the Oticon Foundation, the University College North Jutland Research and Development Fund, and the Research Foundation of the Danish Association of Midwives for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years; no other relationships or activities that could appear to have influenced the submitted work.

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**Figure 1: Study flow chart**

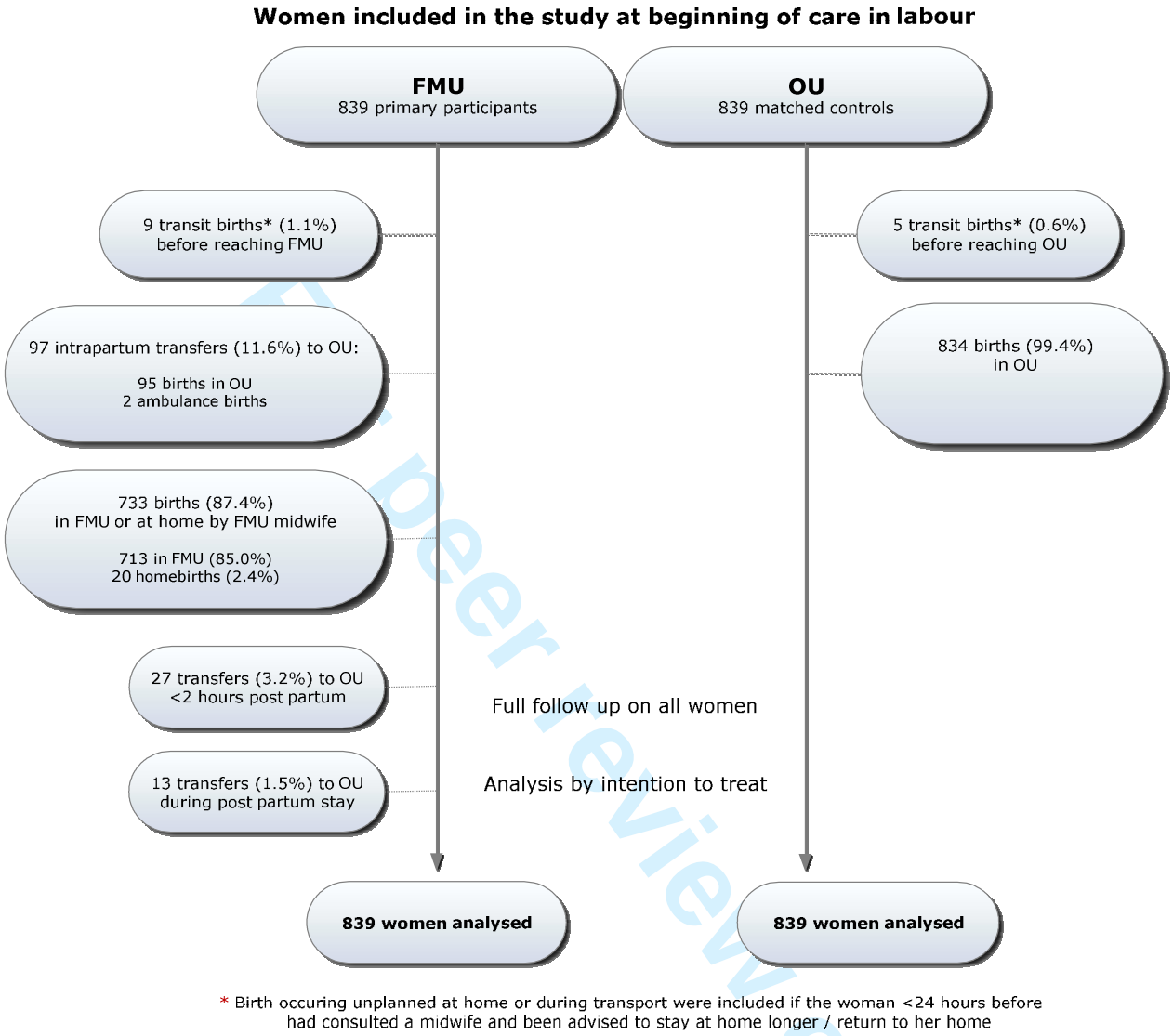



**Table 1: Matching characteristics**

| Characteristics | FMU | (%) | OU | (%) |
|---|---|---|---|---|
| **Complete match retained in all cases** | | | | |
| **Obstetric risk status** | | | | |
| Low risk | 839 | (100) | 839 | (100) |
| **Parity** | | | | |
| Primiparous | 215 | (25.6) | 215 | (25.6) |
| Multiparous | 624 | (74.4) | 624 | (74.4) |
| **Smoking status** | | | | |
| Non-smoker | 684 | (81.5) | 684 | (81.5) |
| 1-9 cigarettes | 59 | (7.0) | 59 | (7.0) |
| 10 or more cigarettes | 96 | (11.5) | 96 | (11.5) |
| **Individuals matched within ranges/groups** | | | | |
| **BMI** | | | | |
| <18 | 17 | (2.1) | 22 | (2.6) |
| 18-24.9 | 528 | (62.9) | 530 | (63.2) |
| 25-29.9 | 226 | (26.9) | 219 | (26.1) |
| >30 | 68 | (8.1) | 68 | (8.1) |
| **Age** | | | | |
| 16-20 | 24 | (2.9) | 25 | (3.0) |
