

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form ([see an example](#)) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Freestanding midwifery-led unit versus obstetric unit: A matched cohort study of outcomes in women at low risk
AUTHORS	Charlotte Overgaard, Anna Margrethe Møller, Morten Fenger-Grøn, Lisbeth B Knudsen, Jane Sandall

VERSION 1 – REVIEW

REVIEWER	J P Neilsen University of Liverpool School of Reproductive & Developmental Medicine
REVIEW RETURNED	29/03/2011

THE STUDY	None
RESULTS & CONCLUSIONS	None
REPORTING & ETHICS	None
GENERAL COMMENTS	<p>This paper addresses a topical issue – the potential benefits and disadvantages (including safety issues) of women giving birth in midwifery-led units, remote from maternity units staffed by both midwives and obstetricians – and provides useful insights. The difficulty is that this is not a randomised controlled trial and the authors address this clearly. I agree that an RCT would have been logistically challenging and possibly not feasible. I am less convinced that an RCT would have raised ethical difficulties. The authors acknowledge that the experimental design (a matched cohort study) may introduce bias through an imbalanced influence of unrecognised confounders, but they appear to have used a robust system of matching women planning to give birth in the OUs to those planning birth in the FMUs.</p> <p>The original sample size was 1027 women in both groups but this plan was scuppered by a decision by regional authorities to close the FMUs. In response the authors added 289 women giving birth in the FMUs before the formal start of the study to give a total of 839 in the FMU group. This is acceptable pragmatism, but inevitably a little 'messy'.</p> <p>The methods are very clearly described, including the statistical methods. Transfer from the FMUs to an OU is an undesirable, if inevitable, event and should be included, I feel, as an outcome measure, rather than background information. This is an important downside to plans to give birth in a FMU and two women gave birth in an ambulance en route (not optimal). Transfer figures should be included in the abstract and final summary to give a balanced overview of the pros and cons to clinicians, policy makers and women facing the choice of place of birth. In particular, of the 137 women transferred, 68 were primigravid. This means that almost a third (31.6%) of primigravid women were subjected to an ambulance journey of 30 minutes on average, either intrapartum or after birth. This needs specific highlighting.</p>

	<p>I agree with the authors that the study shows advantages to FMU care and that 'pregnant prospective mothers should be given an informed choice of place of birth' (abstract) but the presentation of the overall findings currently lacks balance.</p> <p>The annual number of births at the FMUs were 170 and 130, ie on average a birth every two or three days. Whilst accepting that the service was for a sparse population, it would have been useful to have some comment on economic implications, even if no formal economic evaluation had been undertaken.</p> <p>It is interesting that shoulder dystocia and occipito-posterior position were less common in the FMU group. The authors speculate sensibly on the possible reasons. It would also be useful to have the birth weight data in the two groups. Did the matching process somehow produce differences between the groups?</p> <p>Minor points: Reference 55 showed that CTG increased intervention (agreed) but decreased the risk of neonatal convulsions (not 'without improving neonatal outcome'). The paper is very well written but there are a few phrases that need modification to colloquial English eg amniotic water to amniotic fluid.</p>
--	---

VERSION 1 – AUTHOR RESPONSE

Response to reviewer 1: J P Neilsen

This paper addresses a topical issue – the potential benefits and disadvantages (including safety issues) of women giving birth in midwifery-led units, remote from maternity units staffed by both midwives and obstetricians – and provides useful insights.

The difficulty is that this is not a randomised controlled trial and the authors address this clearly. I agree that an RCT would have been logistically challenging and possibly not feasible.

I am less convinced that an RCT would have raised ethical difficulties.
Ethical difficulties is no longer mentioned in the manuscript

The authors acknowledge that the experimental design (a matched cohort study) may introduce bias through an imbalanced influence of unrecognised confounders, but they appear to have used a robust system of matching women planning to give birth in the OUs to those planning birth in the FMUs.
As the table displaying matching groups and participant characteristics could be important for readers in the judgment of this key issue and we have therefore suggested it is not placed in electronic supplements.

