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The Birthplace national prospective cohort study: perinatal and maternal outcomes by planned place of birth
Birthplace in England research programme. Final report part 4

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Glossary of terms/abbreviations

NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
DH	Department of Health
AMU	Alongside Midwifery Unit
CI	Confidence Interval
DCF	Data Collection Form
DH	Department of Health
FMU	Freestanding Midwifery Unit
IMD	Index of Multiple Deprivation
NCT	NCT (formerly National Childbirth Trust)
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
NPEU	National Perinatal Epidemiology Unit
OR	Odds Ratio
OU	Obstetric Unit
RCM	Royal College of Midwives
RCOG	Royal College of Obstetricians and Gynaecologists

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Jennifer Hollowell is the lead researcher/epidemiologist. JH led the NPEU prospective cohort study team and drafted the report.

David Puddicombe is the Birthplace project researcher/epidemiologist. DP drafted the statistical analysis plan, conducted the main analyses, and drafted sections of the report.

Rachel Rowe was the initial Birthplace project researcher. RR contributed to the design of the study and provided input to the analysis of transfer data.

Christine McCourt, Alison Macfarlane , Mary Newburn, Jane Sandall and Louise Silverton are co-investigators and were members of the writing committee for this report

Louise Linsell is a Senior Medical Statistician. LL contributed to the drafting of the statistical analysis plan and conducted the propensity score analysis.

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All authors contributed to interpretation of findings and the drafting and revision of the report.

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Executive Summary

Background

In the NHS in England, intrapartum maternity care is provided in four settings: at home, in freestanding midwifery units (FMU), in alongside midwifery units (AMU) and in obstetric units (OUs). Available evidence, summarised in the NICE guideline on intrapartum care, indicates that while there is a higher likelihood of a normal birth with less intervention for healthy women who plan to give birth at home or in a midwifery unit compared with planned OU births, there is a lack of good quality evidence comparing the risk of rare but serious adverse outcomes in these birth settings.

Aims

The aim of the Birthplace cohort study was to compare the safety of birth by planned place of birth (home, FMU, AMU, OU) at the start of care in labour. The primary objective was to compare intrapartum and early neonatal mortality and morbidity for babies of women judged to be at 'low risk' of complications prior to the onset of labour.

The primary outcome was a composite of intrapartum stillbirth, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus and fractured clavicle.

Secondary outcomes included the individual components of the primary outcome, other adverse perinatal outcomes, maternal outcomes, interventions during labour and birth, and outcomes for women who transferred.

Methods

The study was a prospective cohort study. Four groups of women were included based on their planned place of birth at the start of care in labour. Women were included in the group in which they planned to give birth at the start of care in labour, regardless of whether they were transferred during labour or immediately after the birth.

We aimed to collect data in every NHS trust providing home birth services in England, every FMU and AMU in England and a random sample of 37 OUs, stratified by unit size and geographical region.

The target sample size was at least 57,000 births, including 30,000 planned OU births, 17,000 planned home births, and 5,000 births in each type of midwifery unit. Participating units/trusts collected data for varying periods of time within the study period 1 April 2008 to 31 April 2010.

Data were recorded by the attending midwives using a study specific data collection form, started during labour care and completed on or after the

fifth postnatal day. To validate outcome events and capture any neonatal outcomes which might not have been known to the attending midwife, additional morbidity forms were completed where the initial form indicated that a relevant outcome/event had occurred, or that the neonate or woman had been admitted for higher level care.

Each unit/trust provided monthly counts of eligible women to enable response rates to be calculated.

Women were classified as 'low risk' if, immediately prior to the onset of labour, they did not have any of the medical or obstetric risk factors listed in the NICE intrapartum care guidelines in which there is increased risk for the woman or baby and care in an OU would be expected to reduce this risk. Women known to have any of these conditions prior to the onset of labour were categorized as 'higher risk'.

Logistic regression was used to calculate odds ratios and confidence intervals for each outcome, accounting for clustering, sampling and duration of participation of the unit/trust. We adjusted for maternal age, ethnic group, understanding of English, marital/partner status, BMI in pregnancy, Index of Multiple Deprivation (IMD) score, parity and gestation. Odds ratios with 95% confidence intervals were calculated for the primary outcome and 99% confidence intervals for the secondary outcomes.

Outcomes by planned place of birth were compared separately for women at 'low risk' and those at 'higher risk' of complications prior to the onset of labour.

A pre-specified subgroup analysis was conducted to examine whether the effect of planned place of birth was consistent for nulliparous and multiparous women.

Results

In total, the cohort included 79,774 eligible women, of which 64,538 (81%) were classified as 'low risk'.

There was a high level of participation from all unit types: 97% of trusts providing home birth services, 95% of FMUs and 84% of AMUs. Five of the original sample of 37 OUs had to be replaced by resampling; 36 OUs participated.

74% of participating units/trusts achieved a response rate of 85% or more.

Births to 'low risk' women

Maternal characteristics varied by planned place of birth with the planned home birth group being most dissimilar to the OU group. The largest variation in maternal characteristics was for parity with 27% of the planned home birth group being nulliparous compared with 46%-54% in the other settings.

The incidence of adverse perinatal outcomes was low in all settings. After adjusting for differences in the characteristics of women planning birth in different settings, there were no statistically significant differences between settings in the incidence of the primary outcome for multiparous women. For nulliparous women, we found no difference in outcomes between midwifery units and OUs but adverse perinatal outcomes were more common in the planned home birth group (weighted incidence 9.3 per 1000 births vs. 5.3 per 1000 births in planned OU births).

Instrumental and operative deliveries and other interventions were less frequent in planned home, FMU and AMU births. Women in these groups were significantly more likely to have a 'normal birth', defined as a spontaneous vaginal birth without induction of labour, an epidural or spinal anaesthetic or episiotomy, compared with women in the planned OU group. Higher rates of 'normal birth' were seen in the non-OU groups for both nulliparous and multiparous women.

Babies in the planned home and FMU groups were significantly more likely to be breastfed at least once relative to babies born in the planned OU group.

Adverse maternal outcomes - third or fourth degree perineal trauma, blood transfusion or admission to a higher level of care – tended to occur less frequently in the planned home and FMU groups and blood transfusions were given less frequently in the planned FMU group relative to planned OU births. However, event rates for these outcomes were low and not all of these differences were significant at the 1% level.

Transfers during labour or immediately after birth occurred in over 20% of births in the three non-OU groups but transfer rates were markedly higher in nulliparous women. For nulliparous women, rates varied from 36% in planned FMU births to 45% in planned home births compared with rates of 9-13% in multiparous women.

Births to 'higher risk' women

For 'higher risk' women, comparisons with planned OU births are more difficult to interpret because the groups were not homogeneous in terms of risk. For example, induction of labour was recorded as a risk factor in almost half of the 'higher risk' women in the planned OU group. This both increases the risk of other interventions and, by definition, precludes a 'normal birth'.

Overall 5% of women in the three planned non-OU groups were classified as 'higher risk' and therefore, according to the NICE intrapartum care guideline should have been advised to give birth in an OU. The proportion of 'higher risk' women was 3% for planned FMU births, 4% for planned AMU births and 7% for planned home births.

Findings were consistent with an increased risk of an adverse perinatal outcome for 'higher risk' women in the planned home birth group. Findings for other outcomes in 'higher risk' women – 'normal birth', receipt of

interventions, maternal morbidities and breastfeeding – were broadly consistent with 'better' outcomes for planned non-OU births relative to the planned OU group.

Conclusions

As a result of this study, women can now be provided with more reliable information on outcomes in the available birth settings, and can also be given a more accurate estimate of the overall likelihood of intrapartum transfer.

The evidence presented here supports the policy of offering 'low risk' women a choice of birth setting:

- FMUs and AMUs appear to be safe for babies and offer benefits to both the mother (fewer interventions) and baby (more frequent initiation of breastfeeding).
- For multiparous women, home births appear to be safe for babies and offer benefits to both the mother (fewer interventions) and baby (more frequent initiation of breastfeeding). For women having their first baby, there is some evidence that planning to give birth at home does carry an excess risk of an adverse perinatal outcome, although the increased risk is modest.
- The substantially lower incidence of major interventions, including intrapartum caesarean section, in all three non-OU settings has potential future benefits to both the woman and the NHS. There is a need to address the higher frequency of major interventions and the relatively low proportion of 'normal births' in 'low risk' births in OUs.

Our findings show that a non-negligible proportion of planned home and midwifery unit births are to women at 'higher risk' of complications who, according to current clinical guidelines, should be advised to give birth in an OU. The reasons for this are not clear but some consideration needs to be given to the information and options offered to 'higher risk' women.

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1 Introduction

Since the early 1990s, government policy that all women should give birth in consultant-led obstetric units has been replaced by policies designed to give women a choice of settings for birth.[1-3] As a result, women in England should be able to choose between giving birth at home, in a freestanding midwifery unit (FMU), alongside midwifery unit (AMU) or in an obstetric unit (OU).[4]

The purpose of the Birthplace national prospective cohort study of planned place of birth was to evaluate a range of perinatal and maternal outcomes for the settings currently provided for intrapartum care by the NHS in England.

1.1 The research evidence

Reviews of research which have supported the development of maternity care policies have identified major gaps in the evidence, including the quantification of the risk of adverse outcomes associated with births in different settings.[1, 5-7] The clinical guidance commissioned by the National Institute for Health and Clinical Excellence (NICE) on the care of healthy women and their babies during childbirth commented "Of particular concern is the lack of reliable data, relating to relatively rare but serious outcomes such as perinatal mortality that is directly related to intrapartum events or serious maternal morbidity in all places of birth".[8]

1.1.1 Birth at home

A Cochrane systematic review of home versus hospital birth identified only one randomised controlled trial which included 11 women and was unable to detect any differences in safety or other outcomes between the two settings.[9] A meta-analysis of six observational studies examined perinatal outcomes for 24,092 'low risk' women and their babies.[10] No difference was observed for perinatal mortality. There was evidence that women planning birth at home had a lower risk of induction, augmentation, instrumental vaginal birth, caesarean section, episiotomy, severe perineal lacerations and that their babies were less likely to have low Apgar scores.

The results of several large observational studies comparing home births with birth in an OU have been published since the Birthplace Research Programme began in 2007. A retrospective cohort study from the Netherlands using routine data from over 500,000 women found no evidence of a difference in perinatal mortality or morbidity between 'low risk' women who planned to give birth at home and 'low risk' women who planned to give birth in hospital.[11] Canadian and Swedish studies of planned home births compared to planned hospital births for 'low risk' women also showed no difference in perinatal mortality.[12, 13] Lower rates of obstetric interventions were observed in the planned home birth group for both studies. However, both studies included fewer than 20,000 births and

lacked statistical power to demonstrate differences in rare but important adverse outcomes. A study using data from England and Wales attempted to quantify the intrapartum-related perinatal mortality rates for booked home births from 1994 to 2003 using routine statistics.[14] However, the data available were of poor quality for this comparison and highlighted the need for a more accurate quantification of the risks associated with each planned place of birth. A recent meta-analysis found planned home births, compared to planned hospital births, were associated with less medical intervention, had a similar perinatal mortality rate and an increased neonatal mortality rate.[15] This study has been criticized for failing to report the assessment of the quality of the studies included[16] and for other methodological weaknesses.[17]

1.1.2 Births in midwifery units

A Cochrane systematic review compared birth in alternative birth settings with conventional institutional settings (OUs).[18] The review included nine randomised controlled trials and 10,684 women and the alternative birth settings studied were most similar to AMUs. Alternative birth settings were associated with an increased likelihood of spontaneous vaginal birth, increased maternal satisfaction and fewer medical interventions during labour and birth. There was no association between birth setting and severe perinatal morbidity or mortality (risk ratio (RR) 1.17, 95% CI 0.51-2.67). Also, there was no association between birth setting and serious maternal morbidity or mortality (RR 1.11, 95% CI 0.23-5.36). However, it is likely that the review was underpowered to detect any differences in rare but important severe adverse perinatal and maternal outcomes. No trials of FMUs were included in this review.

Prospective observational studies have shown a lower rate of intervention during labour for births planned in FMUs.[19, 20]

In summary, the evidence indicates that there is a higher likelihood of a normal birth with less intervention for healthy women who plan to give birth at home or in a midwifery unit compared with planned OU births, but there is a lack of good quality evidence comparing the risk of rare but serious adverse outcomes in these birth settings.

2 Aims, objectives and outcomes

2.1 Aims

To compare aspects of the safety of birth by planned place of birth at the start of care in labour: at home, in FMUs, in AMUs and in OUs in England.

2.2 Objectives

2.2.1 Primary objective

To compare intrapartum and early neonatal mortality and specific neonatal morbidities for births planned at home, in FMUs and in AMUs with births planned in OUs, for babies of women judged to be at 'low risk' of complications at labour onset.

2.2.2 Secondary objectives

To compare the following for births planned at home, in FMUs and in AMUs with births planned in OUs:

1. maternal morbidity for women judged to be at 'low risk' of complications at labour onset;
2. intrapartum and early neonatal mortality and specific neonatal morbidities for babies of all women, irrespective of risk status at labour onset;
3. maternal morbidity for all women, irrespective of risk status at labour onset
4. intrapartum and early neonatal mortality and specific neonatal morbidities for babies of women at 'higher risk' of complications at labour onset;
5. maternal morbidity for women at 'higher risk' of complications at labour onset;
6. maternal birth interventions for women judged to be at 'low risk' of complications at labour onset.

Also, using the planned birth at home group as the comparison group:

7. to compare perinatal and maternal outcomes for 'low risk' women who transfer from home, FMUs and AMUs during or immediately after labour;

8. to quantify any associations between indication for transfer, time from decision making until transfer, duration of transfer or events after transfer (including the time taken to be assessed by an obstetrician) and perinatal or maternal outcomes for babies and women who are transferred during or immediately after labour.

2.2.3 Objectives covered in this report

The objectives listed above relate to the overall objectives of the cohort study as defined in the study protocol (see Appendix 1). These include objectives which did not form part of the programme of work funded by the NIHR SDO Programme or by the DH Policy Research Programme. In this report we present those aspects which were specified in the original proposal, and additional elements of these objectives will be the subject of other reports and publications. For example, a detailed analysis of outcomes relating to intrapartum and post-partum transfer will be included in a thesis funded by the NIHR Researcher Development Award. Objectives 2 and 3 relating to all women irrespective of risk will not be undertaken. Although originally included in the protocol, the Birthplace co-investigator group and Advisory Group decided that the analyses relating to all women irrespective of risk would not provide useful information about the safety of planned birth in the different settings and might be misleading.

This report covers the following objectives.

Primary objective

To compare intrapartum and early neonatal mortality and specific neonatal morbidities for births planned at home, in FMUs and in AMUs with births planned in OUs, for babies of women judged to be at 'low risk' of complications at the start of care in labour

Secondary objectives

To compare the following for births planned at home, in FMUs and in AMUs with births planned in OUs:

1. maternal morbidity for women judged to be at 'low risk' of complications at labour onset

3. maternal birth interventions for women judged to be at 'low risk' of complications at labour onset

3. intrapartum and early neonatal mortality and specific neonatal morbidities for babies of women at 'higher risk' of complications at labour onset

4. maternal morbidity for women at 'higher risk' of complications at labour onset

Also, using the planned birth at home group as the comparison group:

5. to compare perinatal and maternal outcomes for 'low risk' women who transfer from home, FMUs and AMUs during labour or immediately after birth

A cost-effectiveness analysis based on the group of 'low risk' women recruited into the study is reported separately (see part 5 of the report) .

After defining the objectives it became clear that there was opportunity for ambiguity in the definition of risk status for women entering the cohort. Specifically the phrase "... for women judged to be at 'low risk' of complications at labour onset" could be misinterpreted. The classification of women into 'low risk' or 'higher risk' for women entering the cohort would in reality have been assessed at the last episode of antenatal care, which may have been weeks or minutes before the onset of labour. Therefore, the definition of risk is not accurately at the time of "labour onset" but at some point prior to labour onset. The definition of risk status was therefore operationalised as being "... for women judged to be at 'low risk' of complications prior to the onset of labour", which is the phrase used throughout the rest of the report.

2.3 Outcome measures

2.3.1 Primary outcome

The primary outcome is a composite of:

- stillbirth after the start of care in labour
- early neonatal death (within 7 days)
- neonatal encephalopathy defined as either a clinical diagnosis of neonatal encephalopathy or 'signs of neonatal encephalopathy'[i]
- meconium aspiration syndrome
- brachial plexus injury
- fractured humerus or clavicle

A clinical diagnosis of neonatal encephalopathy was defined as either a clinical diagnosis of neonatal encephalopathy or a clinical diagnosis of isolated seizures without a known cause other than perinatal asphyxia[ii].

'Signs of neonatal encephalopathy' was defined as admission to neonatal unit within 48 hours of birth for at least 48 hours with signs consistent with a diagnosis of neonatal encephalopathy:

- receipt of parenteral or tube feeding or receipt of supplemental oxygen or respiratory support; and
- absence of meconium aspiration, suspected or confirmed sepsis or other diagnosis consistent with feeding difficulties or need for respiratory support[iii].

A composite outcome was chosen to give the study more power to detect differences in safety between planned places of birth compared with a single outcome, which would have a lower incidence. Using a composite outcome could provide misleading results if planned place of birth affects different contributing outcomes in different ways. For example, if the effect

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[i] The signs of mild encephalopathy can be subtle and include respiratory difficulty and poor feeding rather than features more specifically associated with encephalopathy. In this mature group of babies, any difference in the incidence of neonatal unit admissions for these outcomes is likely to result from differences in the incidence of perinatal asphyxia.

[ii] Presumed cause of isolated seizures based on clinical review of stated cause by a neonatologist blinded to planned place of birth (see section 3.10.1).

[iii] Absence of alternative cause of feeding difficulties or respiratory distress based on clinical review of reasons for neonatal admission by a neonatologist blinded to planned place of birth (see section 3.10.1 below).

of planned place of birth in a particular setting decreased deaths but resulted in increased morbidity there might be little or no difference observed in the primary outcome, even though deaths were being prevented in one setting. The likelihood of this occurring was unknown but the increased statistical power of using a composite outcome outweighed the alternative approach of substantially increasing the sample size to address individual components of the primary outcome.

2.3.2 Secondary outcomes

Perinatal outcomes

- stillbirth after the start of care in labour
- early neonatal death (within 7 days)
- 'neonatal encephalopathy' defined as either a clinical diagnosis of neonatal encephalopathy or 'signs of neonatal encephalopathy' (as above)
- meconium aspiration syndrome
- brachial plexus injury
- fractured humerus
- fractured clavicle
- fractured skull
- cephalohaematoma
- cerebral haemorrhage
- early onset neonatal sepsis[i]
- kernicterus (severe bilirubin encephalopathy)
- seizures
- neonatal unit admission
- Apgar score less than seven at five minutes
- breastfeeding initiation

Maternal outcomes

- mode of birth
  - spontaneous vertex birth
  - vaginal breech birth
  - ventouse delivery
  - forceps delivery
  - intrapartum caesarean section
- 'normal birth' defined as a birth with none of the following interventions[ii]:
  - induction of labour
  - epidural or spinal analgesia
  - general anaesthetic
  - forceps or ventouse
  - caesarean section
  - episiotomy

[i] Culture confirmed; suspected or diagnosed within 48 hours of birth.

[ii] Based on the NCT, RCM and RCOG Maternity Care Working party definition. [21.]

- third or fourth degree perineal trauma
- blood transfusion
- admission to an intensive therapy unit, high dependency unit or specialist unit
- maternal death (within 42 days of giving birth)

Maternal interventions in labour

- syntocinon augmentation
- immersion in water for pain relief
- epidural or spinal analgesia
- general anaesthetic
- active management of the third stage of labour
- episiotomy

3 Methods

Although it would be ideal to evaluate issues of safety and cost-effectiveness of birth in a large randomized controlled trial comparing outcomes for women who were planning birth at home, in a midwifery unit, and in an OU, such a study would be unfeasibly large, lengthy and costly. There are also legitimate concerns that women and those offering care would not accept randomization in this context. There has been only one small pilot randomized controlled trial which attempted to compare planned birth at home with planned birth in an OU and in which 11 multiparous women were randomised.[22] No other randomised trial has been conducted in any country.

3.1 Study design

The study was a prospective cohort study with planned place of birth at the start of care in labour as the exposure and a composite measure of intrapartum and early neonatal mortality and specific neonatal morbidities as the primary outcome. Four groups of women were included based on their planned place of birth at the start of care in labour:

- women whose planned place of birth was at home
- women whose planned place of birth was in a freestanding midwifery unit (FMU)
- women whose planned place of birth was in an alongside midwifery unit (AMU)
- women whose planned place of birth was in an obstetric unit (OU)

Women were included in the group in which they planned to give birth at the start of care in labour regardless of whether they were transferred during labour care or immediately after the birth.

In some trusts, women are able to wait until the start of care in labour at home to decide whether they would prefer a planned home birth or to go to a midwifery or OU. These women were included in the study in the setting where they decided to receive labour care, reflecting their decision in early labour regarding planned place of birth.

3.2 Planned places of birth

Throughout the report we refer to births planned in units or trusts. Units refer to births planned in midwifery or OUs. We use 'trusts' to describe births planned at home because home birth services are delivered within NHS trusts. Each of the planned birth settings was defined as follows.

Planned home births: A birth which occurs for a woman who, at the start of care in labour, intended to give birth at home and who received

care from a midwife during established labour at home, regardless of where the woman actually gives birth. This includes women who make their final decision about planned place of birth during labour.

Planned freestanding midwifery unit births: A birth which occurs for a woman who, at the start of care in labour, intended to give birth in a freestanding midwifery unit and who received care from a midwife during established labour in a freestanding midwifery unit, regardless of where the woman actually gives birth. Freestanding midwifery units are defined as being on a separate geographical site from an OU and transfer will normally be by ambulance or car.

Planned alongside midwifery unit births: A birth which occurs for a woman who, at the start of care in labour, intended to give birth in an alongside midwifery unit and who received care from a midwife during established labour in an alongside midwifery unit, regardless of where the woman actually gives birth. Alongside midwifery units are defined as being in the same building or on the same geographical site as an OU and transfer will normally be by trolley, bed or wheelchair.

Planned obstetric unit births: A birth which occurs for a woman who, at the start of care in labour, intended to give birth in an obstetric unit and who received care from a midwife during established labour in an obstetric unit.

3.3 Sample size

Major perinatal and maternal morbidity are rare in women judged to be at 'low risk' of complications prior to the onset of labour. The incidence of neonatal encephalopathy at term is approximately 1.8 per 1,000 live births.[23] However, the incidence of intrapartum stillbirth after labour onset, early neonatal death and other related neonatal morbidity at term for babies of women at 'low risk' of complications prior to the onset of labour is much less certain. A reasonable estimate of the incidence of the composite primary outcome is 3.6 per 1,000 births. As the vast majority of data on neonatal morbidity are from OUs, this estimate is assumed to be the incidence of the primary outcome in OUs.

In order to have adequate power to detect clinically important differences in outcome that are associated with planned place of birth, the study needed to collect data on at least 20,000 'low risk' women planning to give birth in an OU, at least 17,000 women planning to give birth at home and at least 5,000 women planning to give birth in each type of midwifery unit.

The study aimed to collect data on at least 85% of all eligible women planning birth at home over approximately 16 months, which we estimated to be 17,000 women. With data from 17,000 planned home births, the study would be able to detect an increase in the incidence of the primary outcome from 3.6 per 1,000 births in OUs to 5.7 per 1,000 for planned home births, with a 5% two-sided level of significance and 82% power. Alternatively, the study would be able to detect a reduction in the incidence of the primary outcome from 3.6 per 1,000 births in OUs to 2.0 per 1,000

births for planned home births, with a 5% two-sided level of significance and 80% power.

Data collection was planned for at least 6 months in each type of midwifery unit, which would allow a minimum of 5,000 women from each type of unit to be included. FMUs and AMUs were to be analysed separately when being compared to OUs. With 5,000 women included from each type of midwifery unit, the study would be able to detect an increase in the incidence of the primary outcome from 3.6 per 1,000 births in OUs to 6.8 per 1,000 in midwifery units, with a 5% two-sided level of significance and 80% power. Alternatively, the study would be able to detect a reduction in the incidence of the primary outcome from 3.6 per 1,000 births in OUs to 1.2 per 1,000 births in midwifery units, with a 5% two-sided level of significance and 80% power.

With these sample sizes, assuming 80% power and a 1% level of significance[i] the study would be able to detect similar or smaller relative differences in more common serious outcomes of maternal morbidity amongst women at 'low risk' of complications. For example for blood transfusion which affects approximately 0.5% of women, the detectable relative differences would be similar; and for 3rd and 4th degree perineal trauma which is experienced by 1.2% of women [24, 25] the detectable relative differences would be smaller due to the higher control group event rate.

3.4 Participating NHS trusts, midwifery units and obstetric units

We aimed to collect data in:

- every NHS trust in England providing home birth services
- every FMU and AMU in England
- a stratified random sample of 37 OUs

Eligible trusts and units were identified using data from a national mapping survey of all NHS trusts providing maternity care in England conducted jointly by the Healthcare Commission and the Birthplace Research Programme in 2007[26] (see report part 3).

The target numbers of trusts and units set when the cohort study opened in 2008 are shown in Table 1. Midwifery units that opened during the study period were also invited to participate.

[i] 99% confidence intervals are used for all secondary outcomes to allow for multiple testing due to the large number of secondary outcomes (see section 3.11.3 below).

Table 1. Target number of participating trusts and units, approximate recruitments targets and duration of data collection

Unit type	Target number of participating NHS trusts or units	Target number of women	Planned duration of data collection per NHS trust or unit
Home	150	17,000	16 months
Freestanding midwifery units	57	5,000	6 months
Alongside midwifery units	50	5,000	6 months
Obstetric units	37	30,000*	3 months
Total	294	57,000	-

*to include approximately 20,000 women at 'low risk' of complications at the start of care in labour

A stratified random sample of OUs was selected, with the sample stratified by unit size (<2600 births, 2600-4850 births and >4850 births per year) and geographic location (northern England or southern England). Data from the Department of Geography at the University of Sheffield were used to define northern and southern England. [27] Any sampled OU that declined to participate was replaced by another unit randomly selected from within the same stratum.

The method of sampling was such that each OU in England had approximately the same probability of selection (~37/180). We aimed to include close to 100% of eligible women from each OU over a three month period thus giving each eligible woman the same probability of being included in the sample.

Table 2 describes the elements used to determine the number of OUs sampled from each stratum.

Table 2. Number of OUs sampled in each stratum

Strata	OUs (N)	Births per year	Percentage of total births	OUs needed from stratum[1]	OUs sampled (n)	Probability of selection (n/N)
North 0-2599	33	64,988	11%	6.78	7	0.21
North 2600-4850	37	124,670	21%	7.61	8	0.22
North >4850	11	61,380	10%	2.26	2	0.18
South 0-2599	24	49,581	8%	4.93	5	0.21
South 2600-4850	63	226,747	38%	12.95	13	0.21
South >4850	12	63,685	11%	2.47	2	0.17
Total	180	591,051	100%	37	37	0.21

[1] (OUs*37/180)

The aim was for each participating unit to collect data prospectively for all eligible births within a defined study period falling between January 2008 and April 2010, with the exception of three trusts which started data collection for planned home births in July 2007.

In practice, it was not possible to collect data over the same time period and for the same duration for each trust and for each unit type. The varying duration of participation is described in section 4.2 below and was taken into account in the analysis, as described in the statistical methods (Section 3.11.3 below).

3.5 Eligibility

All women who were attended by an NHS midwife during labour in their planned place of birth, for any amount of time, were eligible for inclusion in the study with the exception of:

- women who had a caesarean section before the start of labour[i]
- women who presented in labour before 37 weeks and 0 days gestation
- women with a multiple pregnancy
- women who were "unbooked" (i.e. had received no antenatal care)

Stillbirths occurring prior to the start of care in labour were excluded.

3.6 Classification of 'risk status' prior to the onset of labour

In order to make meaningful comparisons between the planned places of birth, it was necessary to define women as being known to be at 'low risk' or 'higher risk' of complications prior to the onset of labour using standard criteria applied across all participating centres.

Women were classified as 'low risk' if, immediately prior to the onset of labour, they were not known to have:

- Any of the medical conditions or situations listed in the NICE Intrapartum Care guidelines that result in "increased risk for the woman or baby during or shortly after labour, where care in an obstetric unit would be expected to reduce this risk" [28] (see Table 3 and Table 4).
- Other medical conditions or situations not listed in the NICE guidelines considered to confer an increased risk such that care in an OU would be expected to reduce the risk. These included, but were not limited to:
    - a known fetal anomaly
    - reduced fetal movements
    - obstetric cholestasis
    - cervical suture, cervical fibroid
    - low lying placenta
    - previous 3rd/4th degree tear
    - female genital mutilation
    - symphysis pubis dysfunction
    - recurrent urinary tract infections
    - currrent or recent malignancy
    - Crohn's disease
    - sarcoidosis
    - pneumothorax

[i] Women booked for an elective caesarean section who presented in labour and gave birth by caesarean section were also excluded.

3.7 Complicating conditions at the start of care in labour

Women were assessed by the attending midwife for any risk factors present when they started labour care in their planned place of birth. New risk factors identified at this point could not affect the woman's planned place of birth and hence did not affect the woman's classification of 'risk status' prior to the onset of labour. We refer to any conditions identified at this time as "complicating conditions at the start of care in labour".

These data were collected to enable us to assess the homogeneity of the 'low risk' groups. Some of the categories used for this intentionally had a lower risk threshold than criteria used in clinical guidelines (e.g. "meconium stained liquor" rather than "significant meconium staining" and prolonged rupture of membranes >18 hours" rather than >24 hours). These criteria were not intended to indicate a clinical threshold for management.

Table 3. Medical 'risk factors' (from NICE intrapartum care guideline)

System	Condition
Cardiovascular	Confirmed cardiac disease
	Hypertensive disorders
Respiratory	Asthma requiring an increase in treatment or hospital treatment
	Cystic fibrosis
Haematological	Haemoglobinopathies – sickle-cell disease, beta-thalassaemia major
	History of thromboembolic disorders
	Immune thrombocytopenia purpura or other platelet disorder or platelet count below 100 000
	Von Willebrand's disease
	Bleeding disorder in the woman or unborn baby
	Atypical antibodies which carry a risk of haemolytic disease of the newborn
Infective	Risk factors associated with group B streptococcus whereby antibiotics in labour would be recommended
	Hepatitis B/C with abnormal liver function tests
	Infected with HIV
	Toxoplasmosis – women receiving treatment
	Current active infection of chicken pox/rubella/genital herpes in the woman or baby
	Tuberculosis under treatment
Immune	Systemic lupus erythematosus
	Scleroderma
Endocrine	Hyperthyroidism
	Diabetes
Renal	Abnormal renal function
	Renal disease requiring supervision by a renal specialist
Neurological	Epilepsy
	Myasthenia gravis
	Previous cerebrovascular accident
Gastrointestinal	Liver disease associated with current abnormal liver function tests
Psychiatric	Psychiatric disorder requiring current inpatient care

Table 4. Obstetric history 'risk factors' (from NICE intrapartum care guideline)

Type of condition	Condition or event
Previous complications	Unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty
	Previous baby with neonatal encephalopathy
	Pre-eclampsia requiring preterm birth
	Placental abruption with adverse outcome
	Eclampsia
	Uterine rupture
	Primary postpartum haemorrhage requiring additional treatment or blood transfusion
	Retained placenta requiring manual removal in theatre
	Caesarean section
	Shoulder dystocia
Current pregnancy	Multiple birth
	Placenta praevia
	Pre-eclampsia or pregnancy-induced hypertension
	Preterm labour or preterm pre-labour rupture of membranes
	Placental abruption
	Anaemia – haemoglobin less than 8.5 g/dl at onset of labour
	Confirmed intrauterine death
	Induction of labour
	Substance misuse
	Alcohol dependency requiring assessment or treatment
	Onset of gestational diabetes
	Malpresentation – breech or transverse lie
	Body mass index at booking of greater than 35 kg/m²
	Recurrent antepartum haemorrhage
	Small for gestational age in this pregnancy (less than fifth centile or reduced growth velocity on ultrasound)
Fetal indication	Abnormal fetal heart rate (FHR)/Doppler studies
	Ultrasound diagnosis of oligo-/polyhydramnios
Gynaecological history	Myomectomy
	Hysterotomy

3.8 Data collection

3.8.1 Data relating to labour, delivery and outcome

Data collection was centrally coordinated by the National Perinatal Epidemiology Unit (NPEU) at the University of Oxford. Each participating unit or trust designated a local coordinator to organise and coordinate local data collection. These local coordinators were usually midwives working in one of the participating units or trusts. Training for local coordinators was provided by a National Lead Research Midwife and four Regional Lead Midwives through regional training days. Additional training and ongoing support was provided by the lead midwives, with site visits where required.