| 21-35 | 731 | (87.1) | 716 | (85.3) |
| >35 | 84 | (10.0) | 98 | (11.7) |
| **Ethnicity** | | | | |
| Nordic or Western European | 805 | (96.0) | 809 | (96.4) |
| Eastern European or Asian | 27 | (3.2) | 22 | (2.6) |
| Arab or African | 7 | (0.8) | 8 | (1.0) |
| **Education level*** | | | | |
| No training/education qualifying for the labour market | 216 | (25.7) | 217 | (25.9) |
| Skilled training | 255 | (30.4) | 255 | (30.4) |
| 1-2 ½ years of post-secondary education | 84 | (10.0) | 81 | (9.6) |
| 3-4 years of post-secondary education | 254 | (30.3) | 256 | (30.5) |

| | | | | |
|---|---|---|---|---|
| 5-6 years of post-secondary education | 30 | (3.6) | 30 | (3.6) |
| **Occupation** | | | | |
| No paid work | 160 | (19.1) | 131 | (15.6) |
| Unskilled work | 107 | (12.7) | 119 | (14.2) |
| Skilled work[±] | 542 | (64.6) | 557 | (66.4) |
| Academic work/manager or senior official: | 30 | (3.6) | 32 | (3.8) |
| **Cohabitation status** | | | | |
| Living with partner | 815 | (97.1) | 819 | (97.6) |
| Not living with partner | 24 | (2.9) | 20 | (2.4) |

* Students and trainees were classified along with the educational level for which they were being trained
[±] All non-academic/non-managerial vocations requiring 1-4 years of post-secondary education/training[61]