The original sample size was 1027 women in both groups but this plan was scuppered by a decision by regional authorities to close the FMUs. In response the authors added 289 women giving birth in the FMUs before the formal start of the study to give a total of 839 in the FMU group. This is acceptable pragmatism, but inevitably a little 'messy'.

The methods are very clearly described, including the statistical methods.

Transfer from the FMUs to an OU is an undesirable, if inevitable, event and should be included, I feel, as an outcome measure, rather than background information.
Transfer rates have been added to the table of outcomes

This is an important downside to plans to give birth in a FMU and two women gave birth in an ambulance en route (not optimal). *We agree*
Transfer figures should be included in the abstract and final summary to give a balanced overview of the pros and cons to clinicians, policy makers and women facing the choice of place of birth.
Transfer figures have been added to the abstract and the issue of transfer has been highlighted in the conclusion and the "what this study adds"-box.

In particular, of the 137 women transferred, 68 were primigravid. This means that almost a third (31.6%) of primigravid women were subjected to an ambulance journey of 30 minutes on average, either intrapartum or after birth. This needs specific highlighting.

I agree with the authors that the study shows advantages to FMU care and that 'pregnant prospective mothers should be given an informed choice of place of birth' (abstract) but the presentation of the overall findings currently lacks balance.

We certainly agree that transfers are a very important aspect of FMU care and have done our best to revise the paper accordingly and at the same time taking the length and clarity of the article into consideration.

We hope that the revised manuscript will meet the request for highlighting of the high transfer rates for primiparous women and better balance of the findings.

The annual number of births at the FMUs were 170 and 130, ie on average a birth every two or three days. Whilst accepting that the service was for a sparse population, it would have been useful to have some comment on economic implications, even if no formal economic evaluation had been undertaken.

We agree that economics is an important aspect of FMU care and have recommended this as an area of further study.

As economical aspects of care was outside the scope of this study and very little information on economic aspects are available from the Region of North Jutland, we believe that we will not be able to add any interesting information. The supplementary Table A does however provide quite detailed information about the two model of care (e.g. that FMU midwives worked in 24-hours shifts and that the postnatal wards did not have on-site staff during night) and we could also underline in the text that the FMUs were not closed for economical reasons.

It is interesting that shoulder dystocia and occipito-posterior position were less common in the FMU group. The authors speculate sensibly on the possible reasons. It would also be useful to have the birth weight data in the two groups. Did the matching process somehow produce differences between the groups?

Mean birth weigh in the two groups is already provided in text in the result section (under secondary outcomes), but we have changed the order of factors so birth weight is now mentioned first. There was no difference in birth weight between groups (mean: 3636 kg (FMU) and 3641 kg (OU)).

Minor points:

Reference 55 showed that CTG increased intervention (agreed) but decreased the risk of neonatal convulsions (not 'without improving neonatal outcome').

The paragraph is no longer included in the paper

The paper is very well written but there are a few phrases that need modification to colloquial English eg amniotic water to amniotic fluid.

This has been done

There is a second review for this manuscript, available anonymously on request, but no permission was received from the reviewer to publish their review.

VERSION 2 - REVIEW

REVIEWER	Deirdre J Murphy Professor of Obstetrics & Head of Department, Trinity College Dublin & Coombe Women & Infants University Hospital
----------	---

	<i>Potential conflicts of interest - I was a member of the UK Birthplace study group when I chaired the RCOG Guideline and Audit Committee. One of the authors – Jane Sandall is also a member of this group.</i>
REVIEW RETURNED	27/06/2011