Data were collected for all eligible women using a study specific data collection form (DCF). Because the data collected were fully anonymised and treatment was not affected, consent from the women to participate in the study was not required.

Because some questions were not included for every planned place of birth four slightly different data collection forms were used, one for each planned place of birth (see Appendix 2).

The data collection forms were designed to be started by an attending midwife during labour care and completed on or after the 5th postnatal day. Where multiple midwives attended the women, the woman was transferred to another unit, or the woman was admitted for a higher level of care, the form remained in the woman's notes with instructions to enable any midwife attending the woman to complete relevant sections of the form.

Data were collected retrospectively for eligible women who did not have a form started during labour.

Because of the relatively high proportion of ineligible women giving birth in OUs, the obstetric unit DCFs (Appendix 2) included an additional set of eligibility screening questions relating to elective caesarean section, preterm labour, multiple pregnancy and 'unbooked' births. Obstetric units only completed DCFs for women who passed the additional eligibility checks. For midwifery units and home births, DCFs were completed for all women and ineligible births were excluded at the analysis stage.

Data relating to maternal transfers during labour or immediately after the birth were recorded on the DCF for women who started labour care at home or in a midwifery unit. For women in the planned OU birth group a separate Transfer Form or multiple transfer form (Appendix 2) was completed for women who transferred.

The local coordinator for each unit and trust was responsible for collecting the completed data collection forms, checking the data for completeness,

recording the woman's Index of Multiple Deprivation (IMD) 2007 score[i], removing and storing the front page of the forms (which contained the women's personal identifiers) and posting the forms for data entry.

A data processing company entered the data which were then loaded into a Microsoft Access database at the National Perinatal Epidemiology Unit. Any missing or inconsistent data resulted in a query being sent to the local coordinator for checking and correction. Responses to queries were entered at the NPEU and the database updated. Queries were resent if no response was received but data were not normally queried again if still missing or inconsistent after checking.

3.8.2 Morbidity and resource use data

In order to validate outcome events and to collect more detailed resource use and other information relating to adverse outcome, more detailed information was collected whenever one of the following had been recorded on the data collection form:

- stillbirth, neonatal death, neonatal unit admission, meconium aspiration syndrome, neonatal encephalopathy, brachial plexus injury, fractured humerus, fractured clavicle, fractured skull, neonatal sepsis, cephalohaematoma, cerebral haemorrhage, kernicterus, seizures and admission to a neonatal unit within 48 hours for at least 48 hours with evidence of feeding difficulties or respiratory distress
- maternal blood transfusion, admission for higher level care

The follow-up data were collected using either a maternal morbidity form (for maternal morbidities and stillbirths) or a neonatal morbidity form (for neonatal admissions, morbidities and neonatal deaths) (see Appendix 2). These forms were completed, usually by midwives, using the maternal and neonatal notes, with help from neonatal unit staff in some cases.

Morbidity forms were posted from the coordinating centre at the NPEU to the local coordinator for each unit and trust.

Heads of Midwifery in each participating trust were contacted at the end of the study to confirm whether there were any maternal deaths during their participating centres' periods of participation.

Morbidity forms that had not been returned by January 2011 were intensively pursued with reports and reminders sent to Heads of Midwifery, local coordinators and other local contacts, including neonatologists and obstetricians. The NPEU team contacted sites individually where morbidity forms were outstanding for babies with a primary outcome event recorded on the data collection form.

[i] IMD scores were obtained by entering the woman's postcode into an online postcode to IMD converter on the Birthplace website

3.8.3 Collection of denominator data (number of eligible women)

In order to estimate response rates, each unit and home birth service was asked to maintain a register of all eligible women during their unit's period of participation. The registers were used by the local coordinators to monitor the return of completed data collection forms and to provide a count of the number of eligible women in their unit, which was faxed to the coordinating centre at the NPEU each month.

At the end of the study, local coordinators were asked to check their denominator counts against data available from their local IT systems or birth registers to verify their monthly denominator figures. Many trusts did not have an independent source of data on planned home births that could be used to verify the number of eligible women during the study period.

3.8.4 Retrospective data collection

In order to minimise the risk of non-response bias, we aimed to include a minimum of 85% of eligible women in each participating unit or trust. At the end of the prospective data collection period, local coordinators were asked to use their local records to identify eligible women who had not been included and to complete data collection forms retrospectively for these women. To reduce the risk of bias arising from the selective inclusion of forms for women whose notes could be easily located, we asked units to complete outstanding forms in batches for complete months and to try to achieve 100% for those months rather than achieving lower response rates spread across the whole study period.

The database was closed to new data collection forms in December 2010. We continued to chase queries relating to variables affecting the primary analysis and outstanding morbidity forms until May 2011. Data were loaded into the database up to May 6th 2011 and the database was frozen on May 16th for the analyses presented here.

3.8.5 Checking of data with Heads of Midwifery

Finally, a report summarising the data received from each trust was sent to each Head of Midwifery to check for completeness. This report included monthly recruitment and denominator data and descriptive statistics for the women included by each centre: the percentage of women classified as 'low risk' and 'higher risk', the percentage of women transferred during labour or immediately after birth, and the percentage of deliveries by caesarean section. Each Head of Midwifery was asked to contact the co-ordinating centre if the data for their units appeared inaccurate or incomplete. They were also asked to confirm whether there were any maternal deaths during their unit's period of participation.

3.9 Data management

3.9.1 Data entry and query management

Data from the data collection forms and the morbidity forms were double entered by a data processing company. Responses to data collection form queries were double entered at the NPEU. Morbidity forms were not queried.

3.9.2 Cleaning the data collection form data

Most data cleaning took place by means of the data checking and queries that were sent to local coordinators throughout the data collection period. The following additional cleaning took place after the database had been closed to new women in December 2010.

Checks were applied to identify:

- Internal inconsistencies and unexpected values, in particular to those relating to: planned place of birth, timing of transfer (if any), birth outcome (stillbirth vs. livebirth); gestational age
- Inconsistent or unexpected dates and/or inconsistent date-time sequences.
- Multiple records for the same birth.

Records which failed any of these checks were manually reviewed and corrected in the database where available information indicated the correct value. For example:

- Stillbirth was corrected to livebirth where multiple subsequent variables indicated a livebirth, e.g. Apgar >0 and breastfed, or where details of a neonatal unit admission were recorded.
- Inconsistent dates or times were corrected where a date/time sequence indicated the correct date.
- For births where the recorded "estimated date of delivery" gave a gestational age of 31 weeks and 6 days or less, the birthweight was compared with growth reference centiles and if the birthweight was above the 95th centile for the calculated gestational age given and above the 5th centile for a gestation of 37 weeks 0 days, the birth was assumed to be term but the gestation was recoded as missing. A gestation of more than 44 weeks and 0 days was considered implausible and recoded as missing.[29]

Records which matched on the date and time of birth and at least two of maternal age, IMD score or birthweight were manually reviewed. Where the records clearly related to the same birth, one record was retained and the other(s) were removed from the dataset. Any form completed prospectively was selected in preference to data collected retrospectively. Where data collection was prospective or retrospective for both forms, one was selected at random.

All free text data entered on the data collection forms were manually reviewed:

- Ineligible births were flagged and removed from the database. These included: elective caesarean section, women who had not received care in labour in their planned place of birth, preterm births (OUs only), antepartum stillbirths.
- 'Other' free text information was coded using existing codes where possible. This included data entered as free text under 'other' at questions C3 (risk factors), C4 (conditions identified at the start of care in labour), T2 (reason for transfer), T4 (mode of transfer), D6/D7 (mode of birth), D5/D6 (place of birth), and E6 (other perinatal morbidity).

Coding schemes for free text responses that did not fit into existing categories were developed for the following (question numbers refer to forms in Appendix 2):

- 'Other' pre-existing medical conditions and obstetric history known prior to the onset of labour (question C3, see Appendix 3 for details of coding).
- Other complicating conditions identified at the start of care in labour (question C4).
- Primary reason for transfer (question T2).
- Mode of transfer (question T4).
- Place of birth (question D5/D6).

3.9.3 Cleaning the morbidity form data

Data collection form data and, neonatal and maternal morbidity form data were matched on ID number and a range of checks were applied:

- Inconsistencies suggesting mismatched records were manually reviewed and corrected where possible.
- Inconsistencies relating to stillbirths and neonatal deaths were manually reviewed and resolved. Where there was a conflict between a Yes/No 'tick-box' and information recorded as text, the text was taken to be correct. For example, "baby stillborn" recorded on the DCF or neonatal morbidity form would have been taken to indicate that the baby had been stillborn even if No had been ticked in response to the question "was this baby a registered stillbirth" on the maternal morbidity form.
- Text searches were used to identify any mention of a diagnosis or event contributing to the primary outcome; retrieved records were manually reviewed to ensure that relevant events had been correctly coded.
- Inconsistent and unexpected dates were manually reviewed and corrected where possible.

- Morbidity forms which clearly did not relate to the data collection form record with the corresponding ID were flagged and removed from the database.

Duplicate morbidity forms were manually reviewed. Where there were minor discrepancies not involving the coding of any of the outcome variables, one record was selected at random unless there was a clear reason why one form could be considered to be more accurate. For example, a neonatal form completed by a neonatologist was generally selected in preference to a form completed by a midwife. Also, a form describing an event in detail (e.g. a neonatal unit admission described with dates and reason for admission) was considered likely to be more accurate than a duplicate form for the same individual where a 'tick box' response indicated that the same event had not taken place. All decisions were documented.

3.9.4 Cleaning the denominator data (number of eligible women)

Where a unit had not supplied denominator counts throughout the study period, or where there were clear errors in the data, as assessed independently by two reviewers, we estimated the denominator as follows.

Denominator data were classified as 'complete' if they were received for every month of participation and the number of eligible women was greater than or equal to the number of data collection forms received for every month. Denominator data were classified as 'adequate' if 'reasonable' denominator data were received for at least 50% of the months of participation, and 'poor or missing' otherwise.

We accepted denominator data as 'reasonable' for months where the response rate appeared to exceed 100% by a small margin. This was necessary because units were not always able to determine the exact number of women who were eligible for the study as the quality of local records and IT systems varied. The threshold for considering denominator data to be 'reasonable' for any given month depended on the number of data collection forms received. In a month with fewer than 10 forms received, denominator data were considered 'reasonable' if the number of forms received was no more than one greater than the number of women reported as eligible. In a month with 10-49 forms received, denominator data were considered reasonable if the number of forms received was no more than two greater than the number of women reported as eligible. In a month with 50 or more forms received, denominator data were considered reasonable if the number of forms received was no more than 5% greater than the number of women reported as eligible.

For units with 'adequate' denominator data we applied their response rate calculated from the months where they had supplied complete eligibility data to estimate the denominator for the unit's entire period of participation. This was done by dividing the total number of forms received by the response rate in months with complete or adequate denominator data.

We did not estimate denominators or response rates for units with 'poor or missing' denominator data.

3.10 Definition and derivation of key analysis variables

Data relating to maternal and perinatal outcomes were collected on both the data collection forms and the morbidity forms. Where the data collection form and morbidity form data did not agree, the morbidity form was considered a more reliable source of data for the following reasons:

- Neonatal diagnoses were not always known to the midwife, particularly for babies who were admitted to a neonatal unit, and suspected diagnoses might not have been confirmed or ruled out at the time the data collection form was completed.
- Outcomes were generally recorded using tick boxes on the data collection form whereas respondents provided more detailed information about events when completing the maternal and neonatal morbidity forms.

3.10.1 Outcome variables requiring clinical review and coding

Neonatal encephalopathy

Neonatal encephalopathy was defined as either a clinical diagnosis of neonatal encephalopathy or 'signs of neonatal encephalopathy':

- A clinical diagnosis of neonatal encephalopathy was defined as either a clinical diagnosis of neonatal encephalopathy or a clinical diagnosis of isolated seizures without a known cause other than perinatal asphyxia.
- 'Signs of neonatal encephalopathy' was defined as admission to a neonatal unit within 48 hours of birth for at least 48 hours with signs consistent with a diagnosis of neonatal encephalopathy:
    - receipt of parenteral or tube feeding or receipt of supplemental oxygen or respiratory support; and
    - absence of meconium aspiration, suspected or confirmed sepsis or other diagnosis consistent with feeding difficulties or need for respiratory support.

The components of the neonatal encephalopathy outcome involving isolated seizures and signs of neonatal encephalopathy were coded based on clinical review of the neonatal morbidity form data, blinded to planned place of birth.

- Diagnoses and other details recorded on the neonatal form for babies with isolated seizures but without a confirmed diagnosis of neonatal encephalopathy were reviewed by a clinician and where no cause of the seizures other than presumed asphyxia could be identified a clinical diagnosis of neonatal encephalopathy was coded as the outcome.
- Diagnoses, reasons for neonatal unit admission and other details recorded on the neonatal form for babies meeting the admission and feeding difficulties or respiratory support criteria (excluding those

with a confirmed diagnosis of neonatal encephalopathy) were reviewed by a clinician and where the clinician judged that there was no alternative diagnosis consistent with feeding difficulties or need for respiratory support 'signs of neonatal encephalopathy' was coded as the outcome.

Early onset neonatal sepsis

Because of potential misclassification of unconfirmed cases of suspected neonatal sepsis, the outcome was defined as culture confirmed early neonatal sepsis. The outcome variable was derived from the morbidity form data using the date of diagnosis of sepsis in combination with responses to the questions relating to a positive blood culture, evidence of infection in the cerebrospinal fluid (CSF) or a positive culture from another usually sterile site.

Kernicterus

The details of purported cases of kernicterus recorded in section I of the neonatal morbidity form were reviewed by a neonatologist blinded to planned place of birth. Cases where the serum bilirubin and treatment details were inconsistent with a diagnosis of kernicterus were recoded to 'No kernicterus'.

3.11 Statistical analysis

3.11.1 Descriptive analysis

Baseline demographic and clinical characteristics were summarised separately for all eligible 'low risk' and 'higher risk' women for whom data were collected.

Women in the four groups of planned place of birth were described with respect to age, ethnicity, understanding of English, marital or partner status, body mass index in pregnancy (BMI), Index of Multiple Deprivation score (IMD), parity, gestation at delivery, the baby's birthweight, and whether any complicating conditions were present at the start of care in labour.

Unweighted numbers and percentages are presented for binary and categorical variables and unweighted means with standard deviations are presented for continuous variables.

3.11.2 Comparative analysis

The analysis population included all eligible women for whom data were collected. Women were analysed in the group in which they planned to give birth at the start of care in labour, regardless of whether they were transferred during labour or immediately after birth.

The OU group was used as the reference group for all comparative analyses in order to maximise statistical efficiency, as the highest number of births were included from these units.

Outcomes are presented as unadjusted, weighted n/1000 or n/100 depending on the frequency of the outcome. Three sets of odds ratios are presented: an unadjusted odds ratio including all women where the outcome is not missing; an unadjusted odds ratio restricted to women included in the adjusted analysis, i.e. women with no missing data for the outcome or potential confounders used in the adjusted analysis (in order to allow a direct comparison with the results of the adjusted analysis); and an adjusted odds ratio controlling for potential confounders.

The potential confounders used in the adjusted analyses to take into account differences in the maternal characteristics between the groups are maternal age, ethnicity, understanding of English, marital or partner status, body mass index in pregnancy, Index of Multiple Deprivation score, parity and gestation at delivery (Table 5). Quantitative variables were treated as unordered categorical variables using either recommended categories or categories used commonly in other research in the field because it was not assumed that there was a linear relationship between the any of the potential confounders and the incidence of the primary outcome.[30, 31] For analyses of the primary outcome, Indian and Bangladeshi women were grouped together because of the small number of Bangladeshi women in the sample and because outcomes are similar in these groups.[32]

The adjusted analysis was pre-specified as the primary analysis for each outcome.

Many of the perinatal outcomes are very rare. Odds ratios were not calculated for outcomes where the number of events was too small to perform a reliable adjusted analysis.

These analyses were repeated for women at 'low risk' without complicating conditions at the start of care in labour care, women at 'higher risk' and for actual place of birth ('low' and 'higher risk' women). The rationale and justification for this analysis is given in section 4.6.

The home birth group was used as the comparison group for the perinatal and maternal outcomes of 'low risk' women who transferred during or immediately after labour. The OU group was not included in these comparisons as transfers from an OU are rare.

Table 5. Categorisation of potential confounders

Covariate	Response categories	
Maternal age at delivery	1	less than 20 years
	2	20 to 24 years
	3	25 to 29 years
	4	30 to 34 years
	5	35 to 39 years
	6	40 + years
Ethnic group	1	White
	2	Indian or Bangladeshi
	3	Pakistani
	4	Black Caribbean
	5	Black African
	6	Mixed
	7	Other
Understanding of English language	1	Fluent
	2	Some understanding/able to communicate verbally
	3	No understanding/not able to communicate verbally
Marital or partner status	1	Married/living with partner
	2	Single/unsupported by partner
BMI in pregnancy (Kg/m^2)	0	Not recorded
	1	less than 18.5
	2	18.5 to 24.9
	3	25.0 to 29.9
	4	30.0 to 35.0
	5	>35.0 (`higher risk' group only)
Index of Multiple Deprivation score	1	1st quintile (least deprived)
	2	2nd quintile
	3	3rd quintile
	4	4th quintile
	5	5th quintile (most deprived)
Parity (Previous pregnancies ≥24 weeks)	1	Nulliparous
	2	1 previous
	3	2 previous
	4	3 or more previous
Gestation at delivery	1	37 weeks
	2	38 weeks
	3	39 weeks
	4	40 weeks
	5	41 weeks
	6	42 to 44 weeks

3.11.3 Statistical methods

Methods for handling the features of the study design - the stratified sampling of OUs, clustering of women and babies in units and trusts, and weighting applied in the analyses - are described below.

Stratification

The stratification used in the random sampling of the OUs could not be taken into account in the analyses because they were the only type of unit sampled; all trusts providing services for home births and midwifery units were invited to participate. Ignoring the stratification used in the sampling design in the analysis does not affect the point estimates. Not taking the stratification into account is likely to have resulted in very slightly increased standard errors and widened confidence intervals, and resulted in more conservative estimates of effect. Relative to adjustments for clustering and weighting, the impact of adjusting standard errors for stratification is usually modest.

Clustering

Women and babies are clustered within OUs, midwifery units and trusts. Clustered data typically have larger sampling variability than taking an independent random sample of individuals, resulting in larger standard errors. To allow for this, each obstetric/midwifery unit and set of home births clustered within the same trust were defined as the primary sampling units and robust variance estimation was used in the calculation of standard errors.

Weighting

Differences in the probability of selection of the OUs, and differences in the duration of data collection within each unit/trust means that the probability of a woman being selected to take part in the study varied. Probability weights were incorporated in the analysis to adjust for this. The weight applied to each observation was inversely proportional to the probability of selection of the unit and the duration of data collection in the unit/trust. A probability of selection of one was assigned to the midwifery units and home births clustered within trust as every midwifery unit or trust providing home birth services in England was invited to participate. The probabilities of selection of OUs within each stratum (listed in Table 2) were applied to the OUs**.**

Women and babies within the same unit or trust were given the same weight in the analysis.

Logistic regression analysis

Logistic regression was used to calculate the odds ratios and confidence intervals for each outcome, using appropriate survey commands to account for the clustering and sampling weights.

For a large minority of women (17%), no body mass index data were recorded in their maternity notes and this was specifically documented on the data collection form. To avoid the exclusion of these women from the

adjusted analysis, 'body mass index not recorded' was used as a category in the regression model.

Confidence intervals

For the analysis of the primary outcome, 95% confidence intervals (CI) are presented for all odds ratios.

For all secondary outcomes, due to the large number of comparisons, 99% confidence intervals are presented for all odds ratios in order to reduce the risk of the true odds ratio being excluded from the CI by chance.

Missing data

The proportion of missing values for primary and secondary outcomes, and each variable used in the adjusted analysis are reported by planned place of birth.

Subgroup analysis by parity

To examine whether the effect of planned place of birth at the start of care in labour is consistent for nulliparous and multiparous women a subgroup analysis was undertaken. For the primary outcome, odds ratios and 95% confidence intervals are presented for the adjusted analysis and the p-value for the statistical test of interaction was calculated using the Wald test. For all secondary outcomes, adjusted odds ratios and 99% confidence intervals are tabulated and presented using forest plots with the p-value for the statistical test of interaction.

Sensitivity analyses

For the primary outcome, a number of sensitivity analyses were performed to assess the robustness of the results to factors which may introduce bias:

Restricted analysis: response rate >=85%

To gauge whether the results are likely to have been affected by non-response bias, the analysis of the primary outcome for 'low risk' women was repeated, restricting the sample to units and trusts that included at least 85% of eligible women.

Propensity score analysis

Women's choice of planned place of birth is likely to be influenced by their age, parity and other socio-demographic characteristics, resulting in comparison groups that do not have a similar balance of characteristics. Incorporating propensity scores, i.e. the 'propensity' of a woman to choose a particular place of birth, in the analysis is a way of controlling for this bias. It also allows a more detailed examination of the impact of imbalanced comparison groups on the results.

Differences in baseline characteristics (see Table 5) and complicating conditions at the start of care in labour (see Table 15) were summarised using standardised differences. All categorical variables were collapsed into binary variables and the standardised difference in proportions are presented. For continuous variables, the standardised difference in means are presented.

For the 'low risk' group of women, three separate models were fitted, one for each non-OU group with the OU as the reference group. In each model, the predicted probability that a woman would choose the non-OU setting as her planned place of birth represents the propensity score. Logistic regression was used to calculate a propensity score for each woman, fitting planned place of birth as the binary dependent variable and the baseline characteristics and complicating conditions at the start of care in labour as independent variables.

For each pairwise comparison of planned place of birth (each non-OU group versus the OU group), women were stratified into quintiles by propensity score and the standardised differences for each covariate were recalculated within each quintile. Dividing the women into subgroups that share similar observed characteristics is a way of controlling for systematic imbalances in these characteristics between the different planned places of birth. It has been shown that using five strata based on the propensity score removes 90% of the bias for each covariate included in the model. [33] Histograms were used to examine the distribution and overlap of the propensity scores for each non-OU/OU comparison. The analysis of the primary outcome was repeated within each quintile to produce quintile-specific estimates of the effect of planned place of birth. The overall odds ratios after adjusting for propensity score quintile are also presented with 95% confidence intervals and the Wald test was used to assess the homogeneity of odds ratios across quintiles.

Multiple imputation

To assess the effect of missing data on the results of the primary analysis, a sensitivity analysis was planned using multiple imputation techniques to impute missing data[34] for each of the potential confounders included in the adjusted regression models, under the assumption that the data were missing at random.[35] This assumes that the reason data are missing is not dependent on the value of the missing data if it were known. Missing outcome data would not be imputed since we cannot assume that these data are missing at random.

Software

All analyses were conducted using Stata SE version 11.1.[36]

3.12 Research ethics approval

The Berkshire Research Ethics Committee gave approval for the study in October 2007 (reference number: 07/H0505/151). An amendment to the original protocol was approved by a sub-committee of the Berkshire Research Ethics Committee in April 2008.

As part of the approval, individual women's consent was not required. All of the data collected were routinely recorded in the maternity, postnatal or neonatal notes and no personally identifiable data were to be sent to the study coordinating centre. The process of seeking and obtaining consent would have been likely to introduce substantial bias in the composition of the comparison groups and the care women received was not changed in any way as a result of the study.

4 Results

4.1 Overview of results section

Results are presented as follows:

- Participation, sample size and response rates and quality of data (sections 4.2)
- Missing data (section 4.3)
- Results for 'low risk' women:
    - Characteristics of women and babies (section 4.5)
    - Complicating conditions at the start of care in labour (section 4.6)
    - Transfers during labour or immediately after the birth (section 4.7)
    - Primary outcome (section 4.9)
    - Primary outcome by parity (section 4.10)
    - Perinatal outcomes (section 4.11)
    - Maternal outcomes (Section 4.12)
    - Primary outcome by transfer status (Section 4.13)
    - Sensitivity analyses (Section 4.14)
- Results for 'higher risk' women:
    - Characteristics of women and babies (Section 4.15)
    - Complicating conditions at the start of care in labour (Section 4.16)
    - Transfers during labour or immediately after the birth (Section 4.17)
    - Primary outcome by planned place of birth (Section 4.18)
    - Primary outcome by parity (Section 4.19)
    - Perinatal outcomes (Section 4.20)
    - Maternal outcomes (Section 4.21)

4.2 Participation, sample size and response rates

The number of trusts and units changed during the study period as trusts merged, units opened and units were closed. Our aim was to include every trust providing home birth services, every FMU, every AMU and a random sample of 37 OUs, stratified by whether they were in northern or southern England and unit size.

Of the 37 OUs that were sampled, five were replaced by resampling from within the same stratum for the following reasons: one unit was converted into an FMU, one unit closed before collecting any data and three declined or failed to participate. Of the 37 OUs in the final sample, one failed to successfully establish data collection. The data for the women and babies from this unit (n=71) were excluded from the analysis.

There was good participation for every unit type: 97% (n=142) of trusts that provided home birth services participated, 95% (n=53) of known FMUs

participated, and 84% (n=43) of AMUs participated. One unit which shared features of an FMU and OU participated but was excluded from the analysis because the unit did not fit our definition of any of the four planned places of birth.

The number of women included per unit/trust and the duration of participation per unit/trust varied both within and between unit types (Table 6). In general, OUs included the most women per unit, followed by AMUs, FMUs and then births planned at home, which had the fewest number of women included per trust. The pattern was the opposite for duration of participation. Trusts collecting data on births planned at home had the longest duration of participation per trust, followed by FMUs, AMUs and then OUs, which had the shortest participation per unit. However, there was a large amount of variation within each unit type. The highest recruiting trust for planned home births included more women than the lowest recruiting OU and the longest participating OU participated for longer than the shortest participating trust collecting data on births planned at home.

Table 6. Summary of unit and trust participation

		Obstetric Unit	Home	Freestanding midwifery unit	Alongside midwifery unit
Units in England[1]	n	180	147	56	51
Selected to participate[2]	n	37+5	-	-	-
Included in analyses					
Units	n	36	142	53	43
	%	86%	97%	95%	84%
Women per unit	median (min-max)	863 (346-1741)	96 (7-707)	174 (1-845)	362 (20-1289)
Period of data collection(days)	median (min-max)	151 (47-281)	529 (93-1034)	364 (34-758)	181 (31-468)

[1] Units open at the start of the study or known to have opened during the study period

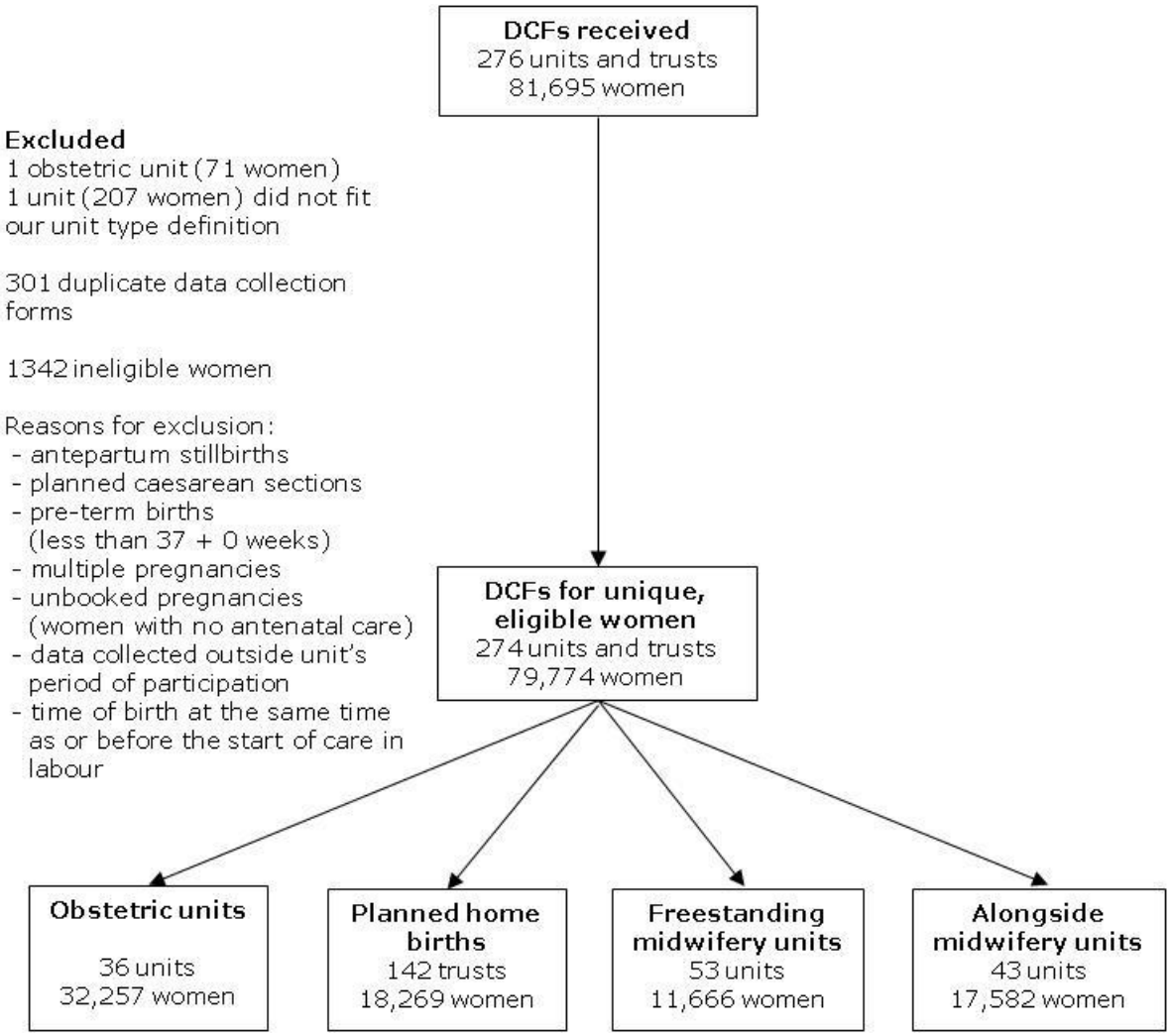
[2] Thirty seven obstetric units were initially sampled. Five units had to be replaced by re-sampling: one closed soon after the sampling was done, one was converted to a freestanding midwifery unit, and three declined or failed to participate. One additional obstetric unit started but failed to establish data collection was excluded from the analyses.

Data were collected for 81,695 women and babies from 276 units and trusts. A total of 1,921 data collection forms were excluded from the analysis dataset: 71 from the OU that failed to successfully establish data collection, 207 from the unit that was a hybrid between an FMU and OU, 301 duplicate forms, and 1,342 forms for women who were not eligible for the analyses specified for this report (Figure 1). Data were excluded as ineligible for antepartum stillbirths, pre-term births (less than 37 weeks and 0 days gestation), multiple pregnancies, 'unbooked' pregnancies (women with no antenatal care), for births which occurred outside a unit's period of

participation, and for births which occurred at the same time as or before the start of care in labour.

Data from 79,774 births from 274 units and trusts were included in the analysis dataset (Figure 1).

Figure 1. Inclusion/exclusion flow-chart



The quality of denominator data by type of unit is shown in Table 7. Response rates could only be calculated for units and trusts that provided complete or adequate denominator data. The majority of units (66% overall) provided complete denominator data and 26% provided adequate denominator data, which enabled an estimation of their total number of eligible women. A small minority (3% for OUs and 9-12% for other settings) of units provided poor or no denominator data.

The proportion of participating units that achieved a response rate of 85% or more is shown in Table 8. Overall, 74% of units/trusts achieved a response rate of 85% or more. The number of women included by units achieving/not achieving the 85% response rate target is shown in Table 9.

Table 7. Quality of denominator data by planned place of birth

	Quality of denominator data						
	Complete		Adequate[1]		Poor or missing		Total units
	n	%	n	%	n	%	n
OU	28	78	7	19	1	3	36
Home	88	62	41	29	13	9	142
FMU	33	62	15	28	5	9	53
AMU	31	72	7	16	5	12	43
Total	180	66	70	26	24	9	274

1 Denominator data were defined as adequate if they were incomplete but had been received for at least 50% of a unit's period of participation.