| **Table 2: Outcomes** | **FMU (%)** | **OU (%)** | **RR** | **95%CI** | **P-value** |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| **Primary outcomes:** | | | | | |
| Apgar score <7 after 5 min | 5 (0.6) | 5 (0.6) | 1 | 0.3-3.4 | 1.0000 |
| Caesarean section | 19 (2.3) | 34 (4.0) | 0.6 | 0.3-0.9 | 0.0400 |
| **Secondary perinatal outcomes** | | | | | |
| Apgar score <9 after 5 min | 15 (1.8) | 20 (2.4) | 0.8 | 0.4-1.5 | 0.4996 |
| Apgar score <7 after 1 min | 22 (2.6) | 25 (3.0) | 0.9 | 0.5-1.6 | 0.7709 |
| Neonatal asphyxia | 27 (3.2) | 41 (4.9) | 0.7 | 0.4-1.1 | 0.1143 |
| Neonatal admittance to NICU | 28 (3.3) | 42 (5.0) | 0.7 | 0.4-1.1 | 0.1143 |
| Neonatal stay in NICU >48 hours | 14 (1.7) | 15 (1.8) | 0.9 | 0.5-1.9 | 1.0000 |
| Neonatal re-admission hospital 0-28 days postpartum | 26 (3.1) | 35 (4.2) | 0.7 | 0.4-1.1 | 0.1480 |
| Child live born | 839 (100) | 839 (100) | | | |
| Perinatal/neonatal death | 1* | 0 | | | |
| **Secondary maternal outcomes** | | | | | |
| Abnormal fetal heart rate leading to action | 34 (4.1) | 98 (11.7) | 0.3 | 0.2-0.5 | 0.0000 |
| Dystocia in labour | 88 (10.5) | 234 (27.9) | 0.4 | 0.3-0.5 | 0.0000 |
| Intrapartum fetal-pelvic complications[‡] | 3 (0.4) | 16 (1.9) | 0.2 | 0.05-0.6 | 0.0044 |
| Shoulder dystocia | 3 (0.4) | 12 (1.4) | 0.3 | 0.1-0.9 | 0.0352 |
| Meconium-stained amniotic fluid | 136 (16.2) | 148 (17.6) | 0.9 | 0.7-1.1 | 0.4004 |
| Occipital posterior presentation at birth[π] | 13 (1.6) | 28 (3.3) | 0.5 | 0.3-0.9 | 0.0201 |
| Postpartum haemorrhage >500 ml | 29 (3.5) | 68 (8.1) | 0.4 | 0.3-0.7 | 0.0001 |
| Postpartum haemorrhage > 1000 ml | 11 (1.3) | 14 (1.7) | 0.8 | 0.4-1.7 | 0.6900 |
| Intact perineum | 514 (61.3) | 466 (55.5) | 1.1 | 1.02-1.2 | 0.0142 |
| $1^{st}/2^{nd}$ degree tear | 290 (34.6) | 337 (40.2) | 0.9 | 0.8-0.97 | 0.0154 |
| $3^{rd}/4^{th}$ degree tears | 19 (2.3) | 24 (2.9) | 0.8 | 0.4-1.4 | 0.5224 |
| Readmission /outpatient visit 0-28 days postpartum | 24 (2.9) | 40(4.8) | 0.6 | 0.4-1.0 | 0.0599 |
| Discharge <6 hours postpartum | 106 (12.6) | 191 (22.8) | 0.6 | 0.5-0.7 | 0.0000 |
| Severe maternal morbidity | 0 | 1[±] | | | |

*The infant was born with severe diaphramic hernia, not detected by ultrasound screening at 19.4 weeks.
[‡] Including diagnosis for: abnormal maternal pelvis, cephalopelvic disproportion and failed ventouse delivery
$\pi$ Deliveries by caesarean section excluded from this analysis
[±] Uterine rupture followed by peripartum hysterectomy in a multipara having epidural analgesia and oxytocin augmentation

**Table 3: Birth interventions and pain relief**

| Outcome | FMU (n) | OU (n) | RR | 95%CI | P-value |
|---|---|---|---|---|---|
| **Birth interventions and pain relief** | | | | | |
| Spontaneous vaginal birth | 796 (94.9) | 751 (89.5) | 1.06 | 1.03-1.09 | 0.0000 |
| Instrumental delivery* | 25 (3.0) | 61 (7.8)) | 0.4 | 0.3-0.6 | 0.0000 |
| Oxytocin augmentation of labour | 69 (8.2) | 154 (18.6) | 0.5 | 0.3-0.6 | 0.0000 |
| Treatment for shoulder dystocia | 1 (0.1) | 10 (1.2) | 0.1 | 0.01-0.8 | 0.0117 |
| One or more uterotonics | 675 (80.5) | 672 (80.1) | 1.0 | 0.9-1.0 | 0.9070 |
| Perineal suturing | 294 (35.0) | 366 (43.6) | 0.8 | 0.7-0.9 | 0.0002 |
| Intrauterine palpation | 5 (0.6) | 16 (1.9) | 0.3 | 0.1-0.9 | 0.0266 |
| **Pain relief** | | | | | |
| Epidural analgesia | 35 (4.2) | 86 (10.3) | 0.4 | 0.3-0.6 | 0.0000 |
| Water tub for pain relief | 269 (32.1) | 197 (23.5) | 1.4 | 1.2-1.6 | 0.0001 |
| **Other** | | | | | |
| Non recumbent position for birth | 188 (22.4) | 158 (18.3) | 1.2 | 0.98-1.4 | 0.0964 |

*FMU midwives had extended authorisation to perform ventouse deliveries in case of acute fetal distress in the second stage of labour (ventouse delivery is included in the ICM Essential Competencies for Midwifery Practice and midwives in many different settings and countries have acquired the necessary skills). This was used only once, in a case of acute bradycardia. Apgar score 2/1, 8/5, 10/10.