GENERAL COMMENTS	<p>Summary</p> <p>Place of birth is both topical and of interest to readers from a clinical and sociological perspective. This study from a Danish setting presents interesting data comparing two freestanding midwifery-led units to an obstetric unit. The study has both strengths and limitations. The strengths include clear classification of the cohorts and robust analyses. The limitations will be outlined below.</p> <p>Points for consideration</p> <p>1) Whilst most reviewers request additional clarifications and explanations I think the paper is currently too long at 4397 words (6 Tables, 1 Figure and two supplementary tables). I appreciate that there is a short published version(PICO) but the full text would only be of interest to specialised readers.</p> <p>2) The study is described as the second largest of its type. If I was a woman booking for care or a clinician advising on care I would want to know the risk of perinatal mortality or significant morbidity in relation to my choice to deliver in a freestanding midwife-led unit. A study of 839 low-risk women collated over more than two years (from units with 300-350 births per year) is too limited. Even one or two serious adverse outcomes would be statistically non-significant and therefore I could not be reassured in a robust manner on safety. The UK Birthplace study hopes to address this with a national prospective cohort study adequately powered to address safety.</p> <p>3) The authors report a 36.7% transfer rate from the free-standing unit for first time mothers and an early postpartum discharge rate (less than 6 hours) for 22.8% of women from the obstetric unit. They do not appear to have considered the option of obstetric unit birth with early transfer home as a safe alternative for first time mothers. The data appear much more supportive of free-standing midwifery-led care for parous women.</p> <p>4) I would prefer to see a study where patients are followed prospectively from the antenatal booking visit. Women are asked to make the decision about where to book for antenatal and intrapartum care in the first trimester. The population who present for delivery will be different and some of those deemed unsuitable for the freestanding midwifery-led care unit may be counted in the apparently low risk obstetric care unit population at the time of delivery. Although the matching appears to be successful they may not be comparing like with like.</p> <p>5) The study design altered due to unit closure and the prospective collection of cases was amended to make up the numbers with a smaller number of cases from one unit with backdating of ascertainment. This is an unfortunate limitation in the study design. I am also concerned that the data are quite dated relating to births from 2004-2006. The epidemiology of childbirth is changing dramatically in terms of maternal age, parity, medical conditions, obesity etc.</p> <p>6) The authors do not address the economic issue which must surely be the key driver in the closure of the units. How can you justify staffing and resourcing a two bedded freestanding maternity unit with barely one delivery a day? How do the midwives maintain expertise? There was mention of training in vacuum</p>
-------------------------	---

	<p>delivery – I cannot see how the staff could have skills in operative vaginal delivery in the context of such a small caseload. Each midwife must perform less than one delivery per shift. It would be helpful if the actual rationale for closing the unit was mentioned and indeed why women chose to deliver there in such small numbers.</p> <p>Summary I think this is an interesting paper that would be of interest to specialists in the field but there are some important limitations that question its suitability for the wider readership of the BMJ.</p> <p>Potential conflicts of interest I was a member of the UK Birthplace study group when I chaired the RCOG Guideline and Audit Committee. One</p>
--	---

There is a fourth review for this manuscript, available anonymously on request, but no permission was received from the reviewer to publish their review.

VERSION 2 – AUTHOR RESPONSE

Summary

Place of birth is both topical and of interest to readers from a clinical and sociological perspective. This study from a Danish setting presents interesting data comparing two freestanding midwifery-led units to an obstetric unit. The study has both strengths and limitations.

- 1)** The strengths include clear classification of the cohorts and robust analyses.

Author group response

It is a pleasure to notice that reviewer 4 agrees with reviewer 1 and 3 on these important issues.

The limitations will be outlined below.

Points for consideration

- 2)** Whilst most reviewers request additional clarifications and explanations I think the paper is currently too long at 4397 words (6 Tables, 1 Figure and two supplementary tables). I appreciate that there is a short published version (PICO) but the full text would only be of interest to specialised readers.

Author group response

We have done our utmost to shorten and condense the manuscript maximally without losing any of the information on context, methods, limitations and generalisability, outlined by the reviewers as important manuscript strengths.

We have followed the extremely helpful suggestions on shortening, provided by reviewer 1, and would kindly request BMJ open to allow the present manuscript length.