Table 8. Proportion of participating trusts/units achieving target 85% response rate

	Response rate				Poor or missing denominator		Total
	<85%		>=85%				
	n	%	n	%	n	%	N
OU	11	31	24	67	1	3	36
Home	16	11	113	80	13	9	142
FMU	13	25	35	66	5	9	53
AMU	7	16	31	72	5	12	43
Total	47	17	203	74	24	9	274

Table 9. Women included by response rate and planned place of birth

	Response rate				Poor or missing denominator		Total
	<85%		>=85%				
	n	%	n	%	n	%	n
OU	8513	26	23230	72	514	2	32257
Home	1446	8	15883	87	940	5	18269
FMU	1479	13	9858	85	329	3	11666
AMU	3077	18	13701	78	804	5	17582
Total	14515	18	62672	79	2587	3	79774

Response rates for the neonatal and maternal morbidity forms are shown in Table 10 and Table 11. Of the 79,774 women included in the study, a neonatal morbidity form was sent for completion for 2770 (3.5%) and, of

these 2615 (94%) were returned. A maternal morbidity form was sent for completion for 1490 (1.9%) women and of these, 1388 (93%) were returned. Some variation was seen in the return rate of both neonatal and maternal morbidity forms by planned place of birth.

Table 10. Neonatal morbidity form return rate by planned place of birth

	Neonatal morbidity forms				
	Returned		Not returned		Total
	n	%	n	%	n
OU	1396	95	73	5	1469
Home	475	95	24	5	499
FMU	315	94	20	6	335
AMU	429	92	38	8	467
Total	2615	94	155	6	2770

Table 11. Maternal morbidity form return rate by planned place of birth

	Maternal morbidity forms				
	Returned		Not returned		Total
	n	%	n	%	n
OU	778	96	36	4	814
Home	211	88	28	12	239
FMU	144	94	9	6	153
AMU	255	90	29	10	284
Total	1388	93	102	7	1490

4.3 Missing data

Data regarding whether the woman was known to have any 'risk factors', prior to the onset of labour, were recorded for over 99% of the 79,774 eligible women for whom data were collected.

Overall, 711 births from 'low risk' women (1.1%) had a missing primary outcome and were excluded from the unadjusted estimates of the incidence of the primary outcome (Table 12).

For the adjusted analyses, births were excluded where any data for potential confounders were missing. Of all births from 'low risk' women, 2.9% (1903 births) were missing some confounder data (Table 12).

Taking both the missing primary outcome data and missing confounder data into account, 3.9% of 'low risk' births (2502) were excluded from the primary analysis (Table 12). In each setting, the completeness of data collection was good with over 95% of 'low risk' women included in the primary adjusted analyses.

Table 12. Summary of missing data for 'low risk' women by planned place of birth

Unit type	All 'low risk'	Primary outcome missing		Confounder missing		Primary analysis Excluded[1]		Included	
	n	n	%	n	%	n	%	n	%
OU	19706	155	0.8	724	3.7	859	4.4	18847	95.6
Home	16840	287	1.7	414	2.5	653	3.9	16187	96.1
FMU	11282	83	0.7	241	2.1	311	2.8	10971	97.2
AMU	16710	186	1.1	524	3.1	679	4.1	16031	95.9
Total	64538	711	1.1	1903	2.9	2502	3.9	62036	96.1

[1] *Births were excluded if either the primary outcome or any of the potential confounders was missing.*

One observation with a primary outcome recorded was dropped from both the unadjusted and adjusted analyses because the woman's 'risk status' was missing. This birth was planned in an AMU and the outcome was clinical neonatal encephalopathy.

Three births with a primary outcome recorded were dropped from the adjusted analyses due to missing confounder data (1.2% of the 250 primary outcome events for 'low risk' births). Two were planned OU births (one meconium aspiration syndrome and one clinical neonatal encephalopathy); one was a planned home birth (clinical neonatal encephalopathy).

The missing data are described in more detail in Appendix 4.

4.4 'Risk profile' of the sample

In total, the cohort included 79,774 eligible women, of which 64,538 were classified as 'low risk': the proportion of 'higher risk' women was 38.4% in the OUs and ranged from 2.5% to 7.4% for other planned places of birth.

Table 13. 'Risk profile' of the sample

	OU n=32257		Home n=18269		FMU n=11666		AMU n=17582		Total n=79774
	n	%	n	%	n	%	n	%	n
Risk status									
'Low risk'	19706	61.1	16840	92.2	11282	96.7	16710	95.0	64538
'Higher risk'	12374	38.4	1346	7.4	289	2.5	776	4.4	14785
Missing	177	0.5	83	0.5	95	0.8	96	0.5	451

4.5 Characteristics of 'low risk' women and babies

Table 14 shows the characteristics of 'low risk' women and their babies by planned place of birth. Characteristics varied by planned place of birth:

- Compared to women planning to give birth in an OU, women planning a birth at home tended to be older (28% aged 35 or over at home compared with 16% aged 35 or over in OUs), were more likely to be white, have a fluent understanding of English, be married or living with a partner, to be living in a more socioeconomically advantaged area, and were markedly more likely to have had one or more previous pregnancies. There was little difference in gestational age although there were slightly more women in OUs at the extremes of gestational age within the limits of 37 to 44 weeks. There was also little difference in the distribution of body mass index (BMI), although BMI was not recorded in the medical notes for 18% of women. The distribution of birthweight indicated that the babies born at home tended to be heavier at birth.
- The characteristics of women planning a birth in a FMU or AMU tended to fall between the OU and home birth group with the characteristics of women in the alongside group generally closer to that of the OU group. Relative to women planning a birth in an OU or AMU, women planning a birth in a FMU were more likely to be white, have a fluent understanding of English and to live in a more socioeconomically advantaged area.
- The most marked contrast between the home birth group and the three other groups was in the distribution of parity: 27% of women planning a birth at home were nulliparous compared to 46% in FMUs, 50% in AMUs and 54% in OUs.

Table 14. Characteristics of 'low risk' women and babies by planned place of birth

	OU n=19706		Home n=16840		FMU n=11282		AMU n=16710	
	n	%	n	%	n	%	n	%
Maternal age								
Mean [SD]	28.2	[6.0]	31.1	[5.2]	28.8	[5.8]	28.3	[5.7]
Under 20	1506	7.7	218	1.3	677	6.0	1069	6.4
20-24	4251	21.6	1706	10.2	2132	18.9	3489	20.9
25-29	5701	29.0	4346	25.9	3267	29.0	5001	30.0
30-34	5063	25.7	5848	34.8	3248	28.8	4582	27.5
35-39	2640	13.4	4017	23.9	1690	15.0	2232	13.4
40+	520	2.6	671	4.0	254	2.3	299	1.8
Missing	25		34		14		38	
Ethnic group								
White	16068	81.7	15937	94.8	10329	91.6	13485	80.9
Indian	477	2.4	67	0.4	87	0.8	509	3.1
Pakistani	636	3.2	41	0.2	164	1.5	545	3.3
Bangladeshi	297	1.5	14	0.1	147	1.3	130	0.8
Black Caribbean	265	1.3	127	0.8	48	0.4	198	1.2
Black African	670	3.4	112	0.7	94	0.8	520	3.1
Mixed	328	1.7	280	1.7	124	1.1	293	1.8
Other	938	4.8	241	1.4	284	2.5	993	6.0
Missing	27		21		5		37	
Understanding of English								
Fluent	18044	92.3	16724	99.5	10927	97.1	15196	91.3
Some	1130	5.8	75	0.4	273	2.4	1176	7.1
None	380	1.9	15	0.1	55	0.5	274	1.6
Missing	152		26		27		64	
Marital/Partner status								
Married/Living together	17097	88.2	16056	96.0	10444	93.6	15014	91.2
Single/Unsupported by partner	2289	11.8	673	4.0	718	6.4	1453	8.8
Missing	320		111		120		243	
Body mass index (kg/m^2)								
Mean [SD]	24.4	[4.0]	24.0	[3.7]	24.1	[3.7]	24.0	[3.8]
Not recorded	3566	18.1	3268	19.5	1861	16.5	2927	17.6
Less than 18.5	570	2.9	321	1.9	234	2.1	438	2.6
18.5-24.9	8856	45.1	8155	48.7	5605	49.8	8218	49.4
25.0-29.9	4731	24.1	3776	22.5	2653	23.6	3789	22.8
30.0-35.0	1928	9.8	1226	7.3	912	8.1	1272	7.6
Missing	55		94		17		66	

	OU n=19706		Home n=16840		FMU n=11282		AMU n=16710	
	n	%	n	%	n	%	n	%
IMD quintiles								
1st Least deprived	3157	16.1	3688	22.1	2496	22.2	2535	15.2
2nd	3618	18.5	3483	20.8	2582	22.9	2648	15.9
3rd	3698	18.9	3650	21.8	2304	20.5	3245	19.5
4th	4084	20.9	3336	19.9	2080	18.5	3852	23.1
5th Most deprived	5023	25.7	2565	15.3	1789	15.9	4382	26.3
Missing	126		118		31		48	
Previous pregnancies >=24 completed weeks								
0 Nulliparous	10626	54.0	4568	27.2	5187	46.0	8350	50.1
1 previous	5757	29.3	6528	38.8	3913	34.7	5621	33.7
2 previous	2028	10.3	3663	21.8	1513	13.4	1933	11.6
3+ previous	1264	6.4	2065	12.3	652	5.8	769	4.6
Missing	31		16		17		37	
Gestation (completed weeks)								
Mean [SD]	39.8	[1.1]	39.8	[1.0]	39.8	[1.0]	39.7	[1.0]
37	717	3.6	378	2.3	315	2.8	474	2.8
38	1969	10.0	1568	9.3	978	8.7	1565	9.4
39	4557	23.2	4089	24.3	2669	23.7	4132	24.8
40	6976	35.5	6596	39.3	4364	38.8	6492	39.0
41	4908	25.0	3866	23.0	2821	25.1	3797	22.8
42-44	523	2.7	302	1.8	108	1.0	195	1.2
Missing[1]	56		41		27		55	
Birthweight (grams)								
Mean [SD]	3452	[462.1]	3552	[444.6]	3487	[435.7]	3462	[436.4]
Less than 2500g	277	1.4	86	0.5	101	0.9	160	1.0
2500-2999g	2867	14.6	1562	9.3	1327	11.8	2135	12.8
3000-3499g	7708	39.2	6015	35.8	4431	39.3	6765	40.6
3500-3999g	6473	32.9	6404	38.1	4025	35.7	5692	34.2
4000-4499g	2026	10.3	2361	14.1	1246	11.1	1703	10.2
≥4500g	322	1.6	362	2.2	146	1.3	206	1.2
Missing	33		50		6		49	

[1] See section 3.9.2

4.6 Complicating conditions at the start of care in labour

There were marked differences between planned places of birth in the proportion of women with complicating conditions identified by the attending midwife at the start of care in labour (Table 15). Almost 20% of women whose planned place of birth at start of labour care was an OU had at least one complicating condition noted at the start of care in labour compared with fewer than 7% for all other planned places of birth. The most common conditions noted by the attending midwife at the start of care in labour were prolonged rupture of membranes and meconium stained liquor. The prevalence of proteinuria was similar for OUs (1.8%) and AMUs (2.2%). For all other complicating conditions, rates were higher in the women planning birth in an OU and similar across the three other settings.

The higher prevalence of women with complicating conditions at the start of care in labour in the planned OU group was unexpected in this 'low risk' group of women. A possible explanation is that in a proportion of cases where complicating conditions such as pre-labour rupture of membranes and/or meconium staining occur in women planning a non-OU birth, the women are advised by their midwife – perhaps by phone – to go directly to the OU. This would result in an OU becoming the planned place of birth "at the start of care in labour".

The higher prevalence of complicating conditions at the start of care in labour was discussed by the co-investigators and the independent Advisory Group prior to the analysis of outcomes. It was agreed to modify the analysis plan to include additional analyses of outcomes by planned place of birth, restricted to women without complicating conditions identified at the start of care in labour. The purpose of this restricted analysis was to enable outcomes to be compared across groups that were homogeneous with regard to risk.

Table 15. Complicating conditions identified at the start of care in labour in 'low risk' women by planned place of birth

	OU n=19706		Home n=16840		FMU n=11282		AMU n=16710	
	n	%	n	%	n	%	n	%
Prolonged rupture of membranes (>18 hours)	1462	7.4	395	2.4	231	2.1	383	2.3
Meconium stained liquor	1254	6.4	242	1.5	140	1.2	233	1.4
Proteinuria (1+ or more)	347	1.8	80	0.5	110	1.0	370	2.2
Hypertension	502	2.6	92	0.6	78	0.7	113	0.7
Abnormal vaginal bleeding	274	1.4	41	0.2	22	0.2	37	0.2
Non-cephalic presentation	108	0.6	37	0.2	25	0.2	29	0.2
Abnormal fetal heart rate	393	2.0	68	0.4	52	0.5	65	0.4
Other	54	0.3	14	0.1	17	0.2	17	0.1
Conditions per woman:								
0	15794	80.5	15757	94.6	10643	94.5	15512	93.1
1	3345	17.0	847	5.1	572	5.1	1078	6.5
2+	490	2.5	51	0.3	50	0.4	78	0.5
Missing	77		185		17		42	

4.7 Transfers during labour or immediately after the birth for 'low risk' women

The pattern of transfer varied by planned place of birth (Table 16):

- In the planned home birth group, 21% of women transferred during labour or after birth. Just over two thirds of these transfers took place during labour, and 31% took place after delivery.
- In the planned FMU group, 22% of women transferred during labour or after birth. Of these transfers, 77% were before the birth.
- In the planned AMU group, 26% of women transferred during labour or after birth. Of these transfers, 83% were before the birth.

Reasons for transfer, expressed as percentages of *all transfers,* are shown in Table 16. and reasons for transfer expressed as percentages of *all women* are shown in Table 17. Numbers are small for most individual reasons:

- The most common reasons for transfer from home were failure to progress (33% overall, after combining first and second stage and

unspecified timing) and meconium staining (12%). Fetal distress (first or second stage) accounted for 7% of transfers from home.

- Women in the planned home birth and FMU groups were less likely to transfer for an epidural compared with the planned AMU group.
- As a proportion of all transfers, retained placenta was more common as a reason for transfer in the home and FMU groups (over 7% of transfers in the home and FMU groups vs. 4.7% of transfers in the AMU group). However, when expressed as a percentage of all planned 'low risk' births in each setting, the transfer rates for retained placenta were broadly similar across the three non-OU settings (1.2–1.6%) (Table 17).
- Neonatal concerns were most common as a reason for transfer in the planned home birth group. These occurred infrequently in the AMU group, probably reflecting the fact that the mother did not need to be transferred if the baby needed admission for a higher level of care.
- Transfers for fetal distress were slightly less common in the home birth group compared with planned FMU and AMU births (7.0% of transfers in the home birth group vs. 10.6% and 11.1% in the FMU and AMU groups). As a proportion of all planned births in each setting, transfer for fetal distress occurred in 1.5% of all planned home births, 2.3% of planned FMU births and 2.9% of all planned AMU births.

Table 16. Transfers during labour or immediately after the birth for 'low risk' women

	OU n=19706		Home n=16840		FMU n=11282		AMU n=16710	
	n	%	n	%	n	%	n	%
Transfer during labour or after the birth?								
No	19571	99.3	13310	79.0	8814	78.1	12300	73.6
Yes	135	0.7	3530	21.0	2468	21.9	4410	26.4
Missing	-		-		-		-	
Timing of start of transfer (as a proportion of all women transferred)								
Before delivery			2387	69.5	1863	77.4	3539	83.1
After delivery			1046	30.5	545	22.6	719	16.9
Missing			97		60		152	
Primary reasons for transfer (as a proportion of all women transferred)								
Failure to progress (1st stage)			755	21.6	542	22.3	849	19.8
Fetal distress (1st stage)			184	5.3	206	8.5	305	7.1
Meconium staining			432	12.4	301	12.4	538	12.5
Epidural request			180	5.2	163	6.7	585	13.6
Hypertension			75	2.1	64	2.6	98	2.3
Malposition			26	0.7	11	0.5	32	0.7
Malpresentation			70	2.0	42	1.7	66	1.5
Antepartum haemorrhage			60	1.7	46	1.9	83	1.9
Failure to progress (2nd stage)			385	11.0	368	15.1	692	16.1
Fetal distress (2nd stage)			41	1.2	35	1.4	147	3.4
Postpartum haemorrhage			142	4.1	90	3.7	123	2.9
Retained placenta			250	7.2	179	7.4	203	4.7
Repair of perineal trauma			386	11.1	184	7.6	369	8.6
Other (detail not recorded)			26	0.7	5	0.2	9	0.2
Other specified reason:								
Prolonged rupture of membranes			23	0.7	12	0.5	40	0.9
Failure to progress (stage not specified)			4	0.1	2	0.1	7	0.2
Fetal distress (stage not specified)			21	0.6	18	0.7	25	0.6
Maternal (antepartum transfer)			47	1.3	33	1.4	55	1.3
Fetal (antepartum transfer)			12	0.3	13	0.5	7	0.2
Pain relief (epidural not specified or other)			72	2.1	4	0.2	6	0.1
Maternal request (not pain relief)			52	1.5	5	0.2	4	0.1
Maternal (postpartum transfer)			25	0.7	20	0.8	12	0.3
Retained products (other than placenta)			1	-	0	-	0	-
Neonatal concerns (postpartum transfer)			180	5.2	63	2.6	5	0.1
Non-medical reason (staffing or equipment)			29	0.8	2	0.1	13	0.3
Non-medical reason (domestic)			2	0.1	0	-	0	-
Non-medical (other)			2	0.1	2	0.1	1	-
Did not meet unit's eligibility criteria			0	-	1	-	6	0.1
Other pre-existing maternal or fetal reason			10	0.3	21	0.9	18	0.4
Missing			38		36		112	

Table 17. Primary reason for transfer expressed as a percentage of all 'low risk' women

	OU n=19706		Home n=16840		FMU n=11282		AMU n=16710	
	n	%	n	%	n	%	n	%
Primary reasons for transfer (as a proportion of all 'low risk' women)								
Failure to progress (1st stage)			755	4.5	542	4.8	849	5.1
Fetal distress (1st stage)			184	1.1	206	1.8	305	1.8
Meconium staining			432	2.6	301	2.7	538	3.2
Epidural request			180	1.1	163	1.4	585	3.5
Hypertension			75	0.4	64	0.6	98	0.6
Malposition			26	0.2	11	0.1	32	0.2
Malpresentation			70	0.4	42	0.4	66	0.4
Antepartum haemorrhage			60	0.4	46	0.4	83	0.5
Failure to progress (2nd stage)			385	2.3	368	3.3	692	4.1
Fetal distress (2nd stage)			41	0.2	35	0.3	147	0.9
Postpartum haemorrhage			142	0.8	90	0.8	123	0.7
Retained placenta			250	1.5	179	1.6	203	1.2
Repair of perineal trauma			386	2.3	184	1.6	369	2.2
Other (detail not recorded)			26	0.2	5	0.0	9	0.1
Other specified reason:				-		-		-
Prolonged rupture of membranes			23	0.1	12	0.1	40	0.2
Failure to progress (stage not specified)			4	0.0	2	0.0	7	0.0
Fetal distress (stage not specified)			21	0.1	18	0.2	25	0.1
Maternal (antepartum transfer)			47	0.3	33	0.3	55	0.3
Fetal (antepartum transfer)			12	0.1	13	0.1	7	0.0
Pain relief (epidural not specified or other)			72	0.4	4	0.0	6	0.0
Maternal request (not pain relief)			52	0.3	5	0.0	4	0.0
Maternal (postpartum transfer)			25	0.1	20	0.2	12	0.1
Retained products (other than placenta)			1	0.0	0	-	0	-
Neonatal concerns (postpartum transfer)			180	1.1	63	0.6	5	0.0
Non-medical reason (staffing or equipment)			29	0.2	2	0.0	13	0.1
Non-medical reason (domestic)			2	0.0	0	-	0	-
Non-medical (other)			2	0.0	2	0.0	1	0.0
Did not meet unit's eligibility criteria			0	-	1	0.0	6	0.0
Other pre-existing maternal or fetal reason			10	0.1	21	0.2	18	0.1
Missing (reason not stated)			38	0.2	36	0.3	112	0.7
Total transferred	135	0.7	3530	21.0	2468	21.9	4410	26.4
Most common reasons for transfer (≥1% in any setting)								
Failure to progress (any stage)			1144	6.8	912	8.1	1548	9.3
Fetal distress			246	1.5	259	2.3	477	2.9
Epidural request			180	1.1	163	1.4	585	3.5
Meconium staining			432	2.6	301	2.7	538	3.2
Retained placenta			250	1.5	179	1.6	203	1.2
Repair of perineal trauma			386	2.3	184	1.6	369	2.2
Neonatal concerns (postpartum transfer)			180	1.1	63	0.6	5	0.0

4.8 Transfers during labour or immediately after birth for 'low risk' women by parity

There were marked difference in transfer rates by parity (Table 18). In all three non-OU groups, more than a third of nulliparous women transferred during labour or immediately after birth. The proportion of nulliparous women transferring was highest (45%) in the planned home birth group.

Transfer rates in multiparous women ranged from 9.4% for planned AMU births to 13% for planned AMU births.

Table 18. Transfers during labour or immediately after birth for 'low risk' women by parity

	OU		Home		FMU		AMU	
	n	%	n	%	n	%	n	%
Nulliparous women	n=10626		n=4568		n=5187		n=8350	
Not transferred	10524	99.0	2511	55.0	3303	63.7	4990	59.8
Transferred	102	1.0	2057	45.0	1884	36.3	3360	40.2
Missing	-		-		-		-	
Multiparous women	n=9049		n=12256		n=6078		n=8323	
Not transferred	9016	99.6	10784	88.0	5505	90.6	7282	87.5
Transferred	33	0.4	1472	12.0	573	9.4	1041	12.5
Missing	-		-		-		-	

The timing of transfer also varied markedly by parity (Table 19). More than three quarters of transfers in nulliparous women (80-87% depending on setting) occurred before delivery; whereas for multiparous women, the proportion of transfers before delivery was substantially lower for planned home and FMU births (55% and 57% respectively) with correspondingly more transfers after delivery occurring after delivery in multiparous women in these two settings (Table 19).

Table 19. Timing of transfer for 'low risk' women by parity

	OU		Home		FMU		AMU	
	n	%	n	%	n	%	n	%
Nulliparous women								
Timing of transfer (as a proportion of nulliparous women transferred):								
Before delivery			1605	79.8	1535	83.4	2825	86.9
After delivery			407	20.2	306	16.6	427	13.1
Missing			45		43		108	
Multiparous women								
Timing of start of transfer (as a proportion of all multiparous women transferred):								
Before delivery			782	55.0	321	57.4	707	70.8
After delivery			639	45.0	238	42.6	291	29.2
Missing			51		14		43	

Reasons for transfer of nulliparous and multiparous women are shown in Table 20 and Table 21, with the more commonly occurring reasons summarised at the foot of each table.

Although there were some differences between settings in reasons for transfer no clear pattern was evident.

The relatively small number of AMU transfers attributed to neonatal concerns is likely to reflect the fact that, unlike births occurring at home or in an FMU, women who give birth in an AMU do not need to be transferred if their baby requires admission.

4.9 Occurrence of the primary outcome in 'low risk' women by planned place of birth

As described in section 2.3, the primary outcome is a composite of the following adverse perinatal outcomes:

- Stillbirth after the start of care in labour.
- Early neonatal death (within 7 days).
- Neonatal encephalopathy defined as either a clinical diagnosis of neonatal encephalopathy or 'signs of neonatal encephalopathy'.
- Meconium aspiration syndrome.
- Brachial plexus injury.
- Fractured humerus or clavicle.

The overall weighted incidence of the primary outcome was 4.3 events per 1000 births in 'low risk' women and 3.1 per 1000 births in 'low risk' women without complicating conditions at the start of care in labour.

The distribution of events contributing to the primary outcome is shown in Table 22. Neonatal encephalopathy and meconium aspiration syndrome were the most common events, together accounting for three quarters of the events in the composite primary outcome. Intrapartum stillbirths and early neonatal deaths accounted for 13% of the events contributing to the primary outcome. Fractured humerus and clavicle were uncommon outcomes and accounted for less than 4% of the primary outcome events.

Table 20. Reason for transfer, nulliparous 'low risk' women

	OU n=10626		Home n=4568		FMU n=5187		AMU n=8350	
	n	%	n	%	n	%	n	%
Primary reasons for transfer (as a proportion of all nulliparous 'low risk' women)								
Failure to progress (1st stage)			539	11.8	462	8.9	731	8.8
Fetal distress (1st stage)			99	2.2	168	3.2	230	2.8
Meconium staining			252	5.5	248	4.8	404	4.8
Epidural request			135	3.0	139	2.7	447	5.4
Hypertension			42	0.9	48	0.9	78	0.9
Malposition			11	0.2	8	0.2	24	0.3
Malpresentation			34	0.7	29	0.6	44	0.5
Antepartum haemorrhage			34	0.7	32	0.6	65	0.8
Failure to progress (2nd stage)			306	6.7	318	6.1	591	7.1
Fetal distress (2nd stage)			30	0.7	29	0.6	108	1.3
Postpartum haemorrhage			54	1.2	37	0.7	56	0.7
Retained placenta			87	1.9	82	1.6	96	1.1
Repair of perineal trauma			204	4.5	145	2.8	263	3.1
Other (detail not recorded)			9	0.2	2	0.0	5	0.1
Other specified reason:						0.0		0.0
Prolonged rupture of membranes			14	0.3	9	0.2	29	0.3
Failure to progress (stage not specified)			1	0.0	1	0.0	6	0.1
Fetal distress (stage not specified)			12	0.3	13	0.3	18	0.2
Maternal (antepartum transfer)			30	0.7	24	0.5	42	0.5
Fetal (antepartum transfer)			7	0.2	2	0.0	6	0.1
Pain relief (epidural not specified or other)			51	1.1	4	0.1	4	0.0
Maternal request (not pain relief)			21	0.5	2	0.0	0	0.0
Maternal (postpartum transfer)			8	0.2	9	0.2	7	0.1
Retained products (other than placenta)	-			-		-		
Neonatal concerns (postpartum transfer)			42	0.9	32	0.6	2	0.0
Non-medical reason (staffing or equipment)			15	0.3	0	0.0	11	0.1
Non-medical reason (domestic)			1	0.0	0	0.0	0	0.0
Non-medical (other)			1	0.0	2	0.0	1	0.0
Did not meet unit's eligibility criteria			0	0.0	0	0.0	2	0.0
Other pre-existing maternal or fetal reason			3	0.1	11	0.2	8	0.1
Missing (reason not stated)			15	0.3	28	0.5	82	1.0
Total transferred	102	1.0	2057	45.0	1884	36.3	3360	40.2
Most common reasons for transfer (≥1% in any setting)								
Failure to progress			846	18.5	781	15.1	1328	15.9
Fetal distress			141	3.1	210	4.0	356	4.3
Meconium staining			252	5.5	248	4.8	404	4.8
Epidural request			135	3.0	139	2.7	447	5.4
Pain relief (epidural not specified or other)			51	1.1	4	0.1	4	0.0
Postpartum haemorrhage			54	1.2	37	0.7	56	0.7
Repair of perineal trauma			204	4.5	145	2.8	263	3.1
Retained placenta			87	1.9	82	1.6	96	1.1

Table 21. Reasons for transfer, multiparous 'low risk' women

	OU n=9049		Home n=12256		FMU n=6078		AMU n=8323	
	n	%	n	%	n	%	n	%
Primary reasons for transfer (as a proportion of all multiparous 'low risk' women)								
Failure to progress (1st stage)			216	1.8	77	1.3	115	1.4
Fetal distress (1st stage)			85	0.7	37	0.6	75	0.9
Meconium staining			180	1.5	53	0.9	133	1.6
Epidural request			45	0.4	24	0.4	137	1.6
Hypertension			33	0.3	16	0.3	20	0.2
Malposition			15	0.1	3	0.0	8	0.1
Malpresentation			36	0.3	13	0.2	22	0.3
Antepartum haemorrhage			26	0.2	14	0.2	18	0.2
Failure to progress (2nd stage)			78	0.6	48	0.8	99	1.2
Fetal distress (2nd stage)			11	0.1	6	0.1	39	0.5
Postpartum haemorrhage			88	0.7	53	0.9	67	0.8
Retained placenta			163	1.3	96	1.6	106	1.3
Repair of perineal trauma			182	1.5	38	0.6	105	1.3
Other (detail not recorded)			17	0.1	3	0.0	4	0.0
Other specified reason:				0.0		0.0		0.0
Prolonged rupture of membranes			9	0.1	3	0.0	11	0.1
Failure to progress (stage not specified)			3	0.0	1	0.0	1	0.0
Fetal distress (stage not specified)			9	0.1	5	0.1	7	0.1
Maternal (antepartum transfer)			17	0.1	9	0.1	13	0.2
Fetal (antepartum transfer)			5	0.0	11	0.2	1	0.0
Pain relief (epidural not specified or other)			21	0.2	0	0.0	2	0.0
Maternal request (not pain relief)			31	0.3	3	0.0	4	0.0
Maternal (postpartum transfer)			17	0.1	11	0.2	5	0.1
Retained products (other than placenta)			1	0.0	0	0.0	0	0.0
Neonatal concerns (postpartum transfer)			138	1.1	31	0.5	3	0.0
Non-medical reason (staffing or equipment)			14	0.1	2	0.0	2	0.0
Non-medical reason (domestic)			1	0.0	0	0.0	0	0.0
Non-medical (other)			1	0.0	0	0.0	0	0.0
Did not meet unit's eligibility criteria			0	0.0	1	0.0	4	0.0
Other pre-existing maternal or fetal reason			7	0.1	9	0.1	10	0.1
Missing (reason not stated)			23	0.2	6	0.1	30	0.4
Total transferred	33	0.4	1472	12.0	573	9.4	1041	12.5
Most common reasons for transfer (≥1% in any setting)								
Failure to progress			297	2.4	126	2.1	215	2.6
Fetal distress			105	0.9	48	0.8	121	1.5
Meconium staining			180	1.5	53	0.9	133	1.6
Epidural request			182	1.5	38	0.6	105	1.3
Repair of perineal trauma			45	0.4	24	0.4	137	1.6
Retained placenta			163	1.3	96	1.6	106	1.3
Neonatal concerns (postpartum transfer)			138	1.1	31	0.5	3	0.0

Table 22. Contribution of individual outcome events to the composite primary outcome in 'low risk' women

	n	% of the primary outcome
Stillbirth	14	5.6
Early neonatal death (within 7 days)	18	7.2
Neonatal encephalopathy (clinical diagnosis)	96	38.4
Neonatal encephalopathy (signs)	18	7.2
Meconium aspiration syndrome	75	30
Brachial plexus injury	20	8
Fractured Humerus	2	0.8
Fractured clavicle	7	2.8
Total	250	100

The categories above are mutually exclusive and outcomes listed higher in the table take precedence over outcomes listed lower down. For example, if a baby with neonatal encephalopathy died within 7 days the outcome is recorded as an early neonatal death in this table.

Table 23 shows the incidence of the primary outcome, the unadjusted and adjusted odds ratios by planned place of birth for all 'low risk' women and for women without complicating conditions at the start of care in labour

For all 'low risk' women, there were no significant differences in the odds of the primary outcome for births planned at home, in an FMU or in an AMU compared with planned OU births.

For the restricted sample of 'low risk' women, without complicating conditions at the start of labour care, the odds of an adverse perinatal outcome were significantly elevated for births planned at home compared with planned OU births (adjusted OR 1.59, 95% CI 1.01-2.52) although the lower bound of the confidence interval was close to one. For planned FMU and AMU births the odds of the primary outcome did not differ from the planned OU births.

Table 23. Primary outcome for babies of 'low risk' women by planned place of birth

	Events	Births	Weighted[1]		Unadjusted[1]		Unadjusted[1, 2]		Adjusted[1, 3]	
	n	n	n/1000	(95% CI)	OR	(95% CI)	OR	(95% CI)	OR	(95% CI)
Planned place of birth						n=63827		n=62036		n=62036
OU	81	19551	4.4	(3.2-5.9)	1	-	1	-	1	-
Home	70	16553	4.2	(3.2-5.4)	0.96	(0.64-1.42)	0.96	(0.65-1.42)	1.16	(0.76-1.77)
FMU	41	11199	3.5	(2.5-4.9)	0.80	(0.51-1.27)	0.82	(0.52-1.28)	0.92	(0.58-1.46)
AMU	58	16524	3.6	(2.6-4.9)	0.82	(0.52-1.27)	0.84	(0.54-1.30)	0.92	(0.60-1.39)
Total	250	63827	4.3	(3.3-5.5)						
Planned place of birth (restricted to women without complicating conditions at the start of care in labour)										
						n=57127		n=55572		n=55572
OU	48	15676	3.1	(2.2-4.2)	1	-	1	-	1	-
Home	62	15538	4.0	(3.0-5.3)	1.31	(0.86-2.00)	1.34	(0.88-2.05)	1.59	(1.01-2.52)
FMU	35	10571	3.2	(2.3-4.6)	1.06	(0.66-1.71)	1.11	(0.69-1.77)	1.22	(0.76-1.96)
AMU	54	15342	3.4	(2.4-4.9)	1.12	(0.70-1.81)	1.19	(0.74-1.91)	1.26	(0.80-1.99)
Total	199	57127	3.1	(2.4-4.0)						

1 Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.
2 Restricted to women included in the adjusted analysis.
3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks, and gestation (completed weeks).