**Table 4: Causes of FMU to OU transfer**

| | Primipara (%) | Multipara (%) | All(%) |
|---|---|---|---|
| **Total number of transfers intrapartum or <2 hours after birth** | **79/215 (36.7)** | **45/624 (7.2)** | **124/839 (14.8)** |
| **Causes for intrapartum transfers** | | | |
| Failure to progress (cervical dilation >3 cm or during second stage)* | **42** (53.2) | **13**(44.8) | **55**(44.4) |
| Meconium-stained amniotic fluid | **9**(11.4) | **5**(11.1) | **14**(11.3) |
| Fetal heart rate abnormality | **5**(6.3) | **5**(11.1) | **10**(8.1) |
| Prolonged latent phase**/rupture of membranes > 24 hours (+birth not imminent) | **3**(3.8) | **4**(8.9) | **7**(5.6 ) |
| Request for epidural analgesia | **5**(6.3) | **1**(2.2) | **6**(4.8) |
| Abnormal fetal presentation (cephalic or caudal presentation) | **4**((5.1) | **1**(2.2) | **5** (4.0) |
| **Causes for transfers after birth but <2 hours postpartum** | | | |
| Perineal trauma (complicated/3rd-4th degree tear) | **10**(12.7) | **6**(13.3) | **16**(12.9) |
| Retained placenta/postpartum haemorrhage <500 ml | **1**(1.3) | **8**(17.8) | **9**(7.3) |
| Minor respiratory problem (infant) | **0** | **2**(4.4) | **2**(1.6) |
| **Total number of transfers intrapartum or <2 hours after birth** | **79(100)** | **45(100)** | **124(100)** |
| | | | |
| **Causes for transfers >2 hours after birth/during postpartum stay** | | | |
| Neonatal cause (light for date, minor respiratory problem, hypoglycaemia, jaundice) | **6**(85.7) | **5**(83.3) | **11**(84.6) |
| Maternal cause (post partum bleeding, infection) | **1**(14.3) | **1**(16.7) | **2**(15.3) |
| **Total number of postpartum transfers** | **7(100)** | **6(100)** | **13(100)** |

*Delay in the first stage of labour was defined as no progress for two hours and delay in the second stage as a duration of active second stage of >2 hours for primiparas and >1 hour for multiparas

* If painful contractions >24 hours and a cervical dilatation <3 cm (or before if preferred by the woman).

## Web only / supplementary information:

### Table A: Characteristics of freestanding midwifery units

| | Hobro FMU | Frederikshavn FMU |
|---|---|---|
| **Geographical setting** | District/community hospital, southern town in region (11 000 inhabitants) | District/community hospital, northern town in region (24 000 inhabitants) |
| **Obstetrical assistance** | Not available<br>No epidurals or argumentation | Not available<br>No epidurals or argumentation |
| **Assistance for maternal and neonatal emergencies *** | 24-hour emergency assistance on site from anaesthesiologist (day) / resuscitation-capable specialist nurse (evening + night). | 24-hour emergency assistance on site from anaesthesiologist (day) / resuscitation-capable specialist nurse (evening + night). |
| **Midwifery staff and training** | Experienced local midwives whose employment predated unit's conversion into FMU, working in 24 hour shifts in an economically sustainable, team care model<br>Multidisciplinary mannequin training in obstetrical emergencies, including ventouse delivery±<br>FMU midwives provided antenatal care and out-of-hours post partum care for all women in the area booked for both OU and FMU birth. FMU midwives also assisted at the nearest OU, if FMU not busy. | Experienced local midwives whose employment predated unit's conversion into FMU, working in 24 hour shifts in a economically sustainable, team care model<br>Multidisciplinary mannequin training in obstetrical emergencies, including ventouse delivery±<br>FMU midwives provided antenatal care and out-of-hours post partum care for all women in the area booked for both OU and FMU birth. FMU midwives also assisted at the nearest OU, if FMU not busy. |
| **Minimum transfer time** | 35 minutes<br>If possible, FMU midwives accompanied women who were transferred to an OU and continued care, supervised by an obstetrician. | 25 minutes<br>If possible, FMU midwives accompanied women who were transferred to an OU and continued care, supervised by an obstetrician. |
| **Women transferred to** | OU, Aalborg Hospital | OU, Vendsyssel Hospital |
| **Some women may choose** | OU, Randers Hospital or OU, Viborg Hospital | OU, Aalborg Hospital |