- 3)** The study is described as the second largest of its type. If I was a woman booking for care or a clinician advising on care I would want to know the risk

of perinatal mortality or significant morbidity in relation to my choice to deliver in a freestanding midwife-led unit. A study of 839 low-risk women collated over more than two years (from units with 300-350 births per year) is too limited. Even one or two serious adverse outcomes would be statistically non-significant and therefore I could not be reassured in a robust manner on safety. The UK Birthplace study hopes to address this with a national prospective cohort study adequately powered to address safety.

Author group response

As discussed earlier, we acknowledge the importance of perinatal mortality as an outcome, however it is a rare outcome in a low risk population and the investigation of this issue requires a sample size that so far has been outside the reach of primary research studies.

The study is powered to look at two clinically important primary outcomes that of Apgar score < 7 at 5 minutes and caesarean section.

4) The authors report a 36.7% transfer rate from the free-standing unit for first time mothers and an early postpartum discharge rate (less than 6 hours) for 22.8% of women from the obstetric unit.

They do not appear to have considered the option of obstetric unit birth with early transfer home as a safe alternative for first time mothers. The data appear much more supportive of free-standing midwifery-led care for parous women.

Author group response

We agree that the data certainly is very supportive of FMU care for multiparous women and that the intrapartum transfer rate is high for first time mothers. We agree that this is important information for women and professionals, and we plan to include in the paper the transfer rate for both first-time mothers and parous women. Our findings provide information upon which women, professionals and policy makers can make decisions. However, these will vary depending upon individual preferences and trade-offs made by women.

5) I would prefer to see a study where patients are followed prospectively from the antenatal booking visit. Women are asked to make the decision about where to book for antenatal and intrapartum care in the first trimester.

The population who present for delivery will be different and some of those deemed unsuitable for the freestanding midwifery-led care unit may be counted in the apparently low risk obstetric care unit population at the time of delivery. Although the matching appears to be successful they may not be comparing like with like.

Author group response

We find this statement puzzling as it is argued by providers and policy makers that making decisions about place of birth is not appropriate during the booking visit, but better left until later in pregnancy for women who are still low risk.

We support the opposite argument made by authors of RCTs of alongside midwifery units (included in the Cochrane review of such units) due to severe problems with cross-over, compromising validity and the interpretation of results. In some studies, (e.g. Hundley 1994) women were recruited in pregnancy but 38% were referred to OU care before the start of care in labour and less than half the women in the AMU group ended up actually receiving the allocated intervention.

Also the 'Birthplace in England' study, well known to the reviewer, also only includes women who are low-risk at the start of care in labour.

As clearly stated in the paper, the risk status of all women in both groups was assessed at the start of care in labour. Exactly as in the 'Birthplace in England' study, women were judged by the same, strict criteria by project staff using the NICE guidelines for intrapartum care, and all women included as controls were eligible for out of hospital birth (FMU/homebirth) at the start of care in labour using the same criteria.

No women with "grey-zone" risk status or any factors increasing the risk for obstetric complications according to the NICE guidelines were included as controls.

6) The study design altered due to unit closure and the prospective collection of cases was amended to make up the numbers with a smaller number of cases from one unit with backdating of ascertainment. This is an unfortunate limitation in the study design.

Author group response

We acknowledge this limitation, but as previously discussed, the reduction of sample size entailed only limited power reductions as shown in detail in the response to the previous reviewer.

Women in the FMU group, giving birth in 2004, were included on basis on the same strict guidelines as women giving birth in 2005 and 2006 and all controls were prospectively included.

7) I am also concerned that the data are quite dated relating to births from 2004-2006. The epidemiology of childbirth is changing dramatically in terms of maternal age, parity, medical conditions, obesity etc.

Author group response

Age and obesity as noted by the reviewer, is increasing among childbearing women, leading to more women being classified as high risk and an increase in medical conditions.

The present study investigates only the effect of place of birth on low risk women. Primiparous women with a BMI >30 were not eligible for inclusion and multiparous women with a BMI >30 were only eligible if they were healthy, and all earlier pregnancies and births had been uncomplicated.