The distributions of events contributing to the primary outcome were broadly similar in each planned place of birth, although the numbers in each category were small (See Table 48 and Table 49 in Appendix 5).

4.10 Occurrence of the primary outcome by parity in 'low risk' women by planned place of birth

A pre-specified subgroup analysis was completed to investigate whether the effect of planned place of birth on the primary and secondary outcomes was consistent for nulliparous and multiparous women.

There was an interaction of borderline significance (p=0.06) between planned place of birth and parity for 'low risk' women overall and a significant interaction (p=0.03) for 'low risk' women without complicating conditions at the start of care in labour indicating that the effect of planned place on the primary outcome was different for nulliparous and multiparous 'low risk' women.

For nulliparous women overall (Table 24), there was a statistically significant increase in the odds of the primary outcome for planned home births compared with planned OU births (adjusted odds ratio 1.75, 95% CI 1.07-2.86); while for multiparous 'low risk' women there were no differences in the primary outcome for births planned at home, in an FMU or in an AMU compared with planned OU births.

Table 24. Primary outcome for 'low risk' women by parity and planned place of birth

	Events	Births	Weighted[1]		Unadjusted[1]		Unadjusted[1, 2]		Adjusted[1, 3]	
					n=63732		n=62036		n=62036	
	n	n	n/1000	(95% CI)	OR	(95% CI)	OR	(95% CI)	OR	(95% CI)
Planned place of birth										
Nulliparous women					n=28443		n=27669		n=27669	
OU	52	10541	5.3	(3.9-7.3)	1	-	1	-	1	-
Home	39	4488	9.3	(6.5-13.1)	1.75	(1.08-2.82)	1.76	(1.10-2.82)	1.75	(1.07-2.86)
FMU	24	5158	4.5	(2.8-7.1)	0.84	(0.48-1.48)	0.85	(0.49-1.48)	0.91	(0.52-1.60)
AMU	38	8256	4.7	(3.1-7.2)	0.89	(0.52-1.51)	0.90	(0.53-1.54)	0.96	(0.58-1.61)
Total	153	28443	5.3	(4.0-7.0)						
Multiparous women					n=35289		n=34367		n=34367	
OU	29	8980	3.3	(2.2-5.0)	1	-	1	-	1	-
Home	31	12050	2.3	(1.6-3.2)	0.70	(0.41-1.19)	0.70	(0.40-1.21)	0.72	(0.41-1.27)
FMU	17	6025	2.7	(1.6-4.6)	0.83	(0.42-1.63)	0.86	(0.44-1.69)	0.91	(0.46-1.80)
AMU	20	8234	2.4	(1.4-4.3)	0.73	(0.36-1.50)	0.77	(0.38-1.57)	0.81	(0.40-1.62)
Total	97	35289	3.1	(2.2-4.5)						

Adjusted regression test of heterogeneity p-values: Home 0.01 ; FMU 0.99 ; AMU 0.69 ; Overall 0.06

1 Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.

2 Restricted to women included in the adjusted analysis.

3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks, and gestation (completed weeks).

A broadly similar pattern was seen for 'low risk' women without complicating conditions at the start of care in labour. In nulliparous 'low risk' women without complicating conditions at the start of care in labour there was a significantly increased odds of the primary outcome for planned home births (adjusted odds ratio 2.80, 95% CI 1.59-4.92) with the weighted absolute event rate for planned home births (unadjusted) more than doubling (9.5 events vs. 3.5 events per 1000 births) relative to the OU group (Table 25). For multiparous 'low risk' women without complicating conditions at the start of care in labour there were no significant differences in the primary outcome for births planned at home, in a FMU or in an AMU compared with planned OU births.

Table 25. Primary outcome for 'low risk' women without complicating conditions at the start of care in labour by parity and planned place of birth

	Events	Births	Weighted[1]		Unadjusted[1]		Unadjusted[1, 2]		Adjusted[1, 3]	
					n=57046		n=55572		n=55572	
	n	n	n/1000	(95% CI)	OR	(95% CI)	OR	(95% CI)	OR	(95% CI)
Planned place of birth (restricted to women without complicating conditions at the start of care in labour)										
Nulliparous women					n=24384		n=23742		n=23742	
OU	28	8018	3.5	(2.4-5.1)	1	-	1	-	1	-
Home	36	4063	9.5	(6.6-13.7)	2.73	(1.60-4.64)	2.81	(1.66-4.76)	2.80	(1.59-4.92)
FMU	22	4785	4.5	(2.8-7.4)	1.30	(0.70-2.40)	1.33	(0.72-2.46)	1.40	(0.74-2.65)
AMU	35	7518	4.4	(2.7-7.0)	1.25	(0.68-2.30)	1.31	(0.71-2.39)	1.38	(0.75-2.52)
Total	121	24384	3.8	(2.8-5.1)						
Multiparous					n=32662		n=31830		n=31830	
OU	20	7637	2.6	(1.5-4.4)	1	-	1	-	1	-
Home	26	11461	2.0	(1.4-2.9)	0.78	(0.41-1.51)	0.80	(0.41-1.54)	0.83	(0.44-1.58)
FMU	13	5772	2.2	(1.3-3.8)	0.85	(0.39-1.83)	0.90	(0.42-1.94)	0.97	(0.46-2.04)
AMU	19	7792	2.5	(1.4-4.5)	0.97	(0.44-2.14)	1.04	(0.47-2.30)	1.09	(0.50-2.39)
Total	78	32662	2.5	(1.6-3.9)						

Adjusted regression test of heterogeneity p-values: Home 0.006 ; FMU 0.47 ; AMU 0.66 ; Overall 0.03

1 Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.

2 Restricted to women included in the adjusted analysis.

3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks, and gestation (completed weeks).

4.11 Perinatal outcomes for babies of 'low risk' women by planned place of birth

Most individual perinatal outcomes were rare and because of the small number of events adjusted odds ratios could not be estimated. Table 26 shows unadjusted, weighted event rates for all of the secondary outcomes and adjusted odds ratios for the three more commonly occurring perinatal outcomes: neonatal unit admission, Apgar <7 at 5 minutes and not breastfed.

As specified in the statistical analysis plan, odds ratios are presented with 99% confidence intervals for all secondary outcomes. These tables relate to perinatal outcomes in births to all 'low risk' women, including women with complicating conditions identified at the start of care in labour. Perinatal outcomes in births to 'low risk' women without complicating conditions at the start of care in labour are shown in Appendix 5.

4.11.1 Neonatal unit admission

Odds ratios for neonatal unit admissions were consistent with a reduced risk of neonatal unit admission for 'low risk' births planned in the non-OU settings. However, the reduced odds of a neonatal unit admission was only statistically significant for births planned in the FMU group (adjusted OR 0.61, 99% CI 0.40-0.91).

4.11.2 Apgar <7 at 5 minutes

The incidence of low Apgar score (<7 at 5 minutes) did not differ between settings.

4.11.3 Not breastfed

The odds of not being breastfed were significantly reduced in the planned home and planned FMU births, i.e. the likelihood of being breastfed at least once was significantly higher in planned home and FMU births. The direction of effect was similar for planned AMU births although the increase in breastfeeding was not significant at the 1% level.

Table 26. Secondary perinatal outcomes for babies of 'low risk' women by planned place of birth

	Events	Births	Weighted[1]		Unadjusted[1]		Unadjusted[1, 2]		Adjusted[1, 3]	
	n	n	n/1000	(99% CI)	OR	(99% CI)	OR	(99% CI)	OR	(99% CI)
Stillbirth										
OU	3	19706	0.2	(0.0-0.7)						
Home	6	16839	0.3	(0.1-1.0)						
FMU	4	11282	0.4	(0.1-2.2)						
AMU	1	16708	0.1	(0.0-0.8)						
Total	14	64535	0.2	(0.1-0.5)						
Early neonatal death (within 7 days)										
OU	5	19637	0.3	(0.1-0.8)						
Home	5	16759	0.3	(0.1-1.0)						
FMU	5	11263	0.4	(0.1-1.3)						
AMU	3	16633	0.1	(0.0-0.7)						
Total	18	64292	0.3	(0.1-0.6)						
Neonatal encephalopathy (clinical or signs)										
OU	42	19587	2.3	(1.4-3.8)						
Home	38	16589	2.1	(1.4-3.4)						
FMU	19	11210	1.7	(0.9-3.2)						
AMU	21	16569	1.6	(0.7-3.7)						
Total	120	63955	2.2	(1.4-3.5)						
Neonatal encephalopathy (clinical diagnosis)										
OU	34	19587	1.9	(1.1-3.3)						
Home	34	16589	1.8	(1.2-2.9)						
FMU	17	11210	1.5	(0.8-3.0)						
AMU	17	16569	1.4	(0.6-3.6)						
Total	102	63955	1.9	(1.2-3.0)						
Neonatal encephalopathy (signs)										
OU	8	19706	0.4	(0.2-0.9)						
Home	4	16840	0.3	(0.1-1.6)						
FMU	2	11282	0.2	(0.0-1.1)						
AMU	4	16710	0.2	(0.1-0.9)						
Total	18	64538	0.3	(0.2-0.7)						
Meconium aspiration syndrome										
OU	28	19587	1.5	(0.8-2.7)						
Home	21	16589	1.3	(0.6-2.7)						
FMU	12	11210	0.9	(0.4-2.0)						
AMU	25	16569	1.3	(0.7-2.7)						
Total	86	63955	1.4	(0.9-2.4)						

1 Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.

2 Restricted to women included in the adjusted analysis.

3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks, and gestation (completed weeks).

Table 26 **(continued): Secondary perinatal outcomes for babies of 'low risk' women by planned place of birth**

	Events	Births	Weighted[1]		Unadjusted[1]		Unadjusted[1, 2]		Adjusted[1, 3]	
	n	n	n/1000	(99% CI)	OR	(99% CI)	OR	(99% CI)	OR	(99% CI)
Brachial plexus injury										
OU	8	19587	0.4	(0.2-1.2)						
Home	6	16589	0.3	(0.1-1.0)						
FMU	2	11210	0.1	(0.0-0.9)						
AMU	8	16569	0.4	(0.2-1.0)						
Total	24	63955	0.4	(0.2-1.0)						
Fractured humerus										
OU	2	19587	0.1	(0.0-0.5)						
Home	1	16589	0.0	(0.0-0.7)						
FMU	0	11210	-	(-)						
AMU	0	16569	-	(-)						
Total	3	63955	0.1	(0.0-0.4)						
Fractured clavicle										
OU	2	19587	0.1	(0.0-0.6)						
Home	2	16589	0.1	(0.0-0.9)						
FMU	2	11210	0.2	(0.0-2.0)						
AMU	2	16569	0.1	(0.0-0.4)						
Total	8	63955	0.1	(0.0-0.5)						
Fractured skull										
OU	0	19587	-	(-)						
Home	0	16589	-	(-)						
FMU	2	11210	0.2	(0.0-1.4)						
AMU	0	16569	-	(-)						
Total	2	63955	0.0	(0.0-0.1)						
Cephalhaematoma										
OU	22	19587	1.1	(0.7-1.8)						
Home	16	16589	0.9	(0.5-1.9)						
FMU	11	11210	1.2	(0.5-3.0)						
AMU	15	16569	0.7	(0.3-1.8)						
Total	64	63955	1.0	(0.7-1.6)						
Cerebral haemorrhage										
OU	1	19587	0.1	(0.0-0.7)						
Home	4	16589	0.2	(0.1-0.8)						
FMU	4	11210	0.3	(0.1-1.3)						
AMU	3	16569	0.1	(0.0-0.6)						
Total	12	63955	0.1	(0.0-0.4)						

1 Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.

2 Restricted to women included in the adjusted analysis.

3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks, and gestation (completed weeks).

Table 26 **(continued): Secondary perinatal outcomes for babies of 'low risk' women by planned place of birth**

	Events	Births	Weighted[1]		Unadjusted[1]		Unadjusted[1, 2]		Adjusted[1, 3]	
	n	n	n/1000	(99% CI)	OR	(99% CI)	OR	(99% CI)	OR	(99% CI)
Sepsis (early onset and culture positive)										
OU	8	19584	0.4	(0.2-0.9)						
Home	6	16586	0.3	(0.1-0.8)						
FMU	0	11206	-	(-)						
AMU	5	16565	0.3	(0.1-0.8)						
Total	19	63941	0.4	(0.2-0.7)						
Kernicterus										
OU	0	19587	-	(-)						
Home	0	16589	-	(-)						
FMU	0	11210	-	(-)						
AMU	0	16569	-	(-)						
Total	0	63955	-	(-)						
Seizures										
OU	19	19587	1.0	(0.5-1.8)						
Home	25	16589	1.3	(0.7-2.3)						
FMU	18	11210	1.5	(0.7-3.0)						
AMU	17	16569	1.5	(0.6-3.7)						
Total	79	63955	1.1	(0.6-1.7)						
Neonatal unit admission						n=64175		n=62330		n=62330
OU	543	19642	28.3	(21.7-36.9)	1	-	1	-	1	-
Home	284	16696	17.3	(14.3-20.8)	0.60	(0.43-0.84)	0.61	(0.43-0.85)	0.73	(0.52-1.01)
FMU	194	11257	16.7	(12.3-22.6)	0.58	(0.39-0.88)	0.58	(0.38-0.87)	0.61	(0.40-0.91)
AMU	307	16580	19.8	(14.8-26.4)	0.69	(0.46-1.04)	0.70	(0.46-1.05)	0.75	(0.50-1.11)
Total	1328	64175	26.6	(21.1-33.6)						
Apgar <7 at 5 minutes						n=64365		n=62478		n=62478
OU	177	19624	9.8	(7.9-12.0)	1	-	1	-	1	-
Home	139	16803	8.4	(6.7-10.7)	0.86	(0.63-1.19)	0.88	(0.64-1.22)	0.94	(0.64-1.36)
FMU	92	11264	7.5	(5.4-10.4)	0.76	(0.52-1.13)	0.78	(0.52-1.15)	0.83	(0.55-1.25)
AMU	122	16674	8.8	(5.7-13.5)	0.90	(0.56-1.45)	0.94	(0.58-1.53)	0.96	(0.59-1.56)
Total	530	64365	9.5	(8.0-11.4)						
Not breastfed			**n/100**			n=63946		n=62088		n=62088
OU	5251	19607	25.6	(20.6-31.3)	1	-	1	-	1	-
Home	1934	16584	11.5	(10.0-13.3)	0.38	(0.27-0.52)	0.38	(0.27-0.52)	0.33	(0.26-0.42)
FMU	2133	11191	19.1	(14.6-24.6)	0.69	(0.45-1.06)	0.69	(0.45-1.06)	0.63	(0.46-0.87)
AMU	3373	16564	18.8	(12.2-27.7)	0.67	(0.38-1.20)	0.68	(0.38-1.21)	0.67	(0.43-1.04)
Total	12691	63946	24.1	(19.9-28.9)						

1 Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.

2 Restricted to women included in the adjusted analysis.

3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks, and gestation (completed weeks).

4.12 Maternal outcomes for 'low risk' birth by planned place of birth

4.12.1 Mode of birth

The majority of 'low risk' women in all settings had a spontaneous vertex birth (Table 27). The proportion varied from 74% in the OU group, 86% in the AMU group, 90% in the FMU group, to 93% in the planned home birth group. The odds of having a spontaneous vertex birth were significantly higher for births planned in all three of the non-OU settings.

With the exception of forceps delivery for women with a planned AMU birth, 'low risk' women who planned birth in a non-OU setting had reduced odds of a ventouse delivery, forceps delivery or intrapartum caesarean section. For planned AMU births, forceps delivery was less common than in planned OU births but the difference was not significant at the 1% level

Maternal outcomes for 'low risk' women without complicating conditions at the start of care in labour overall and by parity are shown in Appendix 5 (Figure 14, Figure 15, Figure 16, Figure 17, Figure 18, and Figure 19). The pattern of outcomes by planned place of birth was similar in this restricted group.

Table 27. Mode of birth for 'low risk' women by planned place of birth

	Events	Births	Weighted[1]		Unadjusted[1]		Unadjusted[1, 2]		Adjusted[1, 3]	
	n	n	%	(99% CI)	OR	(99% CI)	OR	(99% CI)	OR	(99% CI)
Spontaneous vertex birth						n=64483		n=62592		n=62592
OU	14645	19688	73.8	(71.1-76.4)	1	-	1	-	1	-
Home	15590	16825	92.8	(91.7-93.7)	4.55	(3.72-5.55)	4.49	(3.67-5.49)	3.61	(2.97-4.38)
FMU	10150	11280	90.7	(89.1-92.0)	3.44	(2.76-4.29)	3.45	(2.76-4.31)	3.38	(2.70-4.25)
AMU	14413	16690	85.9	(83.7-87.9)	2.17	(1.73-2.71)	2.16	(1.74-2.70)	2.22	(1.76-2.81)
Total	54798	64483	76.4	(73.8-78.7)						
Vaginal breech birth						n=64483		n=62592		n=62592
OU	43	19688	0.2	(0.1-0.3)	1	-	1	-	1	-
Home	63	16825	0.4	(0.3-0.5)	1.73	(0.95-3.13)	1.83	(0.97-3.45)	2.13	(1.15-3.96)
FMU	39	11280	0.4	(0.2-0.6)	1.67	(0.83-3.36)	1.79	(0.86-3.72)	2.00	(1.00-3.99)
AMU	26	16690	0.2	(0.1-0.3)	0.85	(0.39-1.83)	0.94	(0.43-2.07)	0.94	(0.44-2.04)
Total	171	64483	0.2	(0.2-0.3)						
Ventouse delivery						n=64483		n=62592		n=62592
OU	1535	19688	8.1	(6.4-10.1)	1	-	1	-	1	-
Home	342	16825	2.0	(1.6-2.5)	0.23	(0.16-0.32)	0.24	(0.17-0.33)	0.29	(0.21-0.40)
FMU	321	11280	2.7	(2.0-3.5)	0.31	(0.21-0.45)	0.31	(0.21-0.46)	0.32	(0.22-0.47)
AMU	755	16690	4.8	(3.6-6.2)	0.57	(0.39-0.83)	0.57	(0.39-0.83)	0.56	(0.39-0.82)
Total	2953	64483	7.3	(5.9-9.0)						
Forceps delivery						n=64483		n=62592		n=62592
OU	1307	19688	6.8	(5.4-8.4)	1	-	1	-	1	-
Home	372	16825	2.1	(1.8-2.5)	0.30	(0.22-0.40)	0.30	(0.22-0.40)	0.43	(0.32-0.57)
FMU	365	11280	2.9	(2.3-3.7)	0.41	(0.29-0.57)	0.41	(0.29-0.58)	0.45	(0.32-0.63)
AMU	769	16690	4.7	(3.5-6.4)	0.68	(0.46-1.02)	0.68	(0.45-1.01)	0.70	(0.46-1.05)
Total	2813	64483	6.2	(5.1-7.6)						
Intrapartum caesarean section						n=64483		n=62592		n=62592
OU	2158	19688	11.1	(9.5-13.0)	1	-	1	-	1	-
Home	458	16825	2.8	(2.3-3.4)	0.23	(0.17-0.30)	0.23	(0.17-0.30)	0.31	(0.23-0.41)
FMU	405	11280	3.5	(2.8-4.2)	0.29	(0.22-0.38)	0.28	(0.21-0.37)	0.32	(0.24-0.42)
AMU	727	16690	4.4	(3.5-5.5)	0.37	(0.27-0.49)	0.37	(0.28-0.49)	0.39	(0.29-0.53)
Total	3748	64483	9.9	(8.4-11.5)						

1 Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.

2 Restricted to women included in the adjusted analysis.

3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks, and gestation (completed weeks).

4.12.2 'Normal birth'

'Normal birth' was defined as a birth with none of the following interventions (see section 2.3.2 above):

- induction of labour[i]
- epidural or spinal analgesia
- general anaesthetic
- forceps or ventouse
- caesarean section
- episiotomy

The proportion of 'low risk' women with a 'normal birth' varied from 58% for planned OU births, 77% in the AMU group, 83% in the FMU group, to 88% for planned home births (Table 28). Women with a planned birth in the three planned non-OU settings had significantly increased odds of a 'normal birth'.

Note that because this outcome occurs frequently the odds ratio exaggerates the effect size. For example, when comparing home vs. OU groups the incidence of 'normal birth' is 88% vs. 58% which is less than a doubling of the chances of having a 'normal birth, while the adjusted odds ratio is 4.47.

For planned OU births, there appeared to be an association between complicating conditions at the start of labour care and 'normal birth': 40% of women with a complicating condition identified at the start of care in labour had a 'normal birth' compared with 63% of women without any complicating conditions at the start of care in labour.

An increased odds of a 'normal birth' in the three planned non-OU settings was still seen when the analysis was restricted to 'low risk' women without complicating conditions at the start of care in labour, although the effect was slightly attenuated.

'Normal birth' for 'low risk' women without complicating conditions at the start of care in labour overall and by parity are shown in Figure 14, Figure 15, and Figure 16 in Appendix 5.

[i] Note that women with induction of labour are excluded from the 'low risk' group of women.

Table 28. 'Normal birth' for 'low risk' women by planned place of birth

	Events	Births	Weighted[1]		Unadjusted[1]		Unadjusted[1, 2]		Adjusted[1, 3]	
	n	n	%	(99% CI)	OR	(99% CI)	OR	(99% CI)	OR	(99% CI)
Planned place of birth					**n=64105**		**n=62253**		**n=62253**	
OU	11392	19570	57.6	(54.1-60.9)	1	-	1	-	1	-
Home	14566	16619	87.9	(86.6-89.1)	5.37	(4.48-6.45)	5.30	(4.41-6.36)	4.47	(3.74-5.36)
FMU	9335	11258	83.3	(81.3-85.1)	3.67	(3.02-4.45)	3.68	(3.03-4.46)	3.86	(3.16-4.72)
AMU	12787	16658	76.0	(73.3-78.6)	2.34	(1.91-2.86)	2.33	(1.91-2.84)	2.50	(2.02-3.08)
Total	48080	64105	61.5	(58.2-64.7)						
Planned place of birth (restricted to women without complicating conditions at the start of care in labour)										
					n=57452		n=55849		n=55849	
OU	9840	15689	62.2	(58.6-65.6)	1	-	1	-	1	-
Home	13902	15675	89.0	(87.7-90.1)	4.90	(4.04-5.94)	4.85	(4.00-5.90)	4.12	(3.37-5.04)
FMU	8892	10620	84.1	(82.0-86.0)	3.22	(2.61-3.97)	3.22	(2.61-3.96)	3.42	(2.74-4.27)
AMU	12024	15468	77.1	(74.5-79.6)	2.05	(1.67-2.52)	2.04	(1.66-2.51)	2.21	(1.77-2.75)
Total	44658	57452	65.9	(62.6-69.1)						

1 Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.
2 Restricted to women included in the adjusted analysis.
3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks, and gestation (completed weeks).

4.12.3 Other maternal outcomes

Other adverse maternal outcomes for 'low risk' women are shown in Table 29.

Perineal trauma

For 'low risk' women, the proportion of women with third or fourth degree perineal trauma ranged from 1.9% (planned home births) to 3.2% (planned OU and AMU births). Results were consistent with reduced odds of third or fourth degree perineal trauma in 'low risk' women with a planned home or FMU birth, but the reductions were not significant at the 1% level.

Blood transfusion

The proportion of women receiving a blood transfusion was low in all settings (0.5% to 1.2%). The odds of a blood transfusion were lower in births planned in the three non-OU settings, although the reduction relative to the planned OU group was significant at the 1% level only for planned FMU births.

Maternal admission for higher level care

Admission of the mother to a high dependency area, intensive care unit or other higher level of care was uncommon in all settings; the odds were significantly reduced at the 1% level for planned FMU births.

Maternal deaths

No maternal deaths occurred.

Table 29. Other maternal outcomes for 'low risk' women by planned place of birth

	Events	Births	Weighted [1]		Unadjusted[1]		Unadjusted[1, 2]		Adjusted[1, 3]	
	n	n	%	(99% CI)	OR	(99% CI)	OR	(99% CI)	OR	(99% CI)
Third or fourth degree perineal trauma						n=64354		n=62482		n=62482
OU	625	19638	3.2	(2.7-3.7)	1	-	1	-	1	-
Home	318	16800	1.9	(1.6-2.3)	0.59	(0.46-0.76)	0.58	(0.45-0.76)	0.77	(0.57-1.05)
FMU	259	11262	2.3	(1.9-2.9)	0.74	(0.57-0.96)	0.72	(0.56-0.94)	0.78	(0.58-1.05)
AMU	535	16654	3.2	(2.6-4.0)	1.03	(0.78-1.35)	1.02	(0.77-1.34)	1.04	(0.79-1.38)
Total	1737	64354	3.1	(2.7-3.6)						
Blood transfusion						n=64044		n=62219		n=62219
OU	241	19579	1.2	(1.0-1.6)	1	-	1	-	1	-
Home	101	16687	0.6	(0.5-0.9)	0.52	(0.35-0.77)	0.54	(0.36-0.80)	0.72	(0.47-1.12)
FMU	67	11230	0.5	(0.4-0.7)	0.41	(0.27-0.62)	0.42	(0.28-0.64)	0.48	(0.32-0.73)
AMU	136	16548	0.9	(0.7-1.2)	0.74	(0.53-1.04)	0.72	(0.52-1.00)	0.75	(0.55-1.02)
Total	545	64044	1.2	(0.9-1.4)						
Admission to a higher level of care						n=64538		n=62635		n=62635
OU	117	19706	0.6	(0.3-1.1)	1	-	1	-	1	-
Home	58	16840	0.4	(0.2-0.6)	0.61	(0.29-1.27)	0.61	(0.29-1.27)	0.77	(0.36-1.65)
FMU	24	11282	0.2	(0.1-0.3)	0.27	(0.10-0.67)	0.27	(0.11-0.69)	0.32	(0.13-0.84)
AMU	82	16710	0.7	(0.3-1.5)	1.12	(0.43-2.93)	1.14	(0.43-3.03)	1.17	(0.46-2.99)
Total	281	64538	0.6	(0.4-1.0)						
Maternal death										
OU	0	19706	-	(-)						
Home	0	16840	-	(-)						
FMU	0	11282	-	(-)						
AMU	0	16710	-	(-)						
Total	0	64538	-	(-)						

1 Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.

2 Restricted to women included in the adjusted analysis.

3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks, and gestation (completed weeks).

4.12.4 Maternal interventions during labour for 'low risk' women by planned place of birth

Maternal interventions during labour for 'low risk' women are shown in Table 30.

Syntocinon augmentation

In 'low risk' women, the proportion of women receiving syntocinon augmentation ranged from 5% (planned home births) to 24% (planned OU births).The odds of receiving syntocinon augmentation was significantly lower in births planned in the three non-OU settings.

Immersion in water for pain relief

The odds of using immersion in water for pain relief was significantly higher in births planned in the three non-OU settings relative to planned OU births. Women with a planned FMU birth were most likely to use immersion in water (46% compared to around one third for planned home and AMU births and 9% in planned OU births).

Analgesia and anaesthesia

The odds of receiving epidural or spinal analgesia or of receiving general anaesthesia was significantly reduced in births planned in the three non-OU settings relative to planned OU births.

Active management of the 3rd stage

The vast majority (94%) of 'low risk' women with a planned OU birth received active management of the 3rd stage. The odds of not receiving active management of the 3rd stage were significantly increased in births planned in the three non-OU settings relative to planned OU births.

Episiotomy

Around 19% of 'low risk' women with a planned OU birth had an episiotomy, compared with 5% of planned home births, 9% of planned FMU births and 14% of planned AMU births. The odds of receiving an episiotomy were significantly reduced in births planned in each of the three non-OU settings relative to planned OU births.

Table 30. Maternal interventions during labour for 'low risk' women by planned place of birth

	Events	Births	Weighted[1]		Unadjusted[1]		Unadjusted[1, 2]		Adjusted[1, 3]	
	n	n	%	(99% CI)	OR	(99% CI)	OR	(99% CI)	OR	(99% CI)
Syntocinon augmentation						n=64174		n=62314		n=62314
OU	4549	19483	23.5	(21.1-26.2)	1	-	1	-	1	-
Home	943	16794	5.4	(4.8-6.1)	0.19	(0.15-0.23)	0.19	(0.15-0.23)	0.25	(0.21-0.31)
FMU	878	11238	7.1	(6.0-8.5)	0.25	(0.20-0.32)	0.25	(0.19-0.32)	0.26	(0.20-0.33)
AMU	1708	16659	10.3	(8.9-11.8)	0.37	(0.30-0.46)	0.38	(0.30-0.46)	0.37	(0.30-0.46)
Total	8078	64174	20.9	(18.7-23.3)						
Immersion in water for pain relief						n=64086		n=62214		n=62214
OU	1836	19680	9.1	(6.4-12.6)	1	-	1	-	1	-
Home	5523	16443	33.3	(30.1-36.6)	5.01	(3.36-7.48)	4.91	(3.31-7.28)	5.40	(3.64-8.00)
FMU	5253	11270	45.7	(35.6-56.3)	8.47	(4.82-14.88)	8.27	(4.72-14.50)	8.36	(4.76-14.69)
AMU	5062	16693	30.2	(23.4-38.1)	4.35	(2.61-7.26)	4.21	(2.54-6.99)	4.46	(2.71-7.34)
Total	17674	64086	13.4	(10.5-16.9)						
Epidural or spinal analgesia						n=64287		n=62434		n=62434
OU	5817	19576	30.7	(27.5-34.2)	1	-	1	-	1	-
Home	1418	16799	8.3	(7.3-9.4)	0.20	(0.16-0.25)	0.20	(0.17-0.25)	0.25	(0.20-0.31)
FMU	1251	11251	10.6	(9.1-12.3)	0.27	(0.21-0.34)	0.27	(0.21-0.33)	0.27	(0.22-0.34)
AMU	2464	16661	15.3	(13.2-17.7)	0.41	(0.32-0.51)	0.41	(0.32-0.51)	0.40	(0.32-0.50)
Total	10950	64287	27.6	(24.6-30.8)						
General anaesthetic						n=64019		n=62177		n=62177
OU	285	19421	1.5	(1.1-1.8)	1	-	1	-	1	-
Home	77	16714	0.5	(0.3-0.6)	0.31	(0.20-0.46)	0.31	(0.21-0.47)	0.40	(0.26-0.60)
FMU	61	11243	0.5	(0.3-0.8)	0.36	(0.21-0.61)	0.36	(0.21-0.62)	0.40	(0.23-0.69)
AMU	99	16641	0.6	(0.4-0.9)	0.43	(0.28-0.67)	0.44	(0.29-0.67)	0.47	(0.31-0.72)
Total	522	64019	1.3	(1.0-1.6)						
No active management of the 3rd stage						n=64074		n=62210		n=62210
OU	1188	19683	6.1	(4.6-8.1)	1	-	1	-	1	-
Home	5092	16428	31.3	(27.6-35.2)	6.97	(4.94-9.83)	6.99	(4.96-9.84)	6.75	(4.74-9.60)
FMU	2568	11271	22.1	(15.8-30.0)	4.35	(2.62-7.22)	4.39	(2.65-7.28)	4.42	(2.67-7.31)
AMU	2565	16692	14.1	(10.2-19.1)	2.51	(1.57-4.01)	2.50	(1.56-3.99)	2.46	(1.55-3.91)
Total	11413	64074	8.5	(6.9-10.4)						
Episiotomy						n=64312		n=62422		n=62422
OU	3780	19678	19.3	(17.4-21.4)	1	-	1	-	1	-
Home	933	16670	5.4	(4.8-6.1)	0.24	(0.20-0.29)	0.24	(0.20-0.29)	0.33	(0.28-0.39)
FMU	995	11275	8.6	(7.3-10.1)	0.39	(0.32-0.49)	0.39	(0.31-0.49)	0.40	(0.32-0.51)
AMU	2098	16689	13.1	(11.4-14.9)	0.63	(0.51-0.77)	0.63	(0.51-0.77)	0.62	(0.50-0.77)
Total	7806	64312	17.8	(16.0-19.6)						

1 Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.

2 Restricted to women included in the adjusted analysis.

3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks, and gestation (completed weeks).

4.13 Primary outcome by transfer status for 'low risk' women

Table 31 shows outcomes for 'low risk' women and their babies according to whether they did or did not transfer during labour or immediately after birth for the three non-OU settings. As noted previously (section 4.8), transfer patterns for women in the AMU group differ from the other two settings because in the AMU setting a woman does not need to be transferred if her baby requires admission, whereas a woman is normally transferred with her baby from home or an FMU if there are neonatal concerns.