| | | |
|---|---|---|
| **transfer to:** | (out-of-region hospitals) | |
| **Number of birthing rooms** | 2 | 2 |
| **Birthing facilities** | Conventional birthing rooms with easy access to birthing pool and shower. Other facilities such as resting room, living room, corridor and kitchen were also used | Large birthing rooms with birthing pool, shower and both double bed and obstetric bed. Other facilities such as living room, corridor and kitchen were also used |
| **Care characteristics** | One-to-one care and continuous support in labour most often available<br>Mobility and use of different labour positions encouraged. Music used for relaxation | One-to-one care and continuous support in labour most often available<br>Mobility and use of different labour positions encouraged. Music used for relaxation |
| **Cardiotocography (CTG)** | Admission CTG offered to all women<br>Transfer performed if CTG indicated | Admission CTG offered to all women<br>Transfer performed if CTG indicated |
| **Early labour assessment** | Home visits occasionally offered | Home visits occasionally offered (10-20%) |
| **Homebirth**‡ | Offered as part of service | Offered as part of service |
| **Postnatal care** | 3-4 days in family rooms, family friendly environment, always possible for partner to stay. No postnatal staff during night<br>Full 'baby-friendly' WHO/UNICEF accreditation<br>Women with no post partum complications who had given birth in the OUs could be transferred to the FMUs for post partum care | 3-4 days in 2-bed postnatal rooms, family friendly environment, always possible for partner to stay. No postnatal staff during night.<br>Full 'baby-friendly' WHO/UNICEF accreditation<br>Women with no post partum complications who had given birth in the OUs could be transferred to the FMUs for post partum care |
| **Antenatal care** | The region's 'standard package' of antenatal care offered by FMU midwives | The region's 'standard package' of antenatal care offered by FMU midwives |

* Only for emergencies such as maternal collapse, severe postpartum haemorrhage or need for neonatal resuscitation.
±Ventouse delivery is included in the ICM Essential Competencies for Midwifery Practice and midwives in many different settings and countries (including FMUs in e.g. the UK, Norway and Denmark) have acquired the necessary skills
‡ As selection criteria for home birth and FMU were identical, both home birth and FMU birth were offered to all low-risk women by FMU midwives. Women could change their decision about place of birth at any time, also during labour.

## Table B: Characteristics of obstetric units

| Characteristics | Aalborg OU | Vendsyssel OU |
|---|---|---|
| **Geographical setting** | Specialist, university hospital, located in main city of the region (120.000 inhabitants) | Provincial hospital, centrally placed in the North of the region (25.000 inhabitants) |
| **Facilities** | Neonatal intensive care unit<br>Neonatal surgical<br>Adult intensive care | Generalised paediatric unit with neonatal beds<br>Adult intensive care unit |
| **Consultant obstetrician** | 24-hour service on site | On site during daytime |
| **Consultant paediatrician** | 24-hour service on site | On site during daytime |
| **Consultant anaesthesiologist** | 24-hour service on site | On site during daytime ( resuscitation-capable specialist nurse on site during night) |
| **Midwifery staff** | Mixed level of experience<br>Most OU midwives also provided antenatal care for both high and low risk women in the area<br>24-hour consultant midwife on site | Mixed level of experience<br>Most OU midwives also provided antenatal care for both high and low risk women in the area<br>Consultant midwife on site during daytime |
| **Number of labour rooms** | 12 | 5 |
| **Birthing facilities** | Conventional birthing rooms. 1 room with birthing pool, access to two labour pools<br>Most women stay in birthing room during labour | Conventional birthing rooms, two rooms with birthing pool<br>Most women stay in birthing room during labour |
| **Care characteristics** | One-to-one care and continuous support in labour typically not available | One-to-one care and continuous support in labour typically not available |
| **CTG** | No admission CTG<br>Auscultation used in low-risk labour<br>(continuous CTG used in case of oxytocin augmentation and epidural analgesia) | No admission CTG<br>Auscultation used in low-risk labour<br>(continuous CTG used in case of oxytocin augmentation and epidural analgesia) |
| **Early labour assessment** | Home visits not offered | Home visits not offered |
| **Postnatal care** | Conventional postnatal ward (nurse staff) | Conventional postnatal ward (nurse staff) |

| | | |
|---|---|---|
| (complicated birth) | 2-4 postnatal beds per room | 2-4 postnatal beds per room |
| **Postnatal care** | 3-4 days on midwifery ward | 3-4 days in same conventional postnatal ward |
| (uncomplicated birth) | 2-4 postnatal beds per room | as women with complicated birth |
| | Rarely possible for partner to stay | Rarely possible for partner to stay |
| | Postnatal staff on ward 24 hours a day | Postnatal staff on ward 24 hours a day |
| **Antenatal care** | The region's 'standard package' of antenatal | The region's 'standard package' of antenatal |
| | care offered by OU midwives | care offered by OU midwives |