In Denmark, an analysis from the National Board of Health comparing the key demographics of women giving birth in 2004 to 2008 found an increase in mean BMI from 24.1 to 24.3., little change in parity. In 2004, mean maternal age was 30.6 years and it has since 2007 stabilised around 30.6. We propose to add sentence in the paper to this effect.

8) The authors do not address the economic issue which must surely be the key driver in the closure of the units. How can you justify staffing and resourcing a two bedded freestanding maternity unit with barely one delivery a day?

Author group response

As for all health services, costs of the FMU service was a concern for the regional health authorities of North Jutland. In 2005/2006, the FMUs introduced a case-load model where two/three midwives provided antepartum and intrapartum care for all women booked for delivery at the unit. This model was economically sustainable and with its very high level of continuity of care, it was very well received among women. The midwives also provided antenatal care for other women in the area (both high risk and low risk) who were booked for intrapartum care at an OU.

The FMUs also provided post partum care for both women booked for FMU birth and other women with no post partum complications, who wished to be transferred to an FMU post partum. Though 1-2 midwives/nurses were occupied only with post partum care during daytime, the FMU midwives were during late evening and night called to the post natal ward if women needed assistance.

We would add this important contextual information to the paper.

- 9) How do the midwives maintain expertise? There was mention of training in vacuum delivery – I cannot see how the staff could have skills in operative vaginal delivery in the context of such a small caseload. Each midwife must perform less than one delivery per shift.

Author group response

This is an interesting debate as to how many procedures clinicians need to maintain competence. The annual number of FMU births per midwife was 40-70, depending on whether the midwife was working full time or part time or in a case-load model. The activities of the FMU midwives were however not restricted to intrapartum care in the FMUs.

In case of transfer, the FMU midwife would if possible accompany women in need of transfer to an OU and continue care under the supervision of an obstetrician.

All FMU midwives provided antenatal care for both women booked for FMU delivery but also other local high and low risk women booked for OU care.

Furthermore, if the OUs were very busy and there were no labouring women at the FMUs, the FMU midwife would assist at the nearest OU.

The FMU midwives were trained in dealing with obstetric emergencies by consultant obstetricians and consultant midwives by use of mannequins and they kept up their skills the same way. Some also had "ALSO"- certification.

- 10) It would be helpful if the actual rationale for closing the unit was mentioned

Author group response

Denmark has no national childbirth policy and maternity services are planned and organised by the regional health authorities on the basis on guidelines from the National Board of Health.

The local health authorities in the partly rural and sparsely populated region of North Jutland chose to go against the recommendation by the National Board of Health to centralise maternity care service and transformed two small maternity units into FMUs – a new concept within Danish maternity care services. The result was a conflict between

regional and national authorities. The rationale for closing the units is briefly mentioned in the article, but more information can be given.

11) And indeed why women chose to deliver there in such small numbers.

Author group response

Approximately one third of eligible women in the sparsely populated and dominantly rural catchment areas of the FMUs choose FMU care.

An independent investigation of North Jutland women's choice of place of birth suggested the influence of several factors – most importantly, the FMU concept was new and not well known to many women and the regional health services were reluctant to "advertise" the new service as this is uncommon in Denmark until the outcomes had been evaluated.

There was no active maternity user group in North Jutland to spread information and facilitate women's discussions about pros and cons of different models of care. In addition, many women had good experiences with OU care and did not want to try another concept, whereas others were advised against FMU care by their General Practitioner or by family or friends. Similar findings have been found in other countries when new maternity services are developed, highlighting the importance of robust evaluation prior to scale up.

12) Summary

I think this is an interesting paper that would be of interest to specialists in the field but there are some important limitations that question its suitability for the wider readership of the BMJ.

Author group response

These concerns have been addressed in our response to the previous reviewer.

13) Potential conflicts of interest

I was a member of the UK Birthplace study group when I chaired the RCOG Guideline and Audit Committee. One of the authors – Jane Sandall is also a member of this group.

Author group response

These have been declared by Jane Sandall.