Unadjusted event rates were consistent with a higher incidence of adverse perinatal outcomes for women in the planned home birth group who transferred before delivery, although the confidence intervals overlapped with the FMU group. For women who did not transfer and for women who transferred after delivery, perinatal outcomes did not differ between the home and FMU groups. From both planned home and FMU births, the incidence of adverse perinatal outcomes was highest in women who transferred after delivery. This probably reflects the fact that neonatal concerns are the third most common reason for postpartum transfer, after repair of perineal trauma and retained placenta (see section 4.7).

For 'low risk' women who delivered in their planned place of birth, i.e. who either did not transfer or transferred only after birth (data not shown), the event rate was similar in all three settings (2.5-2.6 per 1000 births). Thirty four births occurred during transfer including one in which a primary outcome event occurred.

Table 31. Primary outcome by transfer status and timing of transfer for 'low risk' women by planned place of birth

	Home n=16,840	FMU n=11,282	AMU n=16,710
Not transferred during labour or immediately after the birth			
Women, n	13310	8814	12300
%	79%	78%	74%
Primary outcome[1] n/1000	1.0	1.1	2.6
95% CI	(0.6-1.6)	(0.5-2.1)	(1.5-4.5)
Transferred before delivery[2]			
Women, n	2387	1863	3539
%	14%	17%	21%
Primary outcome[1] n/1000	14.1	9.6	6.0
95% CI	(9.3-21.5)	(5.6-16.5)	(3.6-10.2)
Transferred after delivery[2]			
Women, n	1046	545	719
%	6%	5%	4%
Primary outcome[1] n/1000	23.8	23.7	2.9
95% CI	(15.3-36.8)	(15.5-36.2)	(0.8-11)

[1] Unadjusted event rate; weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.

[2]Time of transfer missing for 309 transfers (97 home, 60 FMU, 152 AMU).

4.14 Sensitivity analyses

4.14.1 Restricted analysis

Two hundred and fifty (91%) units/trusts (35 OUs (97%), 129 trusts providing home birth services (91%), 48 FMUs (91%) and 38 AMUs (88%)) provided good or adequate denominator data, i.e. counts of the number of eligible women starting labour care in the unit/trust during the study period. Of these, 203 (74% of all units/trusts) had a response rate of ≥85%, i.e. they included 85% or more of eligible women in the study (see Table 7 above)

The weighted incidence of the primary outcome was similar in the units/trusts with a response rate ≥85% compared with the weighted incidence in 'low risk' women overall (4.4 events per 1000 births in the restricted cohort compared with 4.3 per 1000 births).

As in the main analysis, for 'low risk' women without complicating conditions at the start of care in labour, the odds of an adverse perinatal outcome (primary outcome event) were significantly increased in planned home births (odds ratio 1.90, 95% CI 1.11-3.25). There was no significant increase in the planned FMU and AMU births relative to the planned OU group.

The restricted analysis by parity confirmed that the significant increase in adverse perinatal outcomes in planned home births occurred only in nulliparous 'low risk' women (odds ratio for planned home births in nulliparous women 2.18, 95% CI 1.27–3.76 overall; and for planned home births in nulliparous women without complicating conditions at the start of care in labour, odds ratio 4.65, 95% CI 2.42 -8.92)

The only difference between the main findings and the sensitivity analysis was seen when the analysis by parity was restricted to women without complicating conditions at the start of labour care. In this sensitivity analysis, there was a significant increase in the odds of the primary outcome in planned FMU births in 'low risk', nulliparous women without complicating conditions at the start of care in labour. However, the test for interaction between nulliparous and multiparous women in the FMU group was not significant (p=.07) suggesting that this may have been a chance finding.

Detailed results are given in Appendix 6.

4.14.2 Propensity score analysis

Propensity score methods were used to stratify 'low risk' women into more homogeneous groups of equal size (quintiles) based on their probability to plan birth in a particular setting.

In the propensity score analysis, reasonable balance in baseline characteristics was achieved when the women were stratified into quintiles according to their propensity to choose a particular birth setting (see Appendix 7). There was no evidence of heterogeneity across the strata-specific odds ratios for the primary outcome in the three non-OU settings compared to the OU. The overall odds ratios adjusted for propensity score quintile were consistent with the main findings

4.14.3 Multiple imputation of missing data

As presented in section 4.3, the number of women with missing covariate information is minimal (<4% in each setting), much lower than anticipated. The project statisticians and study investigators considered that a multiple imputation analysis would not alter the conclusions arising from the results of the primary analysis and that sufficient sensitivity analyses were otherwise planned. It was therefore decided that multiple imputation of missing data was unnecessary and the analysis was therefore not carried out.

4.15 Characteristics of 'higher risk' women and babies

As described in section 3.6 above, women were classified as 'higher risk' if they had any of the factors listed in the NICE intrapartum care guidelines as "indicating increased risk suggesting planned birth in an obstetric unit".

The proportion of 'higher risk' women varied by planned place of birth. In the three non-OU groups, the highest proportion of 'higher risk' women was found in the planned home birth group (7%) followed by 4% in the planned AMU group and 3% in the planned FMU group. In the planned OU group, the proportion of 'higher risk' women was 38%. Note, however, that this does not represent the overall proportion of 'higher risk' women planning to give birth in OUs since some 'higher risk' groups were not included in the study cohort , e.g. births by elective caesarean section, preterm births, etc. (see eligibility criteria, section 3.5).

Table 32 shows the characteristics of 'higher risk' women and their babies by planned place of birth. Characteristics varied by planned place of birth. However, the number of 'higher risk' women in the three non-OU groups was relatively small, particularly for planned FMU births (n=289), so some differences may be due to sampling variability.

- Compared to women planning to give birth in an OU, 'higher risk' women planning a birth at home tended to be older (33% aged 35 or over at home compared with 20% aged 35 or over in OUs). As was seen for 'low risk' women, they were more likely to be white, have a fluent understanding of English, be married or living with a partner and they were also markedly more likely to have higher parity: 24% vs. 14% had two previous pregnancies and 21% vs. 10% had three of more pregnancies. A markedly higher proportion of the 'higher risk' women in the planned home birth group were severely obese (28% with a BMI >35 vs. 15% in the OU group). Birthweight was also higher in the planned home birth group: 21% with a birthweight ≥ 4.0 kg vs. 14% in the OU group.
- As for 'low risk' women, the characteristics of 'higher risk' women planning a birth in an FMU or AMU tended to fall between the OU and home birth group with the characteristics of women in the AMU group generally closer to that of the OU group. 'Higher risk' women planning an FMU or AMU birth were more likely to be severely obese compared with women planning an OU birth (26% and 22% respectively with a BMI >35 vs. 15%), although numbers were relatively small in the FMU group.

Table 32. Characteristics of 'higher risk' women and babies by planned place of birth

	OU n=12374		Home n=1346		FMU n=289		AMU n=776	
	n	%	n	%	n	%	n	%
Maternal age								
Mean [SD]	28.9	6.1]	31.8	[5.5]	30.1	[5.5]	29.4	[5.8]
Under 20	747	6.0	12	0.9	8	2.8	36	4.6
20-24	2454	19.9	131	9.7	44	15.2	139	17.9
25-29	3412	27.6	318	23.6	80	27.7	207	26.7
30-34	3254	26.3	430	31.9	95	32.9	243	31.3
35-39	2004	16.2	357	26.5	54	18.7	130	16.8
40+	486	3.9	98	7.3	8	2.8	21	2.7
Missing	17		0		0		0	
Ethnic group								
White	10187	82.4	1264	94.0	260	90.0	602	77.7
Indian	254	2.1	7	0.5	2	0.7	15	1.9
Pakistani	412	3.3	2	0.1	5	1.7	22	2.8
Bangladeshi	174	1.4	1	0.1	3	1.0	6	0.8
Black Caribbean	181	1.5	20	1.5	1	0.3	14	1.8
Black African	495	4.0	10	0.7	6	2.1	51	6.6
Mixed	181	1.5	21	1.6	7	2.4	16	2.1
Other	476	3.9	20	1.5	5	1.7	49	6.3
Missing	14		1		0		1	
Understanding of English								
Fluent	11403	93.0	1338	99.4	280	97.2	717	92.4
Some	653	5.3	8	0.6	7	2.4	44	5.7
None	208	1.7	0	-	1	0.3	15	1.9
Missing	110		0		1		0	
Marital/Partner status								
Married/Living together	10632	87.1	1274	95.4	268	93.1	692	90.1
Single/Unsupported by partner	1576	12.9	61	4.6	20	6.9	76	9.9
Missing	166		11		1		8	
Body mass index (kg/m^2)								
Mean [SD]	27.8	[7.0]	29.3	[8.1]	28.7	[7.8]	28	[7.7]
Not recorded	1673	13.5	182	13.6	32	11.1	102	13.2
Less than 18.5	244	2.0	25	1.9	5	1.7	24	3.1
18.5-24.9	4222	34.2	419	31.2	100	34.6	266	34.3
25.0-29.9	2788	22.6	243	18.1	59	20.4	150	19.4
30.0-35.0	1526	12.4	93	6.9	18	6.2	60	7.7
>35.0	1901	15.4	381	28.4	75	26.0	173	22.3
Missing	20		3		0		1	

	OU n=12374		Home n=1346		FMU n=289		AMU n=776	
	n	%	n	%	n	%	n	%
IMD quintiles								
1st Least deprived	1750	14.3	273	20.5	66	22.8	114	14.7
2nd	2072	16.9	274	20.6	63	21.8	104	13.4
3rd	2270	18.5	263	19.7	59	20.4	144	18.6
4th	2603	21.3	267	20.0	63	21.8	145	18.7
5th Most deprived	3552	29.0	256	19.2	38	13.1	268	34.6
Missing	127		13		0		1	
Previous pregnancies >=24 completed weeks								
0 Nulliparous	5718	46.3	232	17.3	87	30.2	277	35.9
1 previous	3723	30.1	509	37.9	114	39.6	285	36.9
2 previous	1687	13.7	323	24.0	50	17.4	126	16.3
3+ previous	1230	10.0	280	20.8	37	12.8	84	10.9
Missing	16		2		1		4	
Gestation (completed weeks)								
Mean [SD]	39.7	[1.3]	39.7	[1.1]	39.7	[1.1]	39.7	[1.1]
37	817	6.6	44	3.3	13	4.5	27	3.5
38	1849	15.0	146	10.9	23	8.0	69	9.0
39	2425	19.6	309	23.0	74	25.6	182	23.6
40	3123	25.3	520	38.8	103	35.6	296	38.4
41	3424	27.7	276	20.6	71	24.6	184	23.9
42-44	704	5.7	46	3.4	5	1.7	12	1.6
Missing[1]	32		5		0		6	
Birthweight (grams)								
Mean [SD]	3451	[520.5]	3584	[482.3]	3506	[486.0]	3477	[447.1]
Less than 2500g	405	3.3	15	1.1	3	1.0	10	1.3
2500-2999g	1895	15.3	125	9.3	34	11.8	102	13.2
3000-3499g	4334	35.1	433	32.4	112	38.8	291	37.7
3500-3999g	3944	31.9	485	36.2	98	33.9	280	36.3
4000-4499g	1482	12.0	238	17.8	33	11.4	70	9.1
≥4500g	303	2.5	42	3.1	9	3.1	18	2.3
Missing	11		8		0		5	

[1] See section 3.9.2

4.16 Complicating conditions at the start of care in labour, 'higher risk' women

For 'higher risk' women, there were marked differences between the OU and non-OU groups in the proportion of women with complicating conditions identified by the attending midwife at the start of care in labour (Table 33). Just under one third of women whose planned place of birth was an OU had at least one complicating condition noted at the start of

care in labour compared with fewer than 12% for all other planned places of birth.

Relative to the 'low risk' group, there were more complicating conditions noted at the start of care in labour in all four settings.

Table 33. Conditions identified at the start of care in labour in 'higher risk' women by planned place of birth

	OU n=12374		Home n=1346		FMU n=289		AMU n=776	
	n	%	n	%	n	%	n	%
Prolonged rupture of membranes	1242	10.1	48	3.6	7	2.4	22	2.8
Meconium stained liquor	787	6.4	32	2.4	7	2.4	16	2.1
Proteinuria (1+ or more)	861	7.0	11	0.8	3	1.0	28	3.6
Hypertension	1286	10.4	28	2.1	10	3.5	14	1.8
Abnormal vaginal bleeding	186	1.5	9	0.7	1	0.3	3	0.4
Non-cephalic presentation	91	0.7	5	0.4	0	-	7	0.9
Abnormal fetal heart rate	362	2.9	7	0.5	2	0.7	8	1.0
Other complications	54	0.4	3	0.2	0	-	0	-
Conditions per woman:								
0	8428	68.4	1197	90.3	261	90.6	686	88.6
1	3045	24.7	116	8.7	24	8.3	78	10.1
2+	856	6.9	13	1.0	3	1.0	10	1.3
Missing	45		20		1		2	

4.17 Transfers during labour or immediately after the birth for 'higher risk' women

Compared with transfer rates in 'low risk' women, rates of transfer in 'higher risk' women were higher in the planned home and FMU groups, but not in the planned AMU births.

The pattern of reasons for transfer in 'higher risk' women differed from that in 'low risk' women, although numbers were small. Failure to progress remained the most common reason but maternal complications and concerns (hypertension, postpartum haemorrhage, retained placenta, repair of perineal trauma) were more frequent reasons for transfer in the 'higher risk' group compared with 'low risk' women.

Table 34. Transfers during labour or immediately after the birth for 'higher risk' women

	OU n=12374		Home n=1346		FMU n=289		AMU n=776	
	n	%	n	%	n	%	n	%
Transfer during labour or after the birth?								
No	12325	99.6	993	73.8	204	70.6	569	73.3
Yes	49	0.4	353	26.2	85	29.4	207	26.7
Missing	-		-		-		-	
Timing of start of transfer (as a proportion of all women transferred)								
Before delivery			229	66.8	64	77.1	168	85.7
After delivery			114	33.2	19	22.9	28	14.3
Missing			10		2		11	
Primary reasons for transfer (as a proportion of all women transferred)								
Failure to progress (1st stage)			63	18.1	21	25.0	37	18.1
Fetal distress (1st stage)			17	4.9	4	4.8	14	6.9
Meconium staining			31	8.9	6	7.1	14	6.9
Epidural request			21	6.0	2	2.4	18	8.8
Hypertension			17	4.9	6	7.1	13	6.4
Malposition			5	1.4	0	-	1	0.5
Malpresentation			8	2.3	0	-	10	4.9
Antepartum haemorrhage			10	2.9	2	2.4	3	1.5
Failure to progress (2nd stage)			25	7.2	8	9.5	27	13.2
Fetal distress (2nd stage)			5	1.4	1	1.2	8	3.9
Postpartum haemorrhage			22	6.3	3	3.6	8	3.9
Retained placenta			28	8.0	3	3.6	7	3.4
Repair of perineal trauma			30	8.6	4	4.8	14	6.9
Other (detail not recorded)			1	0.3	0	-	2	1.0
Other specified reason:								
Prolonged rupture of membranes			3	0.9	0	-	2	1.0
Failure to progress (stage not specified)			0	-	0	-	1	0.5
Fetal distress (stage not specified)			6	1.7	3	3.6	2	1.0
Maternal (antepartum transfer)			7	2.0	3	3.6	0	-
Fetal (antepartum transfer)			2	0.6	1	1.2	0	-
Pain relief (epidural not specified or other)			6	1.7	0	-	0	-
Maternal request (not pain relief)			1	0.3	0	-	0	-
Maternal (postpartum transfer)			4	1.1	2	2.4	0	-
Retained products (other than placenta)			-	-	-	-	-	-
Neonatal concerns (postpartum transfer)			27	7.7	5	6.0	0	-
Non-medical reason (staffing or equipment)			1	0.3	0	-	0	-
Non-medical reason (domestic)			1	0.3	0	-	0	-
Non-medical (other)			1	0.3	0	-	0	-
Did not meet unit's eligibility criteria			0	-	1	1.2	8	3.9
Other pre-existing maternal or fetal reason			7	2.0	9	10.7	15	7.4
Missing			4		1		3	

4.18 Occurrence of the primary outcome in 'higher risk' women by planned place of birth

Because of the small number of events, it was not possible to carry out an adjusted analysis of the primary outcome in 'higher risk' women. Tables in this section present unadjusted event rates and associated confidence intervals, weighted to take into account each unit's duration of participation, the sampling of OUs and the clustered nature of the data.

Overall, there were 71 primary outcome events: 57 in the planned OU births, 12 in the planned home births, none in the planned FMU births and two in the planned AMU births. As in 'low risk' women, neonatal encephalopathy and meconium aspiration were the most commonly occurring contributing events (40% and 23% respectively). Stillbirths and early neonatal deaths accounted for 21% of primary outcome events (Table 35).

The crude, weighted incidence of the primary outcome was 4.6 events per 1000 births in 'higher risk' women and 4.6 per 1000 birth in 'higher risk' women without complicating conditions at the start of care in labour.

Table 35. Contribution of individual outcome events to the composite primary outcome, 'higher risk' women

	n	% of the primary outcome
Stillbirth	7	9.9
Early neonatal death (within 7 days)	8	11.3
Neonatal encephalopathy (clinical diagnosis)	20	28.2
Neonatal encephalopathy (signs)	8	11.3
Meconium aspiration syndrome	16	22.5
Brachial plexus injury	10	14.1
Fractured humerus	0	-
Fractured clavicle	2	2.8
Total	71	100

Each of the categories above are mutually exclusive and outcomes listed higher in the table take precedence over outcomes listed lower down. For example, if a baby with neonatal encephalopathy died within 7 days the outcome is recorded as an early neonatal death in this table.

Table 36 shows the incidence of the primary outcome by planned place of birth for all 'higher risk' women and for 'higher risk' women without complicating conditions at the start of care in labour. In both groups, the unadjusted event rate is highest in the planned home birth group, although the number of events is small and the 95% confidence intervals are wide.

Table 36. Primary outcome for babies of 'higher risk' women overall and for women without complicating conditions at the start of care in labour by planned place of birth

	Events	Births	Weighted[1]	
	n	n	n/1000	(95% CI)
Planned place of birth				
OU	57	12308	4.7	(3.6-6.1)
Home	12	1325	7.7	(4.2-14.2)
FMU	0	287	-	(-)
AMU	2	767	2.1	(0.3-13.9)
Total	71	14687	4.6	(3.6-6.1)
Planned place of birth (restricted to women without complicating conditions at the start of care in labour)				
			n=10,255	
OU	37	8395	4.6	(3.5-6.0)
Home	10	1181	7.3	(3.7-14.4)
FMU	0	259	-	(-)
AMU	2	679	2.3	(0.3-15.3)
Total	49	10514	4.6	(3.5-6.0)

[1]Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.

The numbers of primary outcome events were too small for meaningful comparison of the distributions of events between the planned places of birth.

4.19 Occurrence of the primary outcome by parity in 'higher risk' women by planned place of birth

For both nulliparous and multiparous 'higher risk' women the incidence of the primary outcome was highest in the planned home birth group: 12.6 events per 1000 planned home births vs. 6.2 per 1000 in the OU group for nulliparous women; and 6.7 events per 1000 birth in the planned home birth group vs. 3.3 per 1000 births in the OU group for multiparous women (Table 37). The pattern was similar for 'higher risk' women without complicating conditions at the start of care in labour.

Table 37. Primary outcome by parity and planned place of birth for 'higher risk' women

	Events	Births	Weighted[1]	
	n	n	n/1000	(95% CI)
Planned place of birth				
Nulliparous women				
OU	36	5688	6.2	(4.4-8.8)
Home	4	228	12.6	(4.9-32.3)
FMU	0	87	-	(-)
AMU	1	275	2.8	(0.4-18.5)
Total	41	6278	6.2	(4.4-8.8)
Multiparous women				
OU	21	6605	3.3	2.1-5.2
Home	8	1096	6.7	(3.2-14)
FMU	0	199	-	(-)
AMU	1	488	1.7	(0.2-11.3)
Total	30	8388	3.3	(2.1-5.1)
Planned place of birth (restricted to women without complicating conditions at the start of care in labour)				
Nulliparous women				
OU	23	3408	6.6	(4.4-10.0)
Home	3	201	10.8	(3.4-33.4)
FMU	0	74	-	(-)
AMU	1	238	3.2	(0.5-20.6)
Total	27	3921	6.6	(4.4-9.9)
Multiparous women				
OU	14	4979	3.2	(1.9-5.3)
Home	7	979	6.6	(3.0-14.5)
FMU	0	184	-	(-)
AMU	1	437	1.8	(0.3-12.4)
Total	22	6579	3.2	(1.9-5.2)

Adjusted regression test of heterogeneity p-values: Home 0.79 ; FMU (-) ; AMU 0.47 ; Overall 0.53

1 Weighted to reflect each unit's duration of participation , the sampling of OUs and to take the clustered nature of the data into account

4.20 Perinatal outcomes for babies of 'higher risk' women by planned place of birth

Most individual perinatal outcomes were rare and because of the small number of events adjusted odds ratios could not be estimated. Table 38 shows crude event rates (weighted) for all of the secondary outcomes and adjusted odds ratios for the three more commonly occurring perinatal outcomes (neonatal unit admission, Apgar <7 at 5 minutes and not breastfed). Note that 99% confidence intervals have been used as specified in the analysis plan for secondary outcomes. These tables relate to perinatal outcomes in births to all 'higher risk' women including women with complicating conditions at the start of care in labour.

4.20.1 Neonatal unit admission

There was no clear pattern for neonatal unit admission. The odds of neonatal unit admission was reduced in the planned home births, but the reduction was of borderline statistical significance (odds ratio 0.57, 99% CI 0.33-0.97).

4.20.2 Apgar <7 at 5 minutes

There was no consistent pattern for low Apgar score (<7 at 5 minutes) in 'higher risk' births.

4.20.3 Not breastfed

The odds of not being breastfed were significantly reduced in planned home births (odds ratio 0.32, 99% CI 0.23-0.45).

Table 38. Secondary perinatal outcomes for babies of 'higher risk' women by planned place of birth

	Events	Births	Weighted[1]	
	n	n	n/1000	(99% CI)
Stillbirth				
OU	4	12374	0.3	(0.1-0.9)
Home	3	1346	1.8	(0.4-8.0)
FMU	0	289	-	(-)
AMU	0	776	-	(-)
Total	7	14785	0.3	(0.1-0.9)
Early neonatal death (within 7 days)				
OU	6	12346	0.4	(0.2-1.1)
Home	2	1338	1.4	(0.2-7.8)
FMU	0	288	-	(-)
AMU	0	776	-	(-)
Total	8	14748	0.4	(0.2-1.0)
Neonatal encephalopathy (clinical or signs)				
OU	25	12327	2.2	(1.3-3.7)
Home	4	1326	2.4	(0.7-8.3)
FMU	0	288	-	(-)
AMU	1	767	1.0	(0.1-12.7)
Total	30	14708	2.2	(1.3-3.7)
Neonatal encephalopathy (clinical diagnosis)				
OU	17	12327	1.5	(0.7-3.1)
Home	4	1326	2.4	(0.7-8.3)
FMU	0	288	-	(-)
AMU	1	767	1.0	(0.1-12.7)
Total	22	14708	1.5	(0.7-3.1)
Neonatal encephalopathy (signs)				
OU	8	12374	0.7	(0.3-1.7)
Home	0	1346	-	(-)
FMU	0	289	-	(-)
AMU	0	776	-	(-)
Total	8	14785	0.7	(0.3-1.7)
Meconium aspiration syndrome				
OU	15	12327	1.1	(0.5-2.4)
Home	4	1326	2.6	(0.7-10.1)
FMU	0	288	-	(-)
AMU	1	767	1.0	(0.1-12.7)
Total	20	14708	1.1	(0.5-2.4)
Brachial plexus injury				
OU	9	12327	0.8	(0.3-2.4)
Home	1	1326	0.7	(0.1-8.6)
FMU	0	288	-	(-)
AMU	0	767	-	(-)
Total	10	14708	0.8	(0.3-2.3)

	Events	Total	Weighted[1]	
	n	n	n/1000	(99% CI)
Fractured humerus				
OU	1	12327	0.1	(0.0-0.6)
Home	0	1326	-	(-)
FMU	0	288	-	(-)
AMU	0	767	-	(-)
Total	1	14708	0.1	(0.0-0.6)
Fractured clavicle				
OU	2	12327	0.2	(0.0-2.5)
Home	1	1326	0.4	(0.0-5.2)
FMU	0	288	-	(-)
AMU	0	767	-	(-)
Total	3	14708	0.2	(0.0-2.4)
Fractured skull				
OU	2	12327	0.2	(0.0-1.0)
Home	0	1326	-	(-)
FMU	0	288	-	(-)
AMU	0	767	-	(-)
Total	2	14708	0.2	(0.0-1.0)
Cephalhaematoma				
OU	12	12327	1.0	(0.4-2.3)
Home	1	1326	0.4	(0.0-5.4)
FMU	0	288	-	(-)
AMU	0	767	-	(-)
Total	13	14708	1.0	(0.4-2.3)
Cerebral haemorrhage				
OU	1	12327	0.1	(0.0-1.0)
Home	2	1326	1.6	(0.3-9.5)
FMU	0	288	-	(-)
AMU	0	767	-	(-)
Total	3	14708	0.1	(0.0-0.8)
Sepsis (early onset and culture positive)				
OU	7	12326	0.6	(0.2-1.5)
Home	0	1324	-	(-)
FMU	0	288	-	(-)
AMU	0	767	-	(-)
Total	7	14705	0.6	(0.2-1.4)
Kernicterus				
OU	0	12327	-	(-)
Home	0	1326	-	(-)
FMU	0	288	-	(-)
AMU	0	767	-	(-)
Total	0	14708	-	(-)

1 Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.

Table 38 (continued): Secondary perinatal outcomes for babies of 'higher risk' women by planned place of birth

	Events	Total	Weighted[1]		Unadjusted[1]		Unadjusted[1, 2]		Adjusted[1, 3]	
	n	n	n/1000	(99% CI)	OR	(99% CI)	OR	(99% CI)	OR	(99% CI)
Seizures										
OU	12	12327	1.0	(0.5-2.0)						
Home	6	1326	4.2	(1.5-11.6)						
FMU	0	288	-	(-)						
AMU	0	767	-	(-)						
Total	18	14708	1.0	(0.5-1.9)						
Neonatal unit admission						n=14737		n=14218		n=14218
OU	611	12349	52.4	(42.9-64.0)	1	-	1	-	1	-
Home	35	1329	27.2	(17.2-42.9)	0.51	(0.30-0.85)	0.49	(0.29-0.82)	0.57	(0.33-0.97)
FMU	11	286	44.3	(14.5-127.8)	0.84	(0.26-2.70)	0.83	(0.26-2.66)	0.92	(0.28-3.03)
AMU	21	773	28.6	(16.9-47.9)	0.53	(0.30-0.95)	0.54	(0.30-0.96)	0.60	(0.34-1.06)
Total	678	14737	52.0	(42.6-63.4)						
Apgar <7 at 5 minutes						n=14758		n=14239		n=14239
OU	166	12352	13.8	(10.8-17.7)	1	-	1	-	1	-
Home	19	1342	13.9	(7.6-25.1)	1.00	(0.52-1.92)	1.02	(0.53-1.96)	0.95	(0.44-2.02)
FMU	6	289	23.2	(5.7-89.2)	1.69	(0.40-7.13)	1.69	(0.40-7.13)	1.68	(0.38-7.40)
AMU	5	775	4.6	(1.4-15.0)	0.33	(0.10-1.12)	0.33	(0.10-1.14)	0.34	(0.10-1.16)
Total	196	14758	13.8	(10.8-17.5)						
Not breastfed			**n/100**			n=14713		n=14192		n=14192
OU	3838	12327	30.4	(23.4-38.4)	1	-	1	-	1	-
Home	199	1329	14.7	(11.6-18.5)	0.40	(0.25-0.62)	0.39	(0.25-0.60)	0.32	(0.23-0.45)
FMU	69	285	24.5	(15.2-36.9)	0.74	(0.37-1.47)	0.75	(0.38-1.49)	0.73	(0.40-1.33)
AMU	168	772	21.6	(9.7-41.5)	0.63	(0.23-1.73)	0.63	(0.23-1.70)	0.60	(0.27-1.33)
Total	4274	14713	30.2	(23.4-38.1)						

1 Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.

2 Restricted to women included in the adjusted analysis.

3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks, and gestation (completed weeks).

4.21 Maternal outcomes for 'higher risk' birth by planned place of birth

4.21.1 Mode of birth

The majority of 'higher risk' women had a spontaneous vertex birth. The proportion varied from 67% in the planned OU births to 92% in the planned home births (Table 55). The odds of having a spontaneous vertex birth were significantly higher for births planned in all three of the non-OU settings.

'Higher risk' women who planned birth in a non-OU setting had a reduced odds of a ventouse delivery, forceps delivery section, although the

reductions were not significant in all cases. The odds of having an intrapartum caesarean section was significantly reduced for 'higher risk' women with planned births in all three non-OU settings.

Table 39. Mode of birth for 'higher risk' women by planned place of birth

	Events	Births	Weighted[1]		Unadjusted[1]		Unadjusted[1, 2]		Adjusted[1, 3]	
	n	n	%	(99% CI)	OR	(99% CI)	OR	(99% CI)	OR	(99% CI)
Spontaneous vertex birth						n=14775		n=14253		n=14253
OU	8226	12364	65.8	(63.1-68.4)	1	-	1	-	1	-
Home	1235	1346	92.3	(90.3-93.9)	6.22	(4.69-8.24)	6.20	(4.65-8.26)	4.56	(3.42-6.09)
FMU	258	289	89.4	(80.1-94.6)	4.37	(2.07-9.20)	4.61	(2.30-9.22)	4.14	(2.08-8.25)
AMU	673	776	85.6	(81.2-89.2)	3.09	(2.19-4.36)	3.08	(2.17-4.38)	3.05	(2.09-4.46)
Total	10392	14775	66.2	(63.5-68.8)						
Vaginal breech birth						n=14775		n=14253		n=14253
OU	34	12364	0.3	(0.2-0.5)	1	-	1	-	1	-
Home	10	1346	0.7	(0.3-1.6)	2.57	(0.99-6.68)	2.31	(0.85-6.27)	1.85	(0.59-5.81)
FMU	2	289	0.7	(0.1-9.2)	2.67	(0.19-38.02)	2.65	(0.19-37.62)	2.69	(0.18-41.06)
AMU	3	776	0.4	(0.1-1.1)	1.36	(0.41-4.55)	1.37	(0.41-4.57)	1.01	(0.22-4.65)
Total	49	14775	0.3	(0.2-0.5)						
Ventouse delivery						n=14775		n=14253		n=14253
OU	890	12364	7.2	(6.0-8.7)	1	-	1	-	1	-
Home	27	1346	1.8	(1.0-3.3)	0.23	(0.12-0.45)	0.24	(0.13-0.46)	0.34	(0.18-0.64)
FMU	8	289	2.2	(0.6-7.6)	0.29	(0.08-1.08)	0.30	(0.08-1.09)	0.33	(0.09-1.18)
AMU	35	776	5.1	(3.1-8.4)	0.69	(0.39-1.23)	0.68	(0.38-1.20)	0.72	(0.43-1.18)
Total	960	14775	7.2	(5.9-8.6)						
Forceps delivery						n=14775		n=14253		n=14253
OU	867	12364	7.3	(5.6-9.5)	1	-	1	-	1	-
Home	17	1346	1.1	(0.6-2.1)	0.15	(0.07-0.29)	0.15	(0.08-0.29)	0.23	(0.12-0.43)
FMU	8	289	2.1	(1.0-4.5)	0.27	(0.12-0.62)	0.27	(0.12-0.62)	0.33	(0.15-0.75)
AMU	33	776	3.9	(2.2-6.7)	0.51	(0.27-0.97)	0.50	(0.26-0.97)	0.53	(0.28-1.02)
Total	925	14775	7.3	(5.6-9.4)						
Intrapartum caesarean section						n=14775		n=14253		n=14253
OU	2347	12364	19.3	(17.5-21.4)	1	-	1	-	1	-
Home	57	1346	4.1	(2.9-5.7)	0.18	(0.12-0.26)	0.18	(0.12-0.26)	0.24	(0.16-0.35)
FMU	13	289	5.5	(1.9-15.2)	0.24	(0.08-0.76)	0.22	(0.08-0.60)	0.25	(0.10-0.68)
AMU	32	776	5.0	(2.7-9.1)	0.22	(0.11-0.42)	0.23	(0.12-0.44)	0.24	(0.12-0.48)
Total	2449	14775	19.1	(17.2-21.1)						

1 Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.