**Table C: Adverse outcomes:** maternal morbidity, perinatal death, 5 min Apgar score<7, >1 week NICU stay

| Cases | Apgar score | Birth description | Place of birth | Days in NICU | Neonatal events |
|---|---|---|---|---|---|
| **Freestanding Midwifery Unit** | | | | | |
| Case 1 | **3/5** | **The only case of perinatal/neonatal mortality in the study**<br>Multipara<br>FMU in active labour, normal admission CTG, clear amniotic fluid, spontaneous vaginal birth. Respiratory failure 2-3 minutes after birth. Anaesthesiological assistance called, immediate **advanced resuscitation attempted but the infant did not response**.<br><br>The rare and severe condition of the infant was not detected by antenatal ultrasound screening at 19.4 weeks. Had the mother not chosen FMU care, this infant would most likely have been born in the nearest OU, here located in a provincial hospital with a generalised paediatric unit (consultant paediatrician, obstetrician and anaesthesiologist on call outside daytime). Transfer required to specialised unit (305 km away). | FMU | 0 | **Infant dead**<br><br>**Severe congenital malformation** (diaphragmatic hernia).<br><br>Occurrence 1:2500-1:5000, approx. 40% of infants have additional malformations. Total mortality (Danish population): 43%<br><br>Advanced resuscitation on site |
| Case 2 | **4/5** | Primipara<br>Primary rupture of membranes, FMU 20 hours later, 1 cm cervical dilatation, normal admission CTG. Transferred to OU 6 hours later (3 cm dilatation) due to slow progress of labour and request for epidural.<br>In OU: shared care (OU midwife and obstetrician). Epidural, augmentation of labour, pathological CTG pattern. Pyrexia, meconium-stained fluid, fetal blood sampling, episiotomy, instrumental delivery of infant 7 hours after transfer | OU | **36 *** | Ventilation<br>Admitted to NICU shortly after birth, treated for sepsis and asphyxia. Continuous positive airway pressure (CPAP) and antibiotics. **Severe congenital heart disease,** surgery at 6 months<br>Discharged well |
| Case 3 | **5/5** | Primipara<br>Primary rupture of membranes, presents at FMU 10 hours later, clear amniotic fluid, latent phase. Returns home after 6 hours, transferred to OU 24 hours after rupture of membranes.<br>In OU: shared care (OU midwife and obstetrician). Cervical dilatation 1 cm, augmentation of labour, no antibiotics, meconium-stained fluid. Spontaneous vaginal birth 6.5 hours after transfer. | OU | 5.7 | No ventilation, short intubation for trachea suction. Admitted to NICU shortly after birth due to asphyxia and meconium aspiration CPAP, antibiotics<br>Discharged well |
| Case 4 | **5/5** | Primipara<br>FMU during latent phase, 1 cm cervical dilatation. Normal admission CTG. After 9 hours, cervix dilated 3 cm, transferred to OU due to protracted latent phase<br>In OU: shared care (OU midwife and obstetrician). Amniotomy, augmentation of labour, epidural, CTG. Occipital posterior position, clear amniotic fluid. After 23 hours in OU, spontaneous vaginal birth | OU | 0 | No ventilation<br>Child not admitted to NICU<br>Discharged well |
| Case 5 | **6/5** | Multipara | OU | 0.6 | Ventilation, no chest |

| | | | | | |
|---|---|---|---|---|---|
| | | FMU at 2 cm cervical dilatation. Normal admission CTG. Transferred to OU 8 hours later because of no progress<br>In OU: shared care (FMU midwife and obstetrician). Augmentation of labour, epidural. Pyrexia, antibiotics. Clear amniotic fluid. Caesarean section 5 hours after transfer because of pathological CTG | | | compressions.<br>Birth weight low for gestational age (2554 g). Child admitted to NICU for 14 hours, observation only<br>Discharged well |
| Case 6 | (7/5) | Multipara<br>FMU at 2 cm cervical dilatation, frequent painful contractions. **Admission CTG with pathological pattern**, **emergency transferred to OU** 1 hour after admittance. Tocolytic given for transfer, CTG pattern improves<br>In OU: shared care (FMU midwife and obstetrician). CTG, Caesarean section 4 hours after transfer due to fetal distress. Abruptio placentae | OU | **12.5 **** | Ventilation, no chest compressions.<br>Admitted to NICU shortly after birth. CPAP and antibiotics. 2 days later, acute apnoea: Intubation, ventilation and transfer<br>Discharged well |
| Case 7 | (7/5) | Primipara<br>FMU at 1 cm cervical dilatation. Normal admission CTG. Transferred to OU 10 hours later at 7 cm cervical dilatation because of slow progress of labour<br>In OU: shared care (OU midwife and obstetrician). Augmentation of labour, CTG, spontaneous vaginal birth 3 hours after transfer | OU | **11 ***** | No ventilation<br>Admitted to NICU shortly after birth for respiratory problems. CPAP<br>Discharged well |
| Case 8 | 10/5 | **Adverse event with potential adverse outcome**<br>Multipara: Umbilical cord prolapse in multipara after spontaneous rupture of membranes. Local gynaecologist is summoned against protocol and an emergency caesarean section performed.<br>Had guidelines been followed, the woman would have had a tocolytic, pelvic elevation, and the infant would have been pushed up vaginally while an emergency transfer was carried out (minimum duration 20 min.). The women would have been taken directly to the operating theatre where an obstetrician would decide on the further action.<br>**(case included in sensitivity analysis)** | FMU | **0** | The event happened less than two months after the maternity unit had been turned into a FMU.<br>The staff involved had previously worked closely together and chose not to follow the regional guidelines for emergency transfer from FMUs.<br>Apgar score 10/1, 10/5. Infant and mother discharged well |
| **Obstetric Unit** | | | | | |
| Case 9 | **4/5** | Multipara<br>OU at 10 cm cervical dilatation, fast labour. No CTG. Meconium-stained amniotic fluid just before spontaneous vaginal birth | OU | 0.4 | Ventilation, chest compression.<br>Admitted to NICU for 9 hours, CPAP<br>Discharged well |
| Case 10 | **6/5** | **The only case of severe maternal morbidity in the study (The incident also lead to neonatal morbidity).**<br>Multipara<br>OU at 5 cm cervical dilatation. Epidural, augmentation of labour, continuous CTG. Meconium-stained amniotic fluid, fetal distress leading to caesarean section.<br>**Uterine rupture** discovered. Postpartum haemorrhage>2500 ml. **Peripartum hysterectomy**. | OU | 5 | Oxygen mask, no ventilation<br><br>Admitted to NICU shortly after birth, hypertonia and respiratory problems. CPAP<br>Discharged well |
| Case 11 | **6/5** | Primipara<br>OU at 5 cm dilatation. No dilatation for two hours: Augmentation of labour, CTG, meconium-stained fluid. Spinal analgesia (saddle block), followed by short fetal bradycardia. Ventouse delivery 7.5 hours after admission | OU | 4.6 | No ventilation<br>Admitted to NICU shortly after birth for respiratory problems. CPAP, antibiotics<br>Discharged well |
| Case 12 | **6/5** | Multipara | OU | 3.7 | No ventilation |

| | | | | | |
|---|---|---|---|---|---|
| | | OU at 5 cm cervical dilation.<br>Augmentation of labour, meconium-stained labour, continuous CTG, spontaneous vaginal birth | | | Admitted to NICU, hypertonia and respiratory problems. CPAP, treatment for seizures. Discharged well |
| Case 13 | **6/5** | Multipara<br>OU at 10 cm cervical dilation. No CTG, fast labour, clear amniotic fluid, spontaneous vaginal birth | OU | 1.5 | No ventilation<br>Admitted to NICU for respiratory problems CPAP. Discharged well |

*Longest NICU stay in study **Second longest NICU stay ***Third longest NICU stay