2 Restricted to women included in the adjusted analysis.

3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks, and gestation (completed weeks).

4.21.2 'Normal birth'

For 'higher risk' women, the proportion of women with a 'normal birth' varied from 49% for planned OU births to 87% for planned home births (Table 40). Women with a planned birth in the three planned non-OU settings had a significantly increased odds of a 'normal birth'.[i]

Table 40. 'Normal birth' for 'higher risk' women by planned place of birth

	Events	Births	Weighted[1]		Unadjusted[1]		Unadjusted[1, 2]		Adjusted[1, 3]	
	n	n	%	(99% CI)	OR	(99% CI)	OR	(99% CI)	OR	(99% CI)
Normal birth						n=14696		n=14176		n=14176
OU	6080	12312	48.5	(45.2-51.9)	1	-	1	-	1	-
Home	1139	1321	86.9	(84.0-89.3)	7.03	(5.39-9.18)	7.07	(5.39-9.28)	5.34	(4.08-6.98)
FMU	238	289	81.1	(71.8-87.8)	4.54	(2.65-7.77)	4.68	(2.80-7.82)	4.35	(2.46-7.68)
AMU	615	774	78.2	(73.1-82.5)	3.80	(2.79-5.16)	3.85	(2.84-5.21)	3.97	(2.93-5.38)
Total	8072	14696	49.1	(45.8-52.4)						

1 Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.
2 Restricted to women included in the adjusted analysis.
3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks, and gestation (completed weeks).

4.21.3 Other maternal outcomes

Other maternal outcomes are shown in Table 41.

Perineal trauma

For 'higher risk' women, the proportion of women having third or fourth degree perineal trauma ranged from 1.8% (planned home births) to 2.8% (planned OU and AMU births) but the odds did not differ significantly by planned place of birth.

Blood transfusion

There were no significant differences in the receipt of maternal blood transfusions by planned place of birth.

Maternal admission for higher level care

There were no significant differences in maternal admissions for higher level care by planned place of birth.

Maternal deaths

No maternal deaths occurred in 'higher risk' women.

[i] See note in section 4.12.2 regarding the interpretation of odds ratios for common events

Table 41. Other maternal outcomes for 'higher risk' women by planned place of birth

	Events	Total	Weighted[1]		Unadjusted[1]		Unadjusted[1, 2]		Adjusted[1, 3]	
	n	n	%	(99% CI)	OR	(99% CI)	OR	(99% CI)	OR	(99% CI)
Third or fourth degree perineal trauma						n=14744		n=14225		n=14225
OU	347	12338	2.8	(2.3-3.5)	1	-	1	-	1	-
Home	25	1343	1.8	(0.9-3.5)	0.63	(0.31-1.29)	0.63	(0.30-1.32)	0.82	(0.38-1.78)
FMU	5	288	1.5	(0.4-5.3)	0.52	(0.14-1.95)	0.53	(0.14-1.99)	0.55	(0.15-2.05)
AMU	21	775	2.8	(1.5-5.1)	0.99	(0.51-1.91)	1.02	(0.53-1.98)	1.07	(0.55-2.07)
Total	398	14744	2.8	(2.3-3.5)						
Blood transfusion						n=14697		n=14185		n=14185
OU	240	12312	2.0	(1.6-2.4)	1	-	1	-	1	-
Home	17	1329	1.2	(0.6-2.3)	0.59	(0.28-1.21)	0.58	(0.27-1.23)	0.65	(0.30-1.42)
FMU	1	287	0.2	(0.0-2.5)	0.09	(0.01-1.26)	0.09	(0.01-1.26)	0.10	(0.01-1.34)
AMU	7	769	1.2	(0.5-3.0)	0.62	(0.24-1.57)	0.63	(0.25-1.61)	0.62	(0.24-1.57)
Total	265	14697	2.0	(1.6-2.4)						
Admission to a higher level of care						n=14496		n=13975		n=13975
OU	136	12374	1.1	(0.8-1.6)	1	-	1	-	1	-
Home	13	1346	1.0	(0.5-2.1)	0.92	(0.40-2.15)	0.95	(0.41-2.19)	0.99	(0.41-2.36)
FMU	0	289	-	(-)	-	(-)	-	(-)	-	(-)
AMU	7	776	1.1	(0.5-2.6)	1.00	(0.38-2.60)	1.02	(0.39-2.64)	0.96	(0.37-2.51)
Total	156	14785	1.1	(0.8-1.5)						
Maternal death										
OU	0	12374	-	(-)						
Home	0	1346	-	(-)						
FMU	0	289	-	(-)						
AMU	0	776	-	(-)						
Total	0	14785	-	(-)						

1 Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.

2 Restricted to women included in the adjusted analysis.

3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks, and gestation (completed weeks).

4.21.4 Maternal interventions during labour for 'higher risk' women by planned place of birth

Maternal interventions during labour for 'higher risk' women are shown in Table 42.

Syntocinon augmentation

In 'higher risk' women, the proportion of women receiving syntocinon augmentation ranged from 5% (planned home births) to 40% (planned OU births).The high incidence of syntocinon augmentation in the OU group may be partly due to the high incidence of prolonged prelabour rupture of membranes in this group and uncertainty between use of syntocinon for

"augmentation" and "induction" in these circumstances. The odds of receiving syntocinon augmentation were significantly lower in births planned in the three non-OU settings.

Immersion in water for pain relief

The odds of using immersion in water for pain relief was significantly higher in births planned in the three non-OU settings relative to planned OU births. In contrast to 'low risk' births (where the highest proportion was seen in the FMU group), the use of immersion in water for pain relief was highest in the planned home birth group

Analgesia and anaesthesia

In the 'higher risk' women in the planned OU group, a relatively high proportion of women had epidural or spinal analgesia (40%).The odds of receiving epidural or spinal analgesia were significantly reduced in births planned in the three non-OU settings relative to planned OU births.

Odds of receiving general anaesthesia were reduced in the non-OU groups, but the reduction was significant only for planned home and AMU births.

Active management of the 3rd stage

The vast majority (96%) of 'higher risk' women with a planned OU birth received active management of the 3rd stage of labour. The odds of not receiving active management of the 3rd stage were significantly increased in births planned in the three non-OU settings relative to planned OU births.

Episiotomy

Around 18% of 'higher risk' women with a planned OU birth received an episiotomy, compared with 4%, 7% and 12% respectively in the planned home, FMU and AMU births. The odds of receiving an episiotomy was significantly reduced in births planned in each of the three non-OU settings relative to planned OU births.

Table 42. Maternal interventions during labour for 'higher risk' women by planned place of birth

	Events	Total	Weighted[1]		Unadjusted[1]		Unadjusted[1, 2]		Adjusted[1, 3]	
	n	n	%	(99% CI)	OR	(99% CI)	OR	(99% CI)	OR	(99% CI)
Syntocinon augmentation						n=14639		n=14119		n=14119
OU	4932	12233	40.2	(35.9-44.7)	1	-	1	-	1	-
Home	66	1344	4.8	(3.4-6.6)	0.07	(0.05-0.11)	0.07	(0.05-0.11)	0.10	(0.07-0.15)
FMU	22	288	7.8	(3.9-15.0)	0.13	(0.06-0.27)	0.12	(0.06-0.23)	0.13	(0.07-0.26)
AMU	74	774	10.6	(7.3-15.2)	0.18	(0.11-0.28)	0.17	(0.11-0.27)	0.18	(0.12-0.29)
Total	5094	14639	39.7	(35.4-44.2)						
Immersion in water for pain relief						n=14724		n=14204		n=14204
OU	476	12357	3.5	(1.8-6.7)	1	-	1	-	1	-
Home	399	1302	30.9	(27.0-35.2)	12.28	(6.04-24.96)	12.12	(6.00-24.51)	12.57	(6.25-25.27)
FMU	78	289	27.6	(19.2-37.9)	10.45	(4.56-23.94)	9.93	(4.33-22.77)	9.17	(3.91-21.46)
AMU	174	776	21.7	(14.5-31.1)	7.61	(3.29-17.62)	7.43	(3.22-17.13)	8.16	(3.85-17.31)
Total	1127	14724	3.9	(2.1-7.0)						
Epidural or spinal analgesia						n=14697		n=14184		n=14184
OU	4944	12291	41.4	(37.7-45.3)	1	-	1	-	1	-
Home	133	1344	9.4	(7.5-11.7)	0.15	(0.11-0.20)	0.15	(0.11-0.20)	0.19	(0.14-0.26)
FMU	38	289	14.7	(8.5-24.2)	0.24	(0.13-0.46)	0.23	(0.13-0.43)	0.26	(0.14-0.48)
AMU	95	773	13.4	(9.6-18.3)	0.22	(0.15-0.33)	0.21	(0.14-0.32)	0.22	(0.14-0.33)
Total	5210	14697	40.9	(37.2-44.7)						
General anaesthetic						n=14553		n=14038		n=14038
OU	317	12156	2.5	(2.0-3.2)	1	-	1	-	1	-
Home	11	1339	0.9	(0.4-1.9)	0.33	(0.14-0.77)	0.34	(0.15-0.80)	0.41	(0.17-0.95)
FMU	2	287	0.9	(0.1-6.0)	0.35	(0.05-2.49)	0.35	(0.05-2.54)	0.41	(0.06-2.90)
AMU	3	771	0.4	(0.1-1.6)	0.15	(0.04-0.62)	0.16	(0.04-0.64)	0.17	(0.04-0.68)
Total	333	14553	2.5	(2.0-3.2)						
No active management of the 3rd stage						n=14729		n=14211		n=14211
OU	523	12362	4.2	(3.2-5.4)	1	-	1	-	1	-
Home	397	1302	30.9	(24.1-38.7)	10.19	(6.59-15.78)	10.27	(6.60-15.98)	9.85	(6.33-15.33)
FMU	53	289	18.9	(12.3-27.8)	5.30	(3.00-9.38)	5.06	(2.81-9.11)	4.92	(2.72-8.93)
AMU	92	776	10.7	(6.9-16.3)	2.74	(1.57-4.76)	2.70	(1.55-4.70)	2.70	(1.59-4.61)
Total	1065	14729	4.4	(3.5-5.7)						
Episiotomy						n=14746		n=14224		n=14224
OU	2165	12356	17.6	(15.7-19.6)	1	-	1	-	1	-
Home	54	1325	4.0	(2.6-6.1)	0.19	(0.12-0.31)	0.20	(0.12-0.32)	0.30	(0.19-0.47)
FMU	21	289	6.8	(3.5-12.7)	0.34	(0.17-0.69)	0.35	(0.17-0.70)	0.41	(0.20-0.84)
AMU	91	776	12.3	(9.3-16.1)	0.66	(0.47-0.92)	0.64	(0.45-0.90)	0.68	(0.49-0.93)
Total	2331	14746	17.4	(15.6-19.4)						

1 Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.

2 Restricted to women included in the adjusted analysis.

3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks, and gestation (completed weeks).

5 Discussion and conclusions

5.1 Summary of main findings

The purpose of the Birthplace national prospective cohort study was to evaluate a range of perinatal and maternal outcomes for births planned in the four settings currently provided for intrapartum care by the NHS in England, with a particular focus on women known to be at 'low risk' of complications prior to the onset of labour. To maximise statistical efficiency, we used planned OU births as the comparison group. All analyses were by planned place of birth (i.e. 'intention to treat' analyses).

5.1.1 Births in women at 'low risk'

The incidence of adverse perinatal outcomes (intrapartum stillbirth, early neonatal death, neonatal encephalopathy, meconium aspiration and specified birth related injuries including brachial plexus injury) was low in all settings. For all planned birth settings, adverse perinatal outcome, adverse maternal outcomes and intervention during labour were more common in nulliparous women compared with multiparous women.

After adjusting for differences in the characteristics of women planning birth in the different settings, there were no statistically significant differences between birth settings in the odds of adverse perinatal outcome for multiparous women as measured by the study primary outcome measure**.** For nulliparous women, we found no difference between outcomes in midwifery units and OUs but adverse perinatal outcomes were more likely in the planned home birth group.

Instrumental and operative deliveries - ventouse, forceps and intrapartum caesarean section - were less common in planned home, FMU and AMU births in 'low risk' women, although the reduction was not statistically significant at the 1% level for all of these interventions in the AMU group. 'Low risk' women in the planned home, FMU and AMU groups were significantly more likely to have a 'normal birth', defined as a spontaneous vaginal birth without induction of labour, an epidural or spinal anaesthetic or episiotomy, compared with 'low risk' women in the planned OU group. There were higher rates of 'normal birth' in these three groups for both nulliparous and multiparous women.

Babies in the planned home and FMU groups were significantly more likely to be breastfed at least once relative to babies born in the planned OU group.

Adverse maternal outcomes - third or fourth degree perineal trauma, blood transfusion or admission to a higher level of care – tended to occur less frequently in the planned home and FMU groups and blood transfusions

were given less frequently in the planned FMU group relative to planned OU births. However, event rates for these outcomes were low and most of these differences were not significant at the 1% level.

Transfers during labour or immediately after birth occurred in over 20% of births in the three non-OU groups: more than two thirds of transfers took place before the birth. Failure to progress, fetal distress and meconium staining were the most common reasons for transfer during labour; epidural request was more common as a reason for transfer in the AMU group.

Transfers immediately after birth were predominantly for repair of perineal trauma or for retained placenta.

Transfer rates in the three non-OU groups were markedly higher for nulliparous women compared with multiparous women: for nulliparous 'low risk' women, transfer rates ranged from 36% (FMU) to 45% (planned home births) compared with 9-13% for multiparous 'low risk' women.

5.1.2 Births in 'higher risk' women

For 'higher risk' women, comparisons with planned OU births are more difficult to interpret because the groups were not homogeneous in terms of risk. For example, induction of labour was recorded as a risk factor in almost half of the 'higher risk' women in the planned OU group. This both increases the risk of other interventions and, by definition, precludes a 'normal birth'.

Overall 2411 (5%) women in the three planned non-OU groups fell into the 'higher risk' category and therefore, according to the NICE intrapartum care guideline should have been "advised to give birth in an obstetric unit".[28] In these settings, the highest proportion of 'higher risk' women was seen in planned home births (7%), and the lowest in planned FMU births (2.5%). Findings were consistent with an increased incidence of an adverse perinatal outcome for 'higher risk' women in the planned home birth group: 7.7 primary outcome events per 1000 births, 95% CI 4.2 -14.2 in the home birth group vs. 4.7 per 1000 births, 95% CI 3.6-6.1, in the planned OU group. For nulliparous 'higher risk' women in the planned home birth group, the rate of adverse perinatal outcome was 12.6 per 1000 births.

Findings for other outcomes in 'higher risk' women – 'normal birth', receipt of interventions, maternal morbidities and breastfeeding – were broadly consistent with 'better' outcomes for planned non-OU births relative to the planned OU group.

5.2 Strengths and weaknesses of the study

All study designs have their inherent strengths and weaknesses. In order to interpret these results, it is necessary to explore the potential biases and what impact these may have on the interpretation of the findings.

5.2.1 Study design

Ideally this question would have been best addressed by a randomised controlled trial (RCT) where women judged to be at 'low risk' of complications in labour would be allocated, at random, to plan birth in an OU, FMU, AMU or home. However, this design is unlikely to be possible for a number of reasons. In order to measure substantive outcomes of morbidity, large numbers would be required; and in the unlikely event that large numbers of women would agree to accept randomisation, there would not be sufficient capacity in midwifery units or enough midwives with experience of home births to provide the equivalent type of care to be tested. In addition, the timing of randomisation would be problematic. Women would be unlikely to find it acceptable to accept randomisation at the start of labour. The ELSA trial of community-based support in early labour, for example, randomized nulliparous women at 36 weeks on the basis of findings indicating that women wished to know their 'allocation' before labour, preferably by about the 38th week of gestation.[37] Thus randomisation would have to occur at some point prior to labour onset. From the time of randomisation to labour onset, new risk factors will arise in a proportion of women, such as induction of labour for post-maturity, which would indicate planned birth in an OU. Analysing women in the groups in which they were randomised would result in a dilution of the differences between women if all the women with new risk factors started their labour care in an OU. In the ELSA trial, which randomised women at around 36 weeks gestation, over 50% of women randomised developed pregnancy new 'risk factors' between randomisation and the onset of labour: and while not all of these risk factors would have precluded a non-OU birth, around 20% required induction of labour or a planned caesarean section.[37]

In addition, even if a sufficiently large RCT was possible, the generalisability of the findings may be limited. In the UK, many women have a strong preference regarding place of birth and may be unwilling to accept randomisation and women who would accept randomisation may be very different from the women who either want a home birth or who want a hospital birth.[22] These differences may be very difficult to measure, may be associated with different birth outcomes, and would make the results of such a trial (at least in a UK setting) very difficult to interpret.

If a RCT is not possible the least biased observational study is a well designed prospective cohort study. The elements of the design of cohort studies which minimise bias are to (a) try and avoid selection bias, which occurs when women recruited into the cohort are not representative of the group of women from which they are drawn, (b) limit the impact of confounding bias, which occurs because women in different groups vary in ways that affect the outcome under study, (c) minimise misclassification biases which may arise from errors in the classification of individuals into the correct exposure group or differential ascertainment or classification of outcome events.

Selection bias was minimised in two ways. Firstly, consent from the women to participate in the study was not required because the data collected were anonymised and treatment was not affected by participation in the study. This meant that the potential selection biases arising from the need for women to 'opt in' were avoided. This form of selection bias would typically result in single women, non-white women, and women with lower levels of education and higher social deprivation being under-represented.

Secondly, we took a number of actions to ensure a high response rate. Many participating centres collected denominator data prospectively and reported denominators to us monthly, and we encouraged centres that were unable to do this to obtain denominator data retrospectively from hospital computer systems or other sources. This enabled us to identify and provide feedback to units with poor response data and many of these units undertook retrospective data collection in order to increase the proportion of eligible women included in the study.

Despite these problems, the majority of participating centres were able to provide us with adequate data to assess response rates and nearly three quarters of the sites achieved a high response rate (85% or more of eligible women included). A sensitivity analysis which looked at the results for those centres with high response rates did not materially alter the conclusions of the study although the analysis produced different results for planned FMU births for 'low risk' nulliparous women. In this sensitivity analysis, the odds of an adverse perinatal outcome in this group were significantly raised for women without complicating conditions at the start of care in labour but the test for interaction between nulliparous and multiparous women in the FMU group was not significant suggesting that this may have been a chance finding.

There is also a possibility that births which ended in an adverse outcome such as an intrapartum stillbirth or an early neonatal death may have been less likely to be included than births that ended in a normal outcome or a less severe adverse outcome. This might arise if notes were removed for local review and risk management processes or if the data collection forms for women who transferred because of complications during or immediately after labour were less likely to have been completed and returned by the receiving hospital. The overall incidence of intrapartum stillbirth in the Birthplace cohort was 0.2 per 1000 births in 'low risk women and 0.3 per 1000 births in 'higher risk women; and the incidence of early neonatal death was 0.3 per 1000 births in 'low risk' women and 0.4 per 1000 births in 'higher risk women. It is difficult to find comparable data from other contemporary UK sources. The incidence of intrapartum stillbirth has been estimated as 0.27 per 1000 term births in 2002. [38] Similarly the incidence of early neonatal death can be estimated from published ONS data as 0.6 per 1000 term births in 2007-08.[38, 39] But both of these estimates include all births regardless of risk. It seems, therefore, that a risk of intrapartum stillbirth and early neonatal death at term for a group of women judged to be at 'low risk' of complications prior to the onset of labour of 0.5 per 1000 births is reasonable.

Units kept a log of data collection forms started by midwives in the unit to enable the local coordinator to track and chase 'missing' forms but there may have been some loss of women who transferred because of complications during labour or immediately after birth. However, because transfers are rare for OU births, any resulting biases would tend to dilute the observed differences in adverse outcomes between the planned OU and non-OU groups.

In addition, it is possible that missing data, particularly for risk factors or confounders, may not be missing at random. However, intensive data querying procedures ensured that the quantity of missing data was low for all settings, so the impact of any differential missing data on the study findings is likely to have been small.

Not all potential confounders were collected or measured for all women in the sample. BMI was the most commonly non-measured confounder. Despite widespread recommendations that BMI should be recorded for all women at booking, this has not been universally adopted and BMI was not recorded in the maternity notes for 17% of the women in the study cohort. It seems plausible that lack of measurement, or lack of recording of measurement, may be more likely in women judged to be of normal BMI by the midwife at booking but we did not make this assumption in the analysis. We included 'no BMI recorded' as a separate category in the adjusted analysis. Smoking status was not collected on the data collection form. This was a deliberate decision because of the very poor accuracy of this information in the medical records.[40] We were also unable to collect data about the socio-economic status of individual women as this is not consistently recorded in clinical records. Instead, we used the Index of Multiple Deprivation (IMD) score which is based on the socio-economic characteristics of the area in which the woman lives.[41]

Confounding was controlled for in several ways. First, we aimed to compare like-with-like by restricting our primary analysis to 'low risk' women. We based our classification of risk on the NICE Intrapartum Care guideline which had been well adopted by the time Birthplace started collecting data. We used the guideline's list of risk factors that indicate "increased risk suggesting planned birth in an OU" to define our 'higher risk' group; and we listed the conditions on the data collection form as a coding checklist for the midwife completing the form. However, women defined as 'low risk' by this definition probably do not form a homogeneous group in terms of risk.

The guideline also includes tables of factors that should lead to individual assessment by healthcare staff when planning place of birth. While these and other conditions were sometimes recorded under 'other' on the data collection form, the level of detail given varied and the conditions recorded were sometimes considered unlikely to pose an increased risk for the mother or baby such that the presence of the condition would indicate planned birth in an OU. For example, "preterm birth in previous pregnancy" is not a risk factor once the current pregnancy has reached term. The 'other' pre-existing conditions entered as free text by the midwife were individually reviewed by an obstetrician and midwife, blinded to planned

place of birth, and women were reclassified as 'higher risk' where the condition was considered to clearly indicate an OU birth.

It seems probable that a proportion of the women with 'other' conditions that were not considered to merit reclassification as 'higher risk' were nevertheless at an intermediate level of risk. Including these women in the 'low risk' group may have led to residual 'confounding by indication'. This is confounding arising from differential inclusion of women with adverse medical and obstetric histories in the four groups. However, the proportion of women with 'other' conditions was highest in the planned OU group so any resulting bias would have tended to make outcomes appear worse for births planned in the OU group. Thus it is highly unlikely that this explains the observed higher adverse perinatal outcomes observed for 'low risk' nulliparous women in the planned home birth group. It is possible, however, that some of the 'beneficial' reductions in other outcomes seen in the non-OU groups may be attributable to residual confounding due to uncontrolled differences between the risk status of the groups.

We did not adjust for the presence of 'other' conditions in the analysis because this was not one of the adjustment variables pre-specified in the statistical analysis plan. Further sensitivity analyses will be conducted to explore the possible effects of variations in risk on the findings.

Confounding was also controlled for using multivariable adjustment. This was necessary because even with restriction to 'low risk' women, there were differences in other important characteristics, such as parity, between the different planned places of birth. The degree to which this adjustment controlled for confounding is illustrated in the results. Many of the odds ratios changed as a consequence of adjustment suggesting there was confounding. This might be expected because of the different distribution of potential confounders (see Table 14). There is nevertheless scope for residual confounding to be present, either because a particular confounder was not collected (e.g. smoking) or because the estimate of the confounder data collected may be imprecise (e.g. BMI).

5.2.2 Classification of planned place of birth

The four groups of women considered in the study were defined in terms of planned place of birth at the start of care in labour. This is not necessarily equivalent to planned place of birth at onset of labour.

There was a higher prevalence of obstetric and other complicating conditions identified by the midwife at the start of care in labour in 'low risk' women in the planned OU group relative to 'low risk' women in the non-OU groups (20% vs. 5-7% of women). This was not anticipated and suggests that 'low risk' women in the planned OU group may have had higher levels of risk prior to the onset of labour compared with the non-OU groups. However, we have no means of assessing if this was the case and the causes of the observed differences between the groups are uncertain. One possibility is that, as discussed above, women with risk factors other than the conditions used to define our 'higher risk' group may have tended

to be channelled into the planned OU group. Another possibility is that women who develop complicating conditions such as pre-labour rupture of membranes or meconium staining may be advised – perhaps by phone before labour care has started - to switch to an OU in early labour**.** However, there may be other explanations.

In order to assess the possible impact of this on our findings, we conducted an additional restricted analysis in which we excluded women with complicating conditions identified at the start of care in labour. This analysis was not specified in the original statistical analysis plan but was discussed and agreed by the co-investigators and by the independent study Advisory Group prior to the analysis of the outcomes. Although we consider that this additional analysis was informative, it is noteworthy that it did not materially affect our conclusions relating to the primary outcome. For multiparous women, both the main and restricted analyses showed no difference between settings in the primary outcome; and for nulliparous women, the odds of the primary outcome was significantly higher in the planned home birth group irrespective of whether or not the analysis was restricted to women without complicating conditions at the start of care in labour.

By design, the study only included women who received labour care from a midwife in their planned place of birth. This means that the study did not include planned home births where the birth occurred before the midwife arrived or planned births in other settings where the birth occurred before the woman reached the unit.

5.2.3 Participation of units and trusts

Not all trusts in England participated in Birthplace and participation was less complete in some trusts than others. Only one trust actively refused to participate altogether, insisting that consent from women had to be obtained prior to data collection. A small minority of trusts did not provide any data for births planned at home (3%) and this may be because no births were planned at home during the study period. 16% of AMUs and 5% of FMUs also failed to provide any data.

Three OUs felt unable to participate when randomly selected, and these were replaced by trusts within the same sampling strata. Non-participation of these units and trusts may have affected the results if these trusts had particularly good or particularly poor outcomes. The reasons given for non-participation included concerns about midwifery staffing levels not being adequate for data collection, which may suggest these trusts had concerns about their outcomes. However, the overall participation of units and trusts providing maternity care in England was excellent, so the impact of non-participation is likely to be very small.

5.2.4 Association or causality

To what extent the associations we have seen in this cohort study are causal is a matter of judgement taking account of the strengths and weaknesses of this particular study. This is the largest cohort study ever to be undertaken without relying on routine data sources, and with the ability to control for a variety of well collected confounders. There are few missing data, and the results have been explored in sensitivity analyses, which do not change the essential conclusions.

The observed associations are unlikely to have arisen by chance because the confidence intervals used in the analysis have been pre-specified to minimise spurious associations, with 99% confidence intervals used for all analyses of the secondary outcomes, in view of the large number of comparisons being made.

In addition the associations are not implausible. The strength of some of the associations are strong, for example, in relation to caesarean section or instrumental vaginal births, suggesting that residual confounding is unlikely to explain these associations. Similarly, in relation to the association between births planned at home and the primary outcome, which suggests an increase in risk, the observation that the increase is present for women having their first baby but not their second or subsequent baby (with statistical evidence of an interaction) is biologically plausible.

All of this suggests that the associations seen may be causal, i.e. reflect real differences in outcome, but, as discussed below, this does not necessarily mean that the associations are not amenable to change.

5.2.5 Performance of individual units

The numbers of adverse events for babies of mothers at 'low risk' of complications in labour are fortunately very small, hence the need for a large national study and the use of a composite primary outcome. However, this means that there is inadequate statistical power to make comparisons between individual units within the groups for the primary outcome or rare secondary perinatal outcomes. For example, we cannot compare the primary outcome between FMUs, or explore the impact of trust level service configuration factors on the primary outcome. Care in labour is a complex interplay between the clinical characteristic of the women, the inherent unpredictable course of labour and the features of the system of care. Outcomes for the woman and baby may be affected by a variety of staffing and structural issues. These may include individual competencies, thresholds for transfer, the referral pathways particularly in relation to mode of transport, the distance from the planned place of birth to the referral site, and the management of the woman with complications at the initial site when these are recognised, during the transfer and on arrival at the site of birth. Most of these factors will vary between different locations within the same type, particularly for planned birth at home where referral pathways may be less well defined than in midwifery units.

This analysis has evaluated outcomes overall for each setting, grouping women and babies by planned place of birth at the start of care in labour. There is likely to be substantial variation between sites within each unit type and this variation is likely to be amenable to change. For example, in the case studies, it was clear that training in relation to assisting at births for midwives in AMUs or for home births was less than for midwives in FMUs, and that some midwives providing care at home had very limited experience in this setting because the home birth rate in their trust was low. This variability in experience and training is likely to affect midwives' ability to provide safe and effective care. If the numbers of home births increases, the experience of midwives providing care at home will increase, and it could be argued that the outcomes of this setting could improve as a consequence. The results of this study are therefore a view of what was happening in England in the NHS between June 2007 and April 2010.

5.2.6 The need to repeat the cohort study

One important lesson to be learnt from the Birthplace cohort study is that with the constantly changing configuration of services, and increasing financial pressures on the NHS, this study will need to be repeated in coming years. The data collected for the cohort study are not complex and should be available within routine data sources. This is not the case and during the course of Birthplace it became clear that, despite the considerable investment in the National Programme for IT, there has been no overall progress in the quality of electronic data systems for maternity care in England and in some trusts, current systems are inferior to the older systems they replaced. As a result, many trusts have major problems accessing their data. Despite the fact that this has been on the agenda since the 1980s, at the time of writing no trust systematically collects planned place of birth at the start of care in labour, many units with an AMU are unable to disentangle AMU births from OU births, and few trusts have robust systems for capturing the information about women who plan a home birth and start labour care at home.

The estimated total costs of the Birthplace in England Research Programme in its entirety are in the region of £12m (£1.5m research costs, £1.6m service support costs and £8.8m CLRN costs), of which the majority was spent on undertaking the cohort study. It seems unlikely that this study will be undertaken again soon, but it remains important to monitor outcomes by planned place of birth and routine data sources are currently inadequate for the task. This issue needs to be addressed with urgency.

5.3 Key messages

- For 'low risk women', the incidence of adverse perinatal outcomes is low in all birth settings (4.3 primary outcome events per 1000 births).

- The benefits of planned birth at home or in a midwifery unit include fewer interventions, a substantially reduced incidence of intrapartum caesarean section and a higher likelihood of a 'normal birth'.
- For multiparous 'low' risk women there are no differences in adverse perinatal outcomes between settings but the risk of an adverse perinatal outcome appears to be higher for nulliparous women who plan to give birth at home (9.3 primary outcome events per 1000 births vs. 5.3 per 1000 births in an OU).
- For nulliparous 'low risk' women the intrapartum transfer rate is high in settings other than an OU (home 45%; FMU 36%, AMU 40%)
- A non-negligible proportion (5%) of planned home and midwifery unit births are to women at 'higher risk' of complications who, according to current clinical guidelines, should be advised to give birth in an OU.

5.4 Implications for policy and practice

- Guidance given to women on planning place of birth should be updated to reflect the new evidence provided by this study. As a result of this study, women can now be provided with more reliable information on outcomes in the available birth settings, and can also be given a more accurate estimate of the overall likelihood of intrapartum transfer
- The evidence provided by this study supports the policy of offering 'low risk' women a choice of birth setting:
    - FMUs and AMUs appear to be safe for babies and offer benefits to both the mother (fewer interventions) and baby (more frequent initiation of breastfeeding). Nulliparous women should be informed of the relatively high probability of intrapartum transfer in these settings when choosing their planned place of birth.
    - For multiparous women, home births appear to be safe for babies and offer benefits to both the mother (fewer interventions) and baby (more frequent initiation of breastfeeding).
    - The substantially lower incidence of major interventions, including intrapartum caesarean section, in all three non-OU settings has potential future benefits to both the woman and the NHS in terms of avoiding surgical complications and reducing the need for repeat caesarean sections in future births. There is a need to address the higher frequency of major interventions and the relatively low proportion of 'normal births' in 'low risk' women in OUs.
    - The continued provision of a home birth service is important so that multiparous women, and some nulliparous women who are aware of the additional risks to the baby and the high likelihood of transfer, can plan to have their baby at home.

    - Expansion of the provision of FMUs and AMUs would provide a choice of birth setting for 'low risk' nulliparous women who do not wish to opt for an OU birth.
- Findings show that a non-negligible proportion (5%) of planned home and midwifery unit births are to women at 'higher risk' of complications who, according to current clinical guidelines, should be advised to give birth in an OU. The reasons for this are not clear but some consideration needs to be given to the information and options offered to 'higher risk' women.
- There is an urgent need for routine data collection systems to collect data on planned place of birth at the start of care in labour so that outcomes can be monitored by planned place of birth.

5.5 Recommendations for future research

5.5.1 Overview of ongoing projects

Further Birthplace analyses are currently ongoing which will be available in autumn 2011. These include:

- An analysis of the rate of intrapartum related deaths by planned place of birth
- More detailed analysis of the cohort study transfer data (see below)

Two NIHR funded PhD research studies are also ongoing:

1. A quantitative and qualitative study of transfers from midwifery units to OUs during labour. Analysis of Birthplace cohort study data will provide evidence on the factors known prior to the start of labour or at the start of care in labour that are most strongly associated with transfer from midwifery units. A qualitative study will provide evidence about women's experience of transfer, including their information and support needs and their perceptions of care.
2. A prospective, qualitative study of how women and their partners make sense of risk and safety when choosing where to give birth.

Both of these will be completed and available in thesis form in late 2011 with peer-reviewed publications shortly thereafter.

The NIHR SDO programme has also funded two 'follow-on' projects:

- Care provided in Alongside Midwifery Units (AMUs): The aim of this study is to investigate how AMUs may be best organized, managed and staffed to help ensure that they provide quality care for women, and are organisationally sustainable. It will look at organisation and staffing of AMUs, the experiences of users and professionals, and whether the organisation of this kind of unit has any unintended effects. The study is expected to report in October 2012.
- The efficient use of the maternity workforce and the implications for safety and quality in maternity care: An economic perspective. This

study will compile secondary data from a range of public sources before applying econometric techniques to answer important policy questions related to staffing levels and mix and their impact upon productivity and safety. The over-riding aim of this project is to understand the relationships between maternity workforce size, skill mix and quality outcomes including patient safety and quality, effectiveness and unit level efficiency in England. This study will report in 2013.

5.5.2 Recommendations for future research

The following topics would merit further research:

Avoidable or remediable factors in adverse intrapartum outcomes

- What are the aspects of clinical care and service delivery associated with adverse intrapartum related outcomes by planned place of birth and, in particular, what are the potentially avoidable or remediable factors involved in these adverse outcomes?
- What potentially modifiable aspects of current services are associated with poorer outcomes in particular birth settings? For example:
    - Do trusts with a higher volume of planned home birth have better outcomes?
    - Are there differences in outcome associated with features of the system of care, such as staffing, throughput or configuration of services?

Factors affecting choice of 'out of hospital' birth in women at 'higher risk'

- Why do some 'higher risk' women opt for a non-OU birth?
- What are the clinical characteristics of 'higher risk' women who opt for a non-OU birth? Are there some risks that might be adequately managed in an FMU or AMU setting in order to provide an alternative to home birth for women unwilling to opt for birth in an OU?

Strategies to reduce the frequency of unnecessary interventions

- The relatively high frequency of interventions in 'low risk' OU births is not associated with demonstrable benefits in outcomes. Research is required into strategies to reduce unnecessary obstetric interventions.

How can the benefits and risks of the available options for birth setting best be communicated to women and their partners?

- Are there evidence-based aids to decision-making or ways of presenting information that would be particularly useful for midwives and antenatal class leaders to use in discussing place of birth with women and their partners?
- What are the best ways of ensuring that woman and their partners are adequately prepared for transfer without 'pathologising' an otherwise 'normal' pregnancy?

Issues related to intrapartum transfer to an obstetric unit

Given that transfer is potentially distressing for women, it is important to keep transfer rates as low as possible, without increasing the risk of adverse outcomes for women and babies.

- There is considerable variation in transfer rates from different units. What are the characteristics and qualities of units or trusts with particularly low transfer rates? To what extent are the factors contributing to variation in transfer rates modifiable, e.g. staffing levels, throughput?
- What are the potentially modifiable factors contributing to transfers for non-clinical reasons from AMUs?

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Appendix 1 Cohort study protocol

The Birthplace in England Research Programme: study protocol for the Birthplace national prospective cohort study of planned place of birth

Background

Maternity services in England are provided by the NHS and are free of charge at the point of care. NHS midwives and doctors provide care for more than 99% of all births.[1]

Since the Changing Childbirth report in 1993, maternity care policy has aimed to be responsive to women's needs and enable women to make informed choices about their care.[2] This policy direction has continued with the Maternity Standard of the National Service Framework (NSF) for Children, Young People and Maternity Services.[3] Maternity Matters, the implementation plan for the NSF, consolidated this policy direction for maternity care and stated that by the end of 2009, depending on their circumstances, a woman and her partner should be able to choose where they wish to give birth: at home, in a local midwifery unit or in an obstetric unit.[4]

Reviews of research have identified that there is no accurate quantification of the risk of adverse outcomes associated with births planned in the different settings. One major problem in interpreting much of the evidence is that actual place of birth is often used to make inferences about planned place of birth.[5-8]

Birth at home

A Cochrane systematic review of home versus hospital birth identified only one randomised controlled trial which included 11 women and was unable to detect any differences in safety or other outcomes between the two settings.[9] A meta-analysis of six observational studies examined perinatal outcomes for 24,092 'low risk' women and their babies.[10] No difference was observed for perinatal mortality. However, there was evidence that women planning birth at home had a lower risk of induction, augmentation, instrumental vaginal birth, caesarean section, episiotomy, severe perineal lacerations and that their babies were less likely to have low Apgar scores.

The results of several large observational studies comparing home births with birth in an obstetric unit have been published since the Birthplace Research Programme began in 2007. A retrospective cohort study from the Netherlands using routine data from over 500,000 women found no evidence of a difference in perinatal mortality or morbidity between 'low risk' women who planned to give birth at home and 'low risk' women who planned to give birth in hospital.[11] Canadian and Swedish studies of

planned home births compared to planned hospital births for 'low risk' women also showed no difference in perinatal mortality.[12, 13] Lower rates of obstetric interventions were observed in the planned home birth group for both studies. However, both studies included fewer than 20,000 births and lacked statistical power to demonstrate differences in rare but important adverse outcomes. A study from England and Wales attempted to quantify the intrapartum-related perinatal mortality rates for booked home births from 1994 to 2003 using routine statistics.[14] However, the data available were of poor quality for this comparison and highlighted the need for a more accurate quantification of the risks associated with each planned place of birth. A recent meta-analysis found planned home births, compared to planned hospital births, were associated with less medical intervention, had a similar perinatal mortality rate and an increased neonatal mortality rate.[15] This study has been criticized for failing to report the assessment of the quality of the studies included.[16]

Births in midwifery units

NHS midwifery units provide midwife-led care for women who are at 'low risk' of complications at the start of care in labour.[17] Freestanding midwifery units are on a site geographically separate from an obstetric unit. Alongside midwifery units are in the same building or on the same site as an obstetric unit.

A Cochrane systematic review comparing birth in alternative birth settings with conventional institutional settings (obstetric units) included nine randomised controlled trials and 10,684 women.[18] The alternative birth settings had features in common with the units that we define as alongside midwifery units. The alternative birth settings were associated with an increased likelihood of spontaneous vaginal birth, increased maternal satisfaction and fewer medical interventions during labour and birth. There was no association between birth setting and severe perinatal morbidity or mortality. Also, there was no association between birth setting and serious maternal morbidity or mortality. However, it is likely that the review was underpowered to detect any differences in rare but important severe adverse perinatal and maternal outcomes. No trials of freestanding midwifery units were included in the review.

Prospective observational studies show a lower rate of intervention during labour for births planned in free-standing midwifery units.[8, 19]

It is difficult to draw clear conclusions about the effect of planned place of birth on outcomes due to differences in the health care systems in which studies were undertaken, the heterogeneity of studies, poor study design and the use of varied outcome measures. High quality evidence about the risks and benefits associated with the different settings for birth should be available to women. The National Institute for Health and Clinical Excellence's (NICE) clinical guidance on Intrapartum Care included guidance on planning place of birth and stated that "Of particular concern is the lack of reliable data, relating to relatively rare but serious outcomes such as perinatal mortality that is directly related to intrapartum events or

serious maternal morbidity in all places of birth".[20] It is in this context that the Birthplace in England Research Programme has been designed to compare the safety of the settings for birth supported by the NHS in England (http://www.npeu.ox.ac.uk/birthplace).

Aim

To compare aspects of the safety of birth by planned place of birth at the start of care in labour: at home, in freestanding midwifery units, in alongside midwifery units and in obstetric units in England.

Primary objective

To compare intrapartum and early neonatal mortality and specific neonatal morbidities for births planned at home, in freestanding midwifery units and in alongside midwifery units with births planned in obstetric units, for babies of women judged to be at 'low risk' of complications at labour onset.

Using births planned in obstetric units as the reference group will maximise statistical efficiency as the highest number of births will be included from these units. This does not imply obstetric units are assumed to be the standard or optimal places of care.

Secondary objectives

To compare the following for births planned at home, in freestanding midwifery units and in alongside midwifery units with births planned in obstetric units:

1. Maternal morbidity for women judged to be at 'low risk' of complications at labour onset

2. Intrapartum and early neonatal mortality and specific neonatal morbidities for babies of all women, irrespective of risk status at labour onset.

3. Maternal morbidity for all women, irrespective of risk status at labour onset.

4. Intrapartum and early neonatal mortality and specific neonatal morbidities for babies of women at 'higher risk' of complications at labour onset.

5. Maternal morbidity for women at 'higher risk' of complications at labour onset.

6. Maternal birth interventions for women judged to be at 'low risk' of complications at labour onset. Also, using the planned birth at home group as the comparison group:

7. To compare perinatal and maternal outcomes for 'low risk' women who transfer from home, freestanding midwifery units and alongside midwifery units, during or immediately after labour.

8. To quantify any associations between indication for transfer, time from decision making until transfer, duration of transfer or events after transfer (including the time taken to be assessed by an obstetrician) and perinatal or maternal outcomes for babies and women who are transferred during or immediately after labour.

Design

The study design is a prospective cohort study with planned place of birth at the start of care in labour as the exposure and a composite measure of intrapartum and early neonatal mortality and specific neonatal morbidities as the primary outcome.

Definitions

'Low risk': Women will be classified as 'low risk' if they do not have any of the medical conditions or situations listed in the NICE Intrapartum Care guidelines that result in "increased risk for the woman or baby during or shortly after labour, where care in an obstetric unit would be expected to reduce this risk".[20] These risk factors are listed on page 4 of the Birthplace data collection form.

'Higher risk': Women will be classified as 'higher risk' if they have any of the medical conditions or situations listed in the NICE Intrapartum Care guidelines.

Births planned at home: a birth which occurs for a woman who, at the start of care in labour, intended to give birth at home and who received care from a midwife during established labour at home, regardless of where the woman actually gives birth. This includes women who make their final decision about planned place of birth during labour.

Births planned in a freestanding midwifery unit: a birth which occurs for a woman who, at the start of care in labour, intended to give birth in a freestanding midwifery unit and who received care from a midwife during established labour in a freestanding midwifery unit, regardless of where the woman actually gives birth. Freestanding midwifery units are defined as being on a separate geographical site from an obstetric unit and transfer will normally be by ambulance or car.[21]

Births planned in an alongside midwifery unit: a birth which occurs for a woman who, at the start of care in labour, intended to give birth in an alongside midwifery unit and who received care from a midwife during established labour in an alongside midwifery unit, regardless of where the woman actually gives birth. Alongside midwifery units are defined as being in the same building or on the same geographical site as an obstetric unit and transfer will normally be by trolley, bed or wheelchair.[21]

Births planned in an obstetric unit: a birth which occurs for a woman who, at the start of care in labour, intended to give birth in an obstetric unit and who received care from a midwife during established labour in an obstetric unit.

Inclusion criteria

All women who are attended by an NHS midwife during labour in their planned place of birth, for any amount of time, are eligible for inclusion in the study except for:

- women who have a caesarean section before the start of labour
- women who present in labour before 37 weeks and 0 days gestation
- women with a multiple pregnancy
- women who have had no antenatal care

Data will be collected for all women planning birth at home, in a freestanding midwifery unit or in an alongside midwifery unit who are attended by an NHS midwife during labour. Women with any of the exclusion criteria listed above will not be included in the analyses.

Data will not be collected for women who have an unplanned birth at home.

Study sites

The aim is to collect data about planned home births in every NHS trust in England. All midwifery units in England, both freestanding and alongside, will be invited to participate and a stratified random sample of thirty seven obstetric units will be invited to participate. Obstetric units will be stratified by size (<2600 births, 2600-4850 births and >4850 births per year) and geographic location (northern England or southern England). Data from the Department of Geography at the University of Sheffield were used to define northern and southern England.[22] The classification of obstetric units as northern or southern and the size categories were chosen to help ensure that the sample is broadly representative of obstetric units in England. Data from a national mapping survey of all NHS trusts providing maternity care in England provided the sampling frame for the selection of the obstetric units. These mapping data were collected as part of the Birthplace Research Programme in collaboration with the Healthcare Commission's review of maternity services in 2007.[23]

Research ethics approval

The Berkshire Research Ethics Committee gave approval for the study in October 2007 (reference number: 07/H0505/151). An amendment to the original protocol was approved by a sub-committee of the Berkshire Research Ethics Committee in April 2008.

As part of the approval, individual women will not be asked to give consent to participate. All of the data that will be collected are routinely recorded in the maternity, postnatal or neonatal notes and no personally identifiable data will be sent to the study coordinating centre. In addition, the process of seeking and obtaining consent would be likely to introduce substantial bias in the composition of the comparison groups and the care women receive will not change in any way as a result of the study.

Primary outcome

The primary outcome is a composite outcome of stillbirth after the start of care in labour, early neonatal death (<7 days), neonatal encephalopathy defined as either a clinical diagnosis of neonatal encephalopathy or admission to a neonatal unit within 48 hours of birth for at least 48 hours

with evidence of feeding difficulties or respiratory distress, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle.

A composite outcome will give the study more power to detect differences in safety between planned places of birth than a single outcome, which would have a lower incidence. The results could be misleading if the exposure affects different outcomes in different ways. For example, if the effect of planned place of birth in a particular setting decreased deaths but resulted in increased significant morbidity there might be no difference observed in the primary outcome, even though deaths were being prevented in one setting. The likelihood of this occurring is small and the increased statistical power of using a composite outcome outweighs the alternative approach of substantially increasing the sample size to address individual components of the primary outcome.

The signs of mild encephalopathy can be subtle and include respiratory difficulty and poor feeding rather than features more specifically associated with encephalopathy. Since this is a mature group of babies, any difference in the incidence of neonatal unit admissions for these outcomes is likely to result from differences in the incidence of perinatal asphyxia.

Secondary outcomes

The perinatal outcomes that will be investigated are stillbirth after the start of care in labour; early neonatal death (<7 days); a clinical diagnosis of neonatal encephalopathy or admission to a neonatal unit within 48 hours of birth for at least 48 hours with evidence of feeding difficulties or respiratory distress; a clinical diagnosis of neonatal encephalopathy; admission to a neonatal unit within 48 hours of birth for at least 48 hours with evidence of feeding difficulties or respiratory distress; meconium aspiration syndrome; brachial plexus injury; fractured humerus; fractured clavicle; fractured skull; cephalohaematoma; cerebral haemorrhage; early onset neonatal sepsis (within 48 hours of birth); kernicterus (severe bilirubin encephalopathy); seizures; neonatal unit admission; Apgar score less than seven at five minutes; and breastfeeding initiation.

Only diagnosed fractures will be included. Minor fractures, particularly of the clavicle, are often missed and have little or no clinical significance.

The maternal outcomes that will be investigated are mode of birth; normal birth; third or fourth degree perineal trauma; blood transfusion; admission to an intensive therapy unit, high dependency unit or specialist unit; and maternal death (within 42 days of giving birth).

The interventions in labour that will be investigated are syntocinon augmentation; immersion in water for pain relief; epidural or spinal analgesia; general anaesthetic; active management of the third stage of labour; and episiotomy.

Normal birth is defined as a birth with none of the following interventions: induction of labour; epidural or spinal analgesia; general anaesthetic; forceps or ventouse; caesarean section; episiotomy.[24]

Data collection

Data collection will be coordinated by the National Perinatal Epidemiology Unit at the University of Oxford. A National Lead Research Midwife and four Regional Lead Midwives will train a local coordinator at each unit. Study documentation and data collection forms will be posted to each local coordinator from the coordinating centre in Oxford. Contact with each of the study coordinators will be maintained throughout the data collection period by phone, email, regional meetings and site visits by the National and Regional Lead Midwives.

Local coordinators will manage data collection within their trust (for home births) or unit. The majority of local coordinators will be midwives from the trust or unit. The local coordinators will be responsible for running Birthplace within their trust or unit: ensuring that all midwives are informed about Birthplace and have access to data collection forms, keeping a record of the number of eligible women, collecting completed data collection forms from their midwives, checking over data collection forms for completeness, posting completed data collection forms for data entry and responding to any data queries sent from the coordinating centre.

The attending midwife will start a data collection form for each eligible woman during labour care and the forms will be completed after the birth, using information recorded in the woman's maternity notes. Outcomes for women and babies who are transferred from their planned place of birth during or immediately after labour will also be collected.

More detailed information will be collected on mothers and babies that have morbidity identified. An extra data collection form will be used to measure the severity of the adverse outcomes and the resources used to care for these women and babies. These forms will be completed using the maternal and neonatal notes, with help from the neonatal team when necessary.

To ensure as many eligible women as possible are included, the number of women included from each site will be compared with appropriate local records, including records of planned home births, delivery suite and theatre registers and records of transfers to obstetric care. Many trusts do not keep comprehensive records of women planning to give birth at home. For this reason, the local coordinator responsible for collecting data on planned home births in each trust will keep a prospective register of all women eligible for Birthplace. These registers will provide further assurance that the majority of eligible women are identified and included.

Data for eligible women who are missed will be collected retrospectively, using the maternal and neonatal notes as necessary. Double data entry will be used to minimize data entry errors.

Sample size

Major perinatal and maternal morbidity are rare in women judged to be at 'low risk' of complications at the start of care in labour. The incidence of neonatal encephalopathy at term is approximately 1.8 per 1,000 live

births.[25] However, the incidence of intrapartum stillbirth after labour onset, early neonatal death and other related neonatal morbidity at term for babies of women at 'low risk' of complications at the start of care in labour is much less certain. A reasonable estimate of the incidence of the composite primary outcome is 3.6 per 1,000 births. As the vast majority of data on neonatal morbidity are from obstetric units, this estimate is assumed to be the incidence of the primary outcome in obstetric units.

In order to have adequate power to detect clinically important differences in outcome that are associated with planned place of birth, the study will need to collect data on at least 20,000 'low risk' women planning to give birth in an obstetric unit, at least 17,000 women planning to give birth at home and at least 5,000 women planning to give birth in each type of midwifery unit.

The study aims to collect data on at least 85% of all eligible women planning birth at home over approximately 16 months, which we estimate to be 17,000 women. With data from 17,000 planned home births, it will be possible to detect an increase in the incidence of the primary outcome from 3.6 per 1,000 births in obstetric units to 5.7 per 1,000 for planned home births, with a 5% two-sided level of significance and 82% power. Alternatively, the study will be able to detect a reduction in the incidence of the primary outcome from 3.6 per 1,000 births in obstetric units to 2.0 per 1,000 births for planned home births, with a 5% two-sided level of significance and 80% power.

Data collection is planned for at least 6 months in each type of midwifery unit, which will allow a minimum of 5,000 women from each type of unit to be included. Freestanding and alongside midwifery units will be analysed separately when being compared to obstetric units. With 5,000 women included from each type of midwifery unit, the study will be able to detect an increase in the incidence of the primary outcome from 3·6 per 1,000 births in obstetric units to 6·8 per 1,000 in midwifery units, with a 5% two-sided level of significance and 80% power. Alternatively, the study will be able to detect a reduction in the incidence of the primary outcome from 3·6 per 1,000 births in obstetric units to 1·2 per 1,000 births in midwifery units, with a 5% two-sided level of significance and 80% power.

The study will also be able to detect much more modest differences in relatively common serious outcomes of maternal morbidity amongst women at 'low risk' of complications, such as blood transfusion which affects approximately 0·5% of women, and 3rd and 4th degree perineal trauma which is experienced by 1·2% of women.[26, 27]

Analysis

Categorising data by women's planned place of birth at the start of care in labour is appropriate because risk assessment and transfer are important elements of the quality of care provided to women planning birth out of hospital. The characteristics of the women who planned birth in each setting will be described. Odds ratios will be calculated to compare outcomes by planned place of birth using the obstetric unit women as the

reference comparison group. Crude odds ratios will be presented for the primary outcome with 95% confidence intervals. These crude odds ratios will be adjusted in a logistic regression model to take account of potential confounders such as maternal age, ethnic group, understanding of English, marital or partner status, BMI in pregnancy, index of multiple deprivation score, parity and gestation at delivery. The analysis will be weighted to take into account the duration of each home birth trust's and each unit's participation. The clustered nature of the data, within trusts for home births and within units for the other settings, will be taken into account in the analysis. Taking these factors into account will ensure that accurate point estimates and confidence intervals are obtained.

Secondary outcomes will be analysed in the same way as the primary outcome. Odds ratios calculated for the secondary outcomes will be presented with 99% confidence intervals. Since a large number of comparisons will be made it is important to use wider confidence intervals to reduce the likelihood of finding statistically significant associations by chance.

A predefined subgroup analysis will be performed based on outcomes stratified by parity, nulliparous and multiparous. A test for heterogeneity will be performed to investigate whether any differences in outcomes, by planned place of birth, between nulliparous and multiparous women are likely to have been due to chance.

For the primary outcome, a number of sensitivity analyses will be performed to assess the robustness of the results to factors which may introduce bias. These will include: i) restricting the analysis to centres that provided data for at least 85% of eligible women; ii) using propensity score methods for a stratified or restricted analysis based on the likelihood of women giving birth in each setting; and iii) using multiple imputation to include women who have data missing for any of the potentially confounding variables about their characteristics.

Further exploratory analysis will be performed to generate hypotheses for future research.

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Appendix 2 Data collection forms

Data collection forms included

- Planned home birth data collection form (Figure 2)
- Planned OU data collection form (Figure 3)
- Obstetric unit transfer form (Figure 4)
- Multiple maternal transfer form (Figure 5)
- Neonatal morbidity form (Figure 6)
- Maternal morbidity form (Figure 7)

Data collection forms

The planned home birth, FMU, and AMU data collection forms were almost identical. The planned home birth form included one extra question: D1 Did this woman make her final decision about place of birth during labour? The planned home birth form also had an extra option for question E3, which was about the date and time of maternal discharge: Not applicable, delivered at home.

The OU data collection form had four extra eligibility questions, A1 to A4, which were used to exclude women with a caesarean section before the onset of labour, a multiple pregnancy, a gestation of less than 37 weeks and 0 days, and 'unbooked' women (i.e. women who did not have any antenatal care). Also, the OU form did not have a section to collect detailed information about transfers during labour or immediately after the birth.

Obstetric unit transfer form

This form was used to confirm transfers where they had been recorded on an OU data collection form and to collect more detailed information about these transfers.

Multiple maternal transfer form

This form was used to confirm cases where it was recorded that more than one transfer took place during labour and birth and to collect more detailed information about these births.

Morbidity forms

These forms were used to confirm neonatal and maternal morbidities and to collect more detailed information about adverse neonatal and maternal outcomes.

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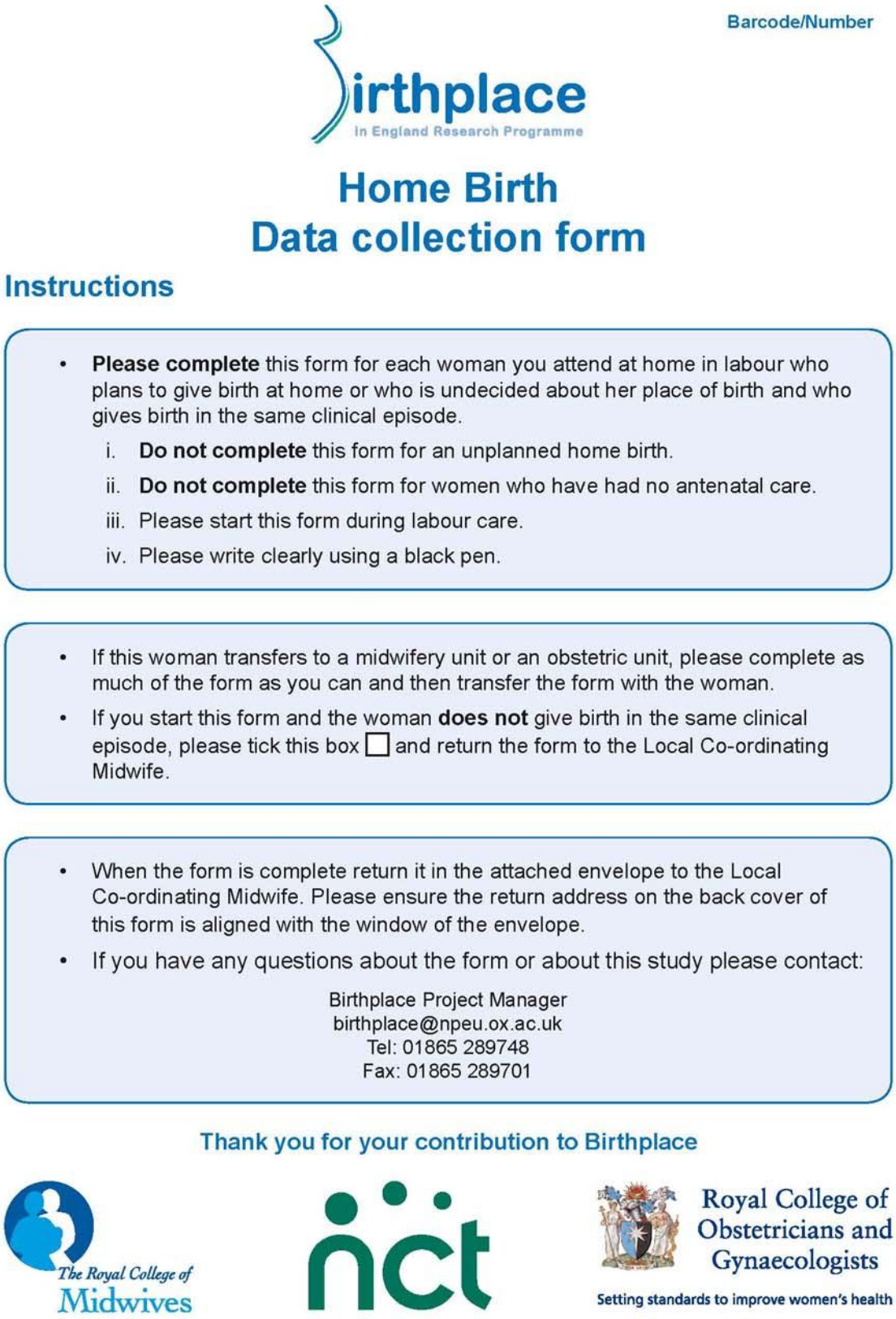
Figure 2. Planned home birth data collection form



Barcode/Number

Birthplace
In England Research Programme

Home Birth
Data collection form

Instructions

- **Please complete** this form for each woman you attend at home in labour who plans to give birth at home or who is undecided about her place of birth and who gives birth in the same clinical episode.
  i. **Do not complete** this form for an unplanned home birth.
  ii. **Do not complete** this form for women who have had no antenatal care.
  iii. Please start this form during labour care.
  iv. Please write clearly using a black pen.

- If this woman transfers to a midwifery unit or an obstetric unit, please complete as much of the form as you can and then transfer the form with the woman.
- If you start this form and the woman **does not** give birth in the same clinical episode, please tick this box ☐ and return the form to the Local Co-ordinating Midwife.

- When the form is complete return it in the attached envelope to the Local Co-ordinating Midwife. Please ensure the return address on the back cover of this form is aligned with the window of the envelope.
- If you have any questions about the form or about this study please contact:

Birthplace Project Manager
birthplace@npeu.ox.ac.uk
Tel: 01865 289748
Fax: 01865 289701

Thank you for your contribution to Birthplace

The Royal College of Midwives

nct

Royal College of Obstetricians and Gynaecologists
Setting standards to improve women's health

Birthplace
in England Research Programme

Section A: Woman's identifying details

This page will be detached from the rest of the form and kept in a secure location in your Trust by the Local Co-ordinating Midwife (LCM). This allows the LCM to deal with any inconsistencies or mistakes in the form or find missing information before sending non-identifying information (pages 2-6) to the study team in Oxford.

Please stick woman's address label here:

OR complete the following details:

A1. Woman's full name: *Please print* _____

A2. Woman's date of birth: D D / M M / Y Y

A3. Woman's NHS number:

A4. Woman's home address: *Please print*

_____

_____

_____

_____

A5. Woman's full postcode:

A6. Section A completed by: *Please print full name* _____

Office use only

After birth

Please fill in this box once the labour episode is complete

A7. Date of delivery: D D / M M / Y Y

A8. Baby's NHS number: *(If known)*

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Birthplace Home Birth
In England Research Programme

Section B: Woman's details

B1. Woman's age at delivery: *(Years)* ☐☐

B2. Woman's ethnic group: *(As recorded in her maternity notes)*

☐☐ *Please write in one code from the list below*

01 White British	09 Pakistani
02 White Irish	10 Bangladeshi
03 Any other White background	11 Any other Asian background
04 Mixed White & Black Caribbean	12 Black Caribbean
05 Mixed White & Black African	13 Black African
06 Mixed White & Asian	14 Any other Black background
07 Any other Mixed background	15 Chinese
08 Indian	16 Any other ethnic group

B3. Woman's understanding of English language:

☐1 Fluent

☐2 Some understanding / Able to communicate verbally

☐3 No understanding / Not able to communicate verbally

B4. Woman's marital / partner status:

☐1 Married / Living with a partner

☐2 Single / Unsupported by partner *(this includes single woman living with family)*

B5. Woman's BMI in pregnancy: ☐☐.☐ *If not recorded tick here* ☐

For LCM use only

B6. IMD score: ☐☐.☐☐

B7. Tick this box if this form was not started around the time of birth and was filled in retrospectively by the LCM: ☐

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Section C: Pregnancy history

Previous pregnancies

C1. Number of pregnancies of ≥ 24 weeks, prior to this pregnancy: *If none, write 0* ☐☐

This pregnancy

C2. Expected date of delivery: ☐☐/☐☐/☐☐

C3. Immediately prior to the onset of labour, was this woman known to have any of the medical conditions or obstetric history items listed opposite?

☐ No

☐ Yes *Please write in code(s) below from tables opposite*

Example: For a woman with previous pre-eclampsia requiring preterm birth, the condition is found in the 'Obstetric history' table under 'Previous complications' and coded '12 C'. For a woman with a condition that is not listed in the tables opposite, please enter the code for 'Other' and write in the condition in the space provided.

12	C	

Code		If Other, please write name of condition clearly

C4. At the start of care in labour, did this woman have any of the following conditions? *Please tick all that apply*

☐ Prolonged rupture of membranes greater than 18 hours

☐ If membranes are ruptured, any meconium stained liquor

☐ Proteinuria of 1+ or more

☐ Hypertension with either:

- diastolic blood pressure of ≥ 90mm Hg on more than one occasion 20 minutes apart or ≥ 100mm Hg on one occasion
- systolic blood pressure ≥ 160mm Hg on at least one occasion

☐ Abnormal vaginal bleeding

☐ Non-cephalic presentation

☐ Abnormal fetal heart rate

☐ Other complications *Please specify* _____

☐ **None of the above**

Medical conditions

Type of condition	Code	Additional information
Cardiovascular	01	A: Confirmed cardiac disease B: Hypertensive disorders
Respiratory	02	A: Asthma requiring an increase in treatment or hospital treatment B: Cystic fibrosis
Haematological	03	A: Haemoglobinopathies – sickle-cell disease, beta-thalassaemia major B: History of thromboembolic disorders C: Immune thrombocytopenia purpura or other platelet disorder or platelet count below 100 000/cubic mm D: Von Willebrand's disease E: Bleeding disorder in the woman or unborn baby F: Atypical antibodies which carry a risk of haemolytic disease of the newborn
Infective	04	A: Risk factors associated with group B streptococcus whereby antibiotics in labour would be recommended B: Hepatitis B/C with abnormal liver function tests C: Infected with HIV D: Toxoplasmosis – woman receiving treatment E: Current active infection of chicken pox/rubella/genital herpes in the woman or baby F: Tuberculosis under treatment
Immune	05	A: Systemic lupus erythematosus B: Scleroderma
Endocrine	06	A: Hyperthyroidism B: Diabetes
Renal	07	A: Abnormal renal function B: Renal disease requiring supervision by a renal specialist
Neurological	08	A: Epilepsy B: Myasthenia gravis C: Previous cerebrovascular accident
Gastrointestinal	09	A: Liver disease associated with current abnormal liver function tests
Psychiatric	10	A: Psychiatric disorder requiring current inpatient care
Other	11	A: Please write in condition or diagnosis

Obstetric history

Type of condition	Code	Additional information
Previous complications	12	A: Unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty B: Previous baby with neonatal encephalopathy C: Pre-eclampsia requiring preterm birth D: Placental abruption with adverse outcome E: Eclampsia F: Uterine rupture G: Primary postpartum haemorrhage requiring additional treatment or blood transfusion H: Retained placenta requiring manual removal in theatre I: Caesarean section J: Shoulder dystocia
Current pregnancy	13	A: Multiple birth B: Placenta praevia C: Pre-eclampsia or pregnancy-induced hypertension D: Preterm labour or preterm prelabour rupture of membranes E: Placental abruption F: Anaemia – haemoglobin less than 8.5 g/dl at onset of labour G: Confirmed intrauterine death H: Induction of labour I: Substance misuse J: Alcohol dependency requiring assessment or treatment K: Onset of gestational diabetes L: Malpresentation – breech or transverse lie M: Body mass index at booking of greater than 35 kg/m^2 N: Recurrent antepartum haemorrhage
Fetal indications	14	A: Small for gestational age in this pregnancy (less than fifth centile or reduced growth velocity on ultrasound) B: Abnormal fetal heart rate (FHR)/Doppler studies C: Ultrasound diagnosis of oligo-/polyhydramnios
Previous gynaecological history	15	A: Myomectomy B: Hysterotomy
Other	16	A: Please write in condition or diagnosis

Section D: Labour and birth

If multiple pregnancy, please complete for the first baby only

D1. **Did this woman make her final decision about place of birth during labour?** ☐ Yes ☐ No

D2. **Date and time midwife started labour care:** ☐☐/☐☐/☐☐ ☐☐:☐☐ (24hr)

D3. **Cervical dilatation at start of labour care:** ☐☐ *(0-10cm)* ☐ Not assessed

D4. **Was this woman transferred to a midwifery unit or an obstetric unit at any time during labour care or immediately after the birth?** ☐ Yes ☐ No

If No, please go to question D5

Maternal Transfer

If woman transferred more than once, please tick this box ☐ *and complete the questions below for care received during the first transfer only*

T1. **Date and time of decision to transfer:** ☐☐/☐☐/☐☐ ☐☐:☐☐ (24hr)

T2. **Primary reason for transfer:** *Please write in one code from list* ☐☐

01 Failure to progress (1st stage)
02 Fetal distress (1st stage)
03 Meconium staining
04 Epidural request
05 Hypertension
06 Malposition
07 Malpresentation
08 Antepartum haemorrhage
09 Failure to progress (2nd stage)
10 Fetal distress (2nd stage)
11 Postpartum haemorrhage
12 Retained placenta
13 Repair of perineal trauma
14 Other *Please specify* _____

T3. **Date and time of start of transfer:** ☐☐/☐☐/☐☐ ☐☐:☐☐ (24hr)

T4. **Mode of transfer:** ☐ 1 Private car ☐ 2 Ambulance ☐ 3 Other

If Other, please specify _____

T5. **Full name of unit woman transferred to:** _____

T6. **Date and time of start of midwifery care in transfer unit:** ☐☐/☐☐/☐☐ ☐☐:☐☐ (24hr)

T7. **Date and time of first clinical assessment by obstetrician:** ☐☐/☐☐/☐☐ ☐☐:☐☐ (24hr)

Tick if not assessed by an obstetrician ☐

T8. **Was labour augmented with syntocinon?** ☐ Yes ☐ No

T9. **Did this woman have an epidural or spinal?** ☐ Yes ☐ No

T10. **Did this woman have a general anaesthetic?** ☐ Yes ☐ No

D5. **Date and time of delivery:** ☐☐/☐☐/☐☐ ☐☐:☐☐ (24hr)

D6. **Place of birth:** ☐ 1 Home ☐ 2 Obstetric unit ☐ 3 Other

If Other, please specify _____

D7. **Mode of birth:** *Please tick one box only*
If caesarean section after failed forceps/ventouse, tick caesarean section

☐ 1 Spontaneous vertex birth ☐ 2 Vaginal breech
☐ 3 Ventouse ☐ 4 Forceps ☐ 5 Caesarean section

Primary reason for instrumental or caesarean delivery _____

D8. **At any time during labour did this woman use immersion in water for pain relief?** ☐ Yes ☐ No

D9. **Did this woman have active management of the 3rd stage?** ☐ Yes ☐ No

D10. **Did this woman have an episiotomy?** ☐ Yes ☐ No

D11. **Was there any perineal trauma involving the anal sphincter?** *(3rd/4th degree tear)* ☐ Yes ☐ No

D12. **Birth outcome:** ☐1 Live birth ☐2 Stillbirth

D13. **Sex of baby:** ☐1 Male ☐2 Female ☐3 Unknown

D14. **Birthweight:** ☐☐☐☐ g

D15. **Apgar at 5 minutes:** ☐☐

D16. **When was the episode of labour care completed?** ☐☐/☐☐/☐☐ ☐☐:☐☐ 24hr
See back cover for guidance

Please place this form in the woman's postnatal notes.

Section E: After birth

*To be completed by the **midwife** on or after the 5th postnatal day and before transfer to the health visitor*

E1. **Within the first 48 hours after birth was this woman admitted to:** *Please tick all that apply*
Do not include recovery ward for operative delivery

☐ High Dependency Area ☐ ICU ☐ Specialist unit *e.g. dialysis unit*

Primary reason for admission _____

If Specialist unit, please specify _____

E2. **Did this woman receive a blood transfusion within 48 hours of birth?** ☐ Yes ☐ No

E3. **Date and time woman discharged home:** ☐☐/☐☐/☐☐ ☐☐:☐☐ 24hr

Not yet discharged ☐

Not applicable, delivered at home ☐

E4. **Did this woman breastfeed her baby at least once?** ☐ Yes ☐ No

E5. **Was the baby admitted to a neonatal unit within 48 hours of birth?** ☐ Yes ☐ No

If Yes, to where was the baby admitted? *Please tick one box only*

☐1 Special Care Baby Unit ☐2 High Dependency Unit ☐3 Neonatal Intensive Care

Date baby was discharged from neonatal unit: ☐☐/☐☐/☐☐

Not yet discharged ☐

E6. **Were any of the following identified in the baby within 48 hours after birth?** *Please tick all that apply*

- ☐ Meconium aspiration syndrome
- ☐ Neonatal encephalopathy
- ☐ Brachial plexus injury
- ☐ Fractured humerus
- ☐ Fractured clavicle
- ☐ Fractured skull
- ☐ Neonatal sepsis
- ☐ **No morbidity identified**
- ☐ Cephalohaematoma
- ☐ Cerebral haemorrhage
- ☐ Kernicterus
- ☐ Seizures
- ☐ Admission to neonatal unit within 48 hrs of birth for at least 48 hrs with evidence of feeding difficulties or respiratory distress
- ☐ Other morbidity

Please specify _____

E7. **Was the baby known to have died at the time this form was completed?** ☐ Yes ☐ No

E8. **Section E completed by:** *Please print full name* _____

☐☐/☐☐/☐☐ ☐☐:☐☐ 24hr

Please fill in the After birth section on page 1

Barcode/Number

Thank you for completing this form.

Please return this form to the Local Co-ordinating Midwife in the envelope provided using the internal post.

Guidance

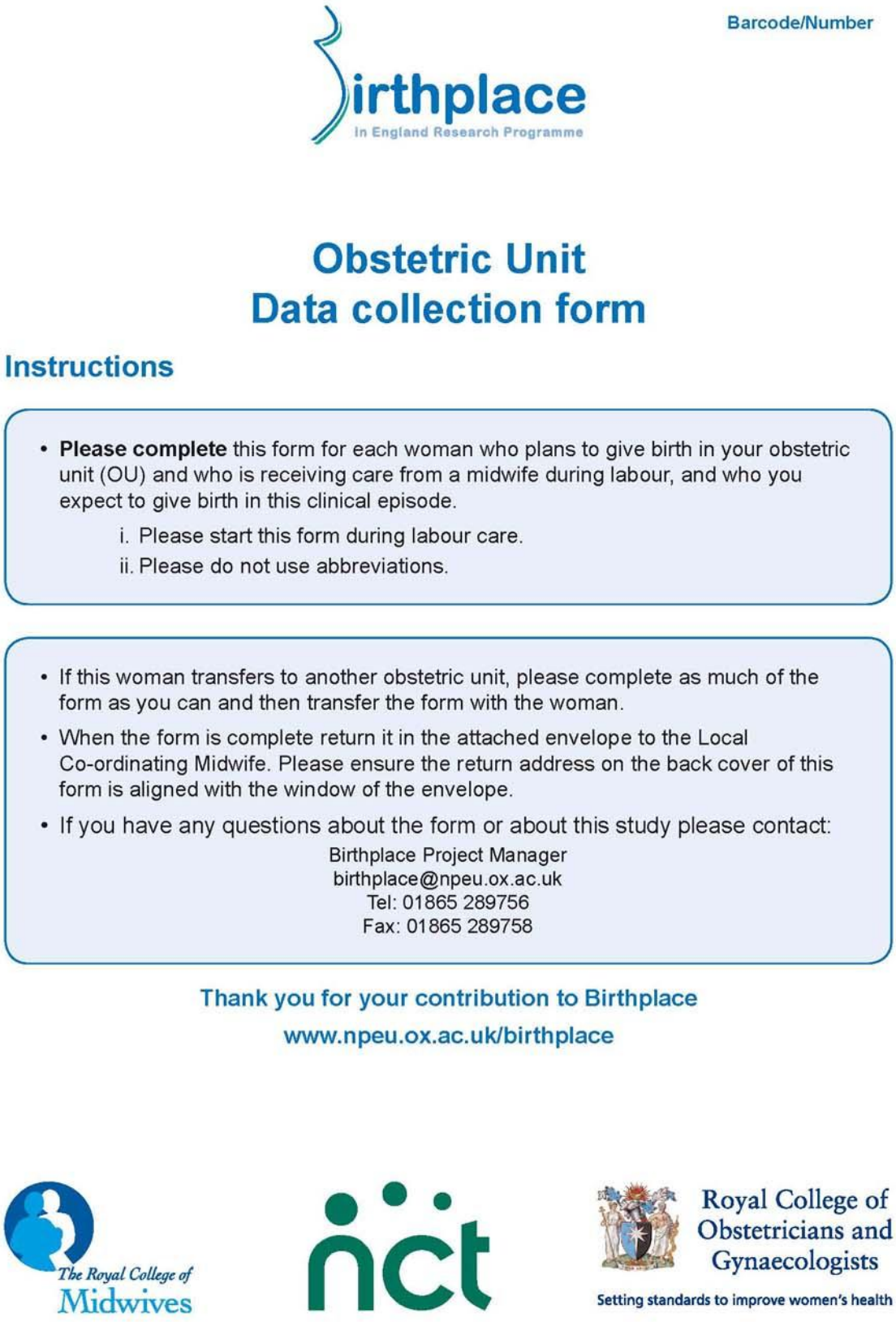
D16.

For women who give birth at home, the episode of labour care is completed when the midwife leaves the woman's home.

For women who give birth in a freestanding midwifery unit, an alongside midwifery unit, or in hospital, the episode of labour care is completed when the woman is discharged from the delivery room or when the midwife begins the postnatal notes, whichever occurs first.

MREC reference number: 07/H0505/151
Version1
14 February 2008

Figure 3. Planned OU data collection form



Barcode/Number

Birthplace
In England Research Programme

Obstetric Unit
Data collection form

Instructions

- **Please complete** this form for each woman who plans to give birth in your obstetric unit (OU) and who is receiving care from a midwife during labour, and who you expect to give birth in this clinical episode.
  i. Please start this form during labour care.
  ii. Please do not use abbreviations.

- If this woman transfers to another obstetric unit, please complete as much of the form as you can and then transfer the form with the woman.
- When the form is complete return it in the attached envelope to the Local Co-ordinating Midwife. Please ensure the return address on the back cover of this form is aligned with the window of the envelope.
- If you have any questions about the form or about this study please contact:

Birthplace Project Manager
birthplace@npeu.ox.ac.uk
Tel: 01865 289756
Fax: 01865 289758

Thank you for your contribution to Birthplace
www.npeu.ox.ac.uk/birthplace

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Section A: Birthplace obstetric unit eligibility criteria

A1. **Is this woman having a caesarean section before the onset of labour?** ☐ Yes ☐ No

A2. **Is this a multiple pregnancy?** ☐ Yes ☐ No

A3. **Is the gestation of this pregnancy 36^{+6} weeks or less?** ☐ Yes ☐ No

A4. **Is this woman "unbooked"?** *i.e. has had no antenatal care* ☐ Yes ☐ No

If you answered 'Yes' to ANY of these questions:

- Do NOT complete the remainder of this form.
- Place the form in the 'Birthplace box' or appropriate location for it to be returned to the Local Coordinating Midwife (LCM).

If you answered 'No' to ALL of these questions:

- Continue completing this form.
- Once you have completed Section D, at the end of the episode of labour, place the form in the woman's postnatal notes so that section E can be completed on or after the 5th postnatal day.

Woman's identifying details

This page will be detached from the rest of the form and kept in a secure location in your Trust by the Local Co-ordinating Midwife (LCM).

Please stick woman's address label here:

OR complete the following details:

A5. **Woman's full name:** *Please print* _____

A6. **Woman's date of birth:** ☐☐/☐☐/☐☐

A7. **Woman's NHS number:** ☐☐☐☐☐☐☐☐☐☐

A8. **Woman's home address:** *Please print*

_____

_____

_____

A9. **Woman's full postcode:** ☐☐☐☐ ☐☐☐

A10. **Section A completed by:** *Please print full name* _____

After birth

Please fill in this box once the labour episode is complete

A11. **Date of delivery:** ☐☐/☐☐/☐☐

A12. **Baby's NHS number:** *(If known)* ☐☐☐☐☐☐☐☐☐☐

Office use only

Project 08/1604/140

Birthplace Obstetric Unit
In England Research Programme

Section B: Woman's details

B1. Woman's age at delivery: *(Years)* ☐☐

B2. Woman's ethnic group: *(As recorded in her maternity notes)*

☐☐ *Please write in one code from the list below*

01 White British	09 Pakistani
02 White Irish	10 Bangladeshi
03 Any other White background	11 Any other Asian background
04 Mixed White & Black Caribbean	12 Black Caribbean
05 Mixed White & Black African	13 Black African
06 Mixed White & Asian	14 Any other Black background
07 Any other Mixed background	15 Chinese
08 Indian	16 Any other ethnic group

B3. Woman's understanding of English language:

☐1 Fluent

☐2 Some understanding/Able to communicate verbally

☐3 No understanding/Not able to communicate verbally

B4. Woman's marital/partner status:

☐1 Married/Living with a partner

☐2 Single/Unsupported by partner *(this includes single woman living with family)*

B5. Woman's BMI in pregnancy: ☐☐.☐ *If not recorded tick here* ☐

For LCM use only

B6. IMD score: *(www.npeu.ox.ac.uk/birthplace/lcm/imd)* ☐☐.☐☐

B7. Tick this box if this form was not started around the time of birth and was filled in retrospectively by the LCM: ☐

Section C: Pregnancy history

Previous pregnancies

C1. Number of pregnancies of ≥ 24 weeks, prior to this pregnancy: *If none, write 0* ☐☐

This pregnancy

C2. Expected date of delivery: ☐☐/☐☐/☐☐

C3. Immediately prior to the onset of labour, was this woman known to have any of the complications listed opposite?

☐ No

☐ Yes *Please write in code(s) below from tables opposite*

Example: For a woman with previous pre-eclampsia requiring preterm birth, the condition is found in the 'Obstetric history' table under 'Previous complications' and coded '12 C'. For a woman with a condition that is not listed in the tables opposite, please enter the code for 'Other' and write in the condition in the space provided.

12	C	

Code		If Other, please write name of condition clearly

C4. At the start of care in labour, did this woman have any of the following conditions? *Please tick all that apply*

☐ Prolonged rupture of membranes greater than 18 hours

☐ If membranes are ruptured, any meconium stained liquor

☐ Proteinuria of 1+ or more

☐ Hypertension with either:
- diastolic blood pressure of ≥ 90mm Hg on more than one occasion 20 minutes apart or ≥ 100mm Hg on one occasion
- systolic blood pressure ≥ 160mm Hg on at least one occasion

☐ Abnormal vaginal bleeding

☐ Non-cephalic presentation

☐ Abnormal fetal heart rate

☐ Other complications *Please specify* _____

☐ **None of the above**

Medical conditions

Type of condition	Code	Additional information
Cardiovascular	01	A: Confirmed cardiac disease B: Hypertensive disorders
Respiratory	02	A: Asthma requiring an increase in treatment or hospital treatment B: Cystic fibrosis
Haematological	03	A: Haemoglobinopathies – sickle-cell disease, beta-thalassaemia major B: History of thromboembolic disorders C: Immune thrombocytopenia purpura or other platelet disorder or platelet count below 100 000/cubic mm D: Von Willebrand's disease E: Bleeding disorder in the woman or unborn baby F: Atypical antibodies which carry a risk of haemolytic disease of the newborn
Infective	04	A: Risk factors associated with group B streptococcus whereby antibiotics in labour would be recommended B: Hepatitis B/C with abnormal liver function tests C: Infected with HIV D: Toxoplasmosis – woman receiving treatment E: Current active infection of chicken pox/rubella/genital herpes in the woman or baby F: Tuberculosis under treatment
Immune	05	A: Systemic lupus erythematosus B: Scleroderma
Endocrine	06	A: Hyperthyroidism B: Diabetes
Renal	07	A: Abnormal renal function B: Renal disease requiring supervision by a renal specialist
Neurological	08	A: Epilepsy B: Myasthenia gravis C: Previous cerebrovascular accident
Gastrointestinal	09	A: Liver disease associated with current abnormal liver function tests
Psychiatric	10	A: Psychiatric disorder requiring current inpatient care
Other	11	A: Please write in condition or diagnosis

Obstetric history

Type of condition	Code	Additional information
Previous complications	12	A: Unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty B: Previous baby with neonatal encephalopathy C: Pre-eclampsia requiring preterm birth D: Placental abruption with adverse outcome E: Eclampsia F: Uterine rupture G: Primary postpartum haemorrhage requiring additional treatment or blood transfusion H: Retained placenta requiring manual removal in theatre I: Caesarean section J: Shoulder dystocia
Current pregnancy	13	A: Multiple birth B: Placenta praevia C: Pre-eclampsia or pregnancy-induced hypertension D: Preterm labour or preterm prelabour rupture of membranes E: Placental abruption F: Anaemia – haemoglobin less than 8.5 g/dl at onset of labour G: Confirmed intrauterine death H: Induction of labour I: Substance misuse J: Alcohol dependency requiring assessment or treatment K: Onset of gestational diabetes L: Malpresentation – breech or transverse lie M: Body mass index at booking of greater than 35 kg/m^2 N: Recurrent antepartum haemorrhage
Fetal indications	14	A: Small for gestational age in this pregnancy (less than fifth centile or reduced growth velocity on ultrasound) B: Abnormal fetal heart rate (FHR)/Doppler studies C: Ultrasound diagnosis of oligo-/polyhydramnios
Previous gynaecological history	15	A: Myomectomy B: Hysterotomy
Other	16	A: Please write in condition or diagnosis

4

Section D: Labour and birth

D1. **Date and time midwife started labour care:** ☐☐/☐☐/☐☐ ☐☐:☐☐ 24hr

D2. **Cervical dilatation at start of labour care:** ☐☐ *(0-10cm)* ☐ Not assessed

D3. **Was this woman transferred to another obstetric unit at any time during labour care or immediately after birth?** ☐ Yes ☐ No

D4. **Was labour augmented with syntocinon?** ☐ Yes ☐ No

D5. **At any time during labour did this woman use immersion in water for pain relief?** ☐ Yes ☐ No

D6. **Did this woman have an epidural or spinal?** ☐ Yes ☐ No

D7. **Did this woman have a general anaesthetic?** ☐ Yes ☐ No

D8. **Date and time of delivery:** ☐☐/☐☐/☐☐ ☐☐:☐☐ 24hr

D9. **Place of birth:** ☐1 Obstetric unit ☐2 Other

If Other, please specify _____

D10. **Mode of birth:** *Please tick one box only*
If caesarean section after failed forceps/ventouse, tick caesarean section

☐1 Spontaneous vertex birth ☐2 Vaginal breech
☐3 Ventouse ☐4 Forceps ☐5 Caesarean section

Primary reason for instrumental or caesarean delivery _____

D11. **Did this woman have active management of the 3rd stage?** ☐ Yes ☐ No

D12. **Did this woman have an episiotomy?** ☐ Yes ☐ No

D13. **Was there any perineal trauma involving the anal sphincter?** *(3rd/4th degree tear)* ☐ Yes ☐ No

D14. **Birth outcome:** ☐1 Live birth ☐2 Stillbirth

D15. **Sex of baby:** ☐1 Male ☐2 Female ☐3 Unknown

D16. **Birthweight:** ☐☐☐☐ g

D17. **Apgar at 5 minutes:** ☐☐

D18. **When was the episode of labour care completed?** ☐☐/☐☐/☐☐ ☐☐:☐☐ 24hr
See back cover for guidance

Please place this form in the woman's postnatal notes.

5

Section E: After birth

*To be completed by the **midwife** on or after the 5th postnatal day and before transfer to the health visitor*

E1. Within the first 48 hours after birth was this woman admitted to: *Please tick all that apply*
Do not include recovery ward for operative delivery

☐ High Dependency Area ☐ ICU ☐ Specialist unit *e.g. dialysis unit*

Primary reason for admission _____

If Specialist unit, please specify unit type _____

E2. Did this woman receive a blood transfusion within 48 hours of birth? ☐ Yes ☐ No

E3. Date and time woman discharged home: D D / M M / Y Y H H : M M (24hr)

Not yet discharged ☐

E4. Did this woman breastfeed her baby at least once? ☐ Yes ☐ No

E5. Was the baby admitted to a neonatal unit within 48 hours of birth? ☐ Yes ☐ No

If Yes, to where was the baby admitted? *Please tick one box only*

☐ 1 Special Care Baby Unit ☐ 2 High Dependency Unit ☐ 3 Neonatal Intensive Care

Date baby was discharged from neonatal unit: D D / M M / Y Y

Not yet discharged ☐

E6. Were any of the following identified in the baby within 48 hours after birth? *Please tick all that apply*

- ☐ Meconium aspiration syndrome
- ☐ Neonatal encephalopathy
- ☐ Brachial plexus injury
- ☐ Fractured humerus
- ☐ Fractured clavicle
- ☐ Fractured skull
- ☐ Neonatal sepsis
- ☐ Cephalohaematoma
- ☐ Cerebral haemorrhage
- ☐ Kernicterus
- ☐ Seizures
- ☐ Admission to neonatal unit within 48 hrs of birth for at least 48 hrs with evidence of feeding difficulties or respiratory distress

☐ **No morbidity identified**

☐ Other morbidity
Please specify _____

E7. Was the baby known to have died at the time this form was completed? ☐ Yes ☐ No

E8. Section E completed by: *Please print full name* _____

E9. Date and time Section E completed: D D / M M / Y Y H H : M M (24hr)

Please fill in the After birth section on page 1

Barcode/Number

Thank you for completing this form.

Please return this form to the Local Co-ordinating Midwife in the envelope provided using the internal post.

Guidance

D18.

The episode of labour care is completed when the woman is discharged from the delivery room or when the midwife begins the postnatal notes, whichever occurs first.

MREC reference number: 07/H0505/151
Version 2
1 October 2008

Figure 4. Obstetric unit transfer form

Birthplace in England Research Programme

LCM no.: _____

Woman's DCF no.: _____

Obstetric Unit Transfer Form

- This form must be completed for each woman who is transferred from one obstetric unit to another between the time the midwife begins the labour notes to the end of labour care, before postnatal care begins.*(see back page for guidance)*.

Maternal Transfer

T1. **Date and time of decision to make this transfer:** ☐☐/☐☐/☐☐☐☐ ☐☐:☐☐ 24hr

T2. **Primary reason for this transfer:** *Please write in one code from list* ☐☐

01 Failure to progress (1st stage)	09 Failure to progress (2nd stage)
02 Fetal distress (1st stage)	10 Fetal distress (2nd stage)
03 Meconium staining	11 Postpartum haemorrhage
04 Epidural request	12 Retained placenta
05 Hypertension	13 Repair of perineal trauma
06 Malposition	14 Other *Please specify*
07 Malpresentation	
08 Antepartum haemorrhage	

T3 **Date and time of start of this transfer:** ☐☐/☐☐/☐☐☐☐ ☐☐:☐☐ 24hr

T4. **Mode of transfer:** ☐ Private car ☐ Ambulance ☐ Other

If Other, please specify _____

T5. **Full name of unit woman transferred from:** _____

T6. **Full name of unit woman transferred to:** _____

T7. **Date and time of start of midwifery care in transfer unit:** ☐☐/☐☐/☐☐☐☐ ☐☐:☐☐ 24hr

T8. **Date and time of first clinical assessment by obstetrician:** ☐☐/☐☐/☐☐☐☐ ☐☐:☐☐ 24hr

Tick if not assessed by an obstetrician ☐

Please write any comments in the box below:

Thank you for your contribution to Birthplace

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Thank you for completing this form.

Please return this form to the Birthplace co-ordinating office.

FREEPOST RRKH-XXAB-JJLK
Birthplace in England Research Programme
NPEU
University of Oxford
Old Road Campus
Headington
Oxford, OX3 7LF

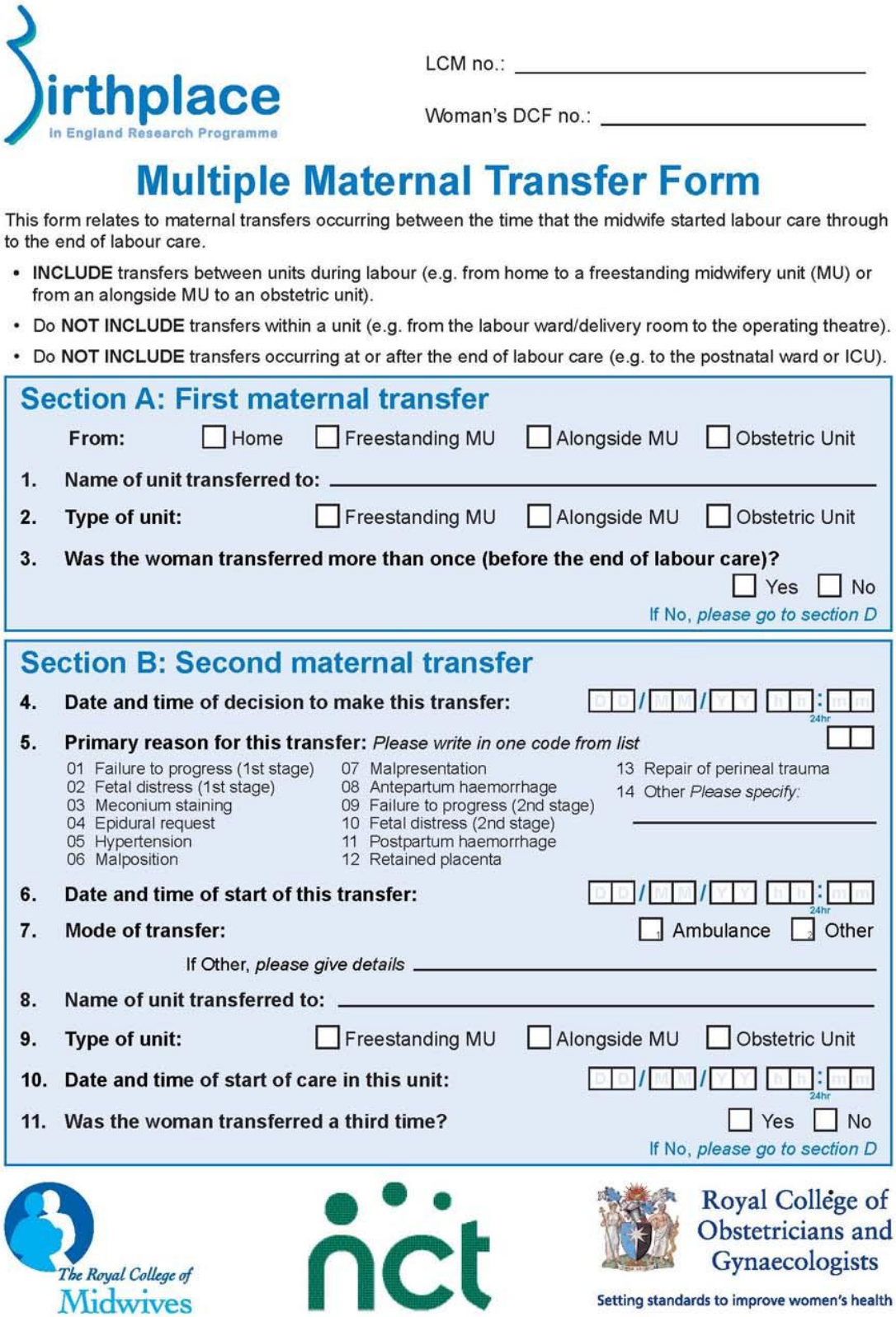
Guidance

Definition of End of Labour Care

The episode of labour care is completed when the woman is discharged from the delivery room or when the midwife begins the postnatal notes, whichever occurs first.

MREC reference number: 07/H0505/151
Version 1
October 2008

Figure 5. Multiple maternal transfer form



Birthplace in England Research Programme

LCM no.: _____

Woman's DCF no.: _____

Multiple Maternal Transfer Form

This form relates to maternal transfers occurring between the time that the midwife started labour care through to the end of labour care.

- **INCLUDE** transfers between units during labour (e.g. from home to a freestanding midwifery unit (MU) or from an alongside MU to an obstetric unit).
- Do **NOT INCLUDE** transfers within a unit (e.g. from the labour ward/delivery room to the operating theatre).
- Do **NOT INCLUDE** transfers occurring at or after the end of labour care (e.g. to the postnatal ward or ICU).

Section A: First maternal transfer

From: ☐ Home ☐ Freestanding MU ☐ Alongside MU ☐ Obstetric Unit

1. **Name of unit transferred to:** _____
2. **Type of unit:** ☐ Freestanding MU ☐ Alongside MU ☐ Obstetric Unit
3. **Was the woman transferred more than once (before the end of labour care)?** ☐ Yes ☐ No

If No, please go to section D

Section B: Second maternal transfer

4. **Date and time of decision to make this transfer:** D D / M M / Y Y h h : m m (24hr)
5. **Primary reason for this transfer:** *Please write in one code from list* ☐☐

01 Failure to progress (1st stage)	07 Malpresentation	13 Repair of perineal trauma
02 Fetal distress (1st stage)	08 Antepartum haemorrhage	14 Other *Please specify:*
03 Meconium staining	09 Failure to progress (2nd stage)	_____
04 Epidural request	10 Fetal distress (2nd stage)	
05 Hypertension	11 Postpartum haemorrhage	
06 Malposition	12 Retained placenta	

6. **Date and time of start of this transfer:** D D / M M / Y Y h h : m m (24hr)
7. **Mode of transfer:** ☐ Ambulance ☐ Other

If Other, *please give details* _____

8. **Name of unit transferred to:** _____
9. **Type of unit:** ☐ Freestanding MU ☐ Alongside MU ☐ Obstetric Unit
10. **Date and time of start of care in this unit:** D D / M M / Y Y h h : m m (24hr)
11. **Was the woman transferred a third time?** ☐ Yes ☐ No

If No, please go to section D

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Section C: Third maternal transfer

12. Date and time of decision to make this transfer: D D / M M / Y Y H H : m m (24hr)

13. Primary reason for this transfer: *Please write in one code from list* ☐☐

01 Failure to progress (1st stage)
02 Fetal distress (1st stage)
03 Meconium staining
04 Epidural request
05 Hypertension
06 Malposition
07 Malpresentation
08 Antepartum haemorrhage
09 Failure to progress (2nd stage)
10 Fetal distress (2nd stage)
11 Postpartum haemorrhage
12 Retained placenta
13 Repair of perineal trauma
14 Other *Please specify:* _____

14. Date and time of start of this transfer: D D / M M / Y Y H H : m m (24hr)

15. Mode of transfer: ☐ Ambulance ☐ Other

If Other, *please give details* _____

16. Name of unit transferred to: _____

17. Type of unit: ☐ Freestanding MU ☐ Alongside MU ☐ Obstetric Unit

18. Date and time of start of care in this unit: D D / M M / Y Y H H : m m (24hr)

Section D: Intrapartum care

19. Date and time of first clinical assessment by an obstetrician:

D D / M M / Y Y H H : m m (24hr)

Tick if not assessed by an obstetrician: ☐

20. Was labour augmented with syntocinon? ☐ Yes ☐ No

21. Did the woman have an epidural or spinal? ☐ Yes ☐ No

22. Did the woman have a general anaesthetic? ☐ Yes ☐ No

Section E: Other details

23. Please record any other information that you think may be relevant