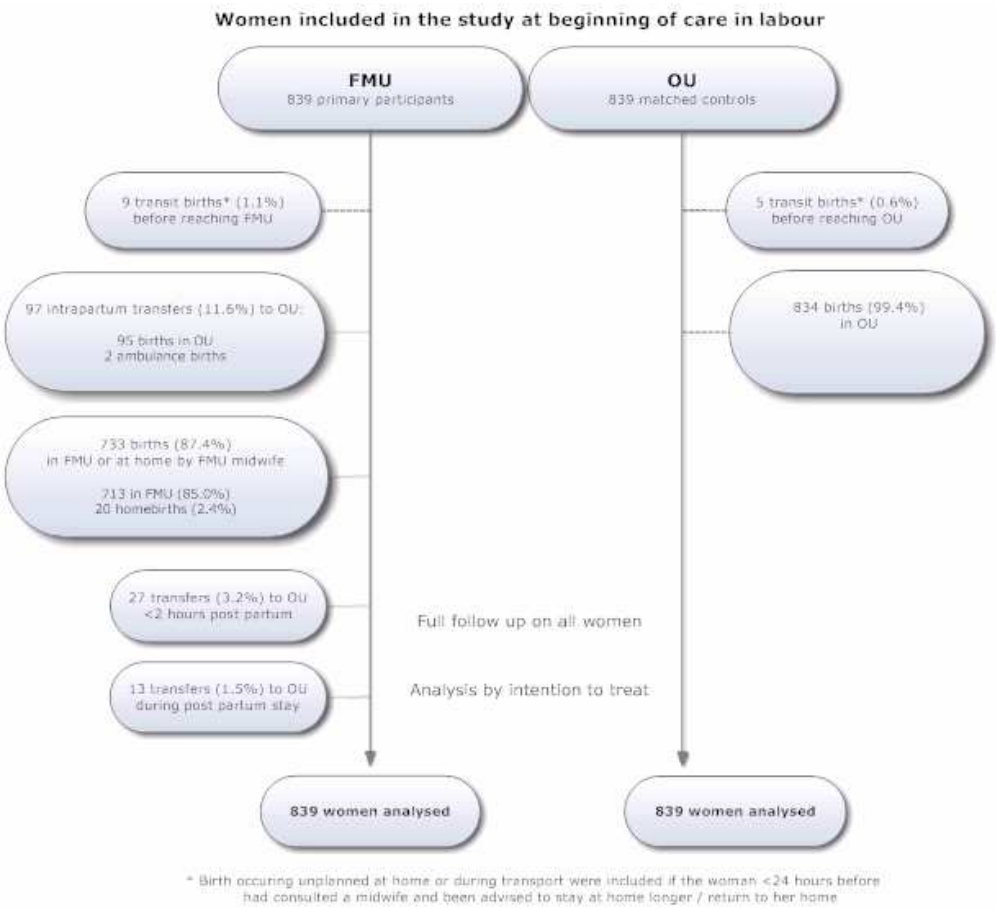
**STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies***

| 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 | 2 + 4 |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | 3 |
| **Introduction** | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 4 + 5 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 5 + (6) |
| **Methods** | | | |
| Study design | 4 | Present key elements of study design early in the paper | 6 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 6-8 + supplementary information in table A + B |
| Participants | 6 | (*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up | 8-9 |
| | | (*b*) For matched studies, give matching criteria and number of exposed and unexposed | 8-9 + table 1 |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 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 | *10* |
| Bias | 9 | Describe any efforts to address potential sources of bias | 14-15 |
| Study size | 10 | Explain how the study size was arrived at | 10-11 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 10 |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding | 11-12 |
| | | (*b*) Describe any methods used to examine subgroups and interactions | 12 |
| | | (*c*) Explain how missing data were addressed | |
| | | (*d*) If applicable, explain how loss to follow-up was addressed | No loss |
| | | (*e*) Describe any sensitivity analyses | |

| | | | |
|---|---|---|---|
| **Results** | | | |
| 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 | 12 |
| | | (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 | 12-13 + table 1 |
| | | (b) Indicate number of participants with missing data for each variable of interest | Table 2 +3 |
| | | (c) Summarise follow-up time (eg, average and total amount) | |
| Outcome data | 15* | Report numbers of outcome events or summary measures over time | |
| 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 | 13-14 + table 2+3 |
| | | (*b*) Report category boundaries when continuous variables were categorized | 14 |
| | | (*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 | 14-15 + table 4 + supplementary information, table C |
| **Discussion** | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 16 |
| **Limitations** | | | |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 16-19 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 19-20 |
| **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 | 23 |

*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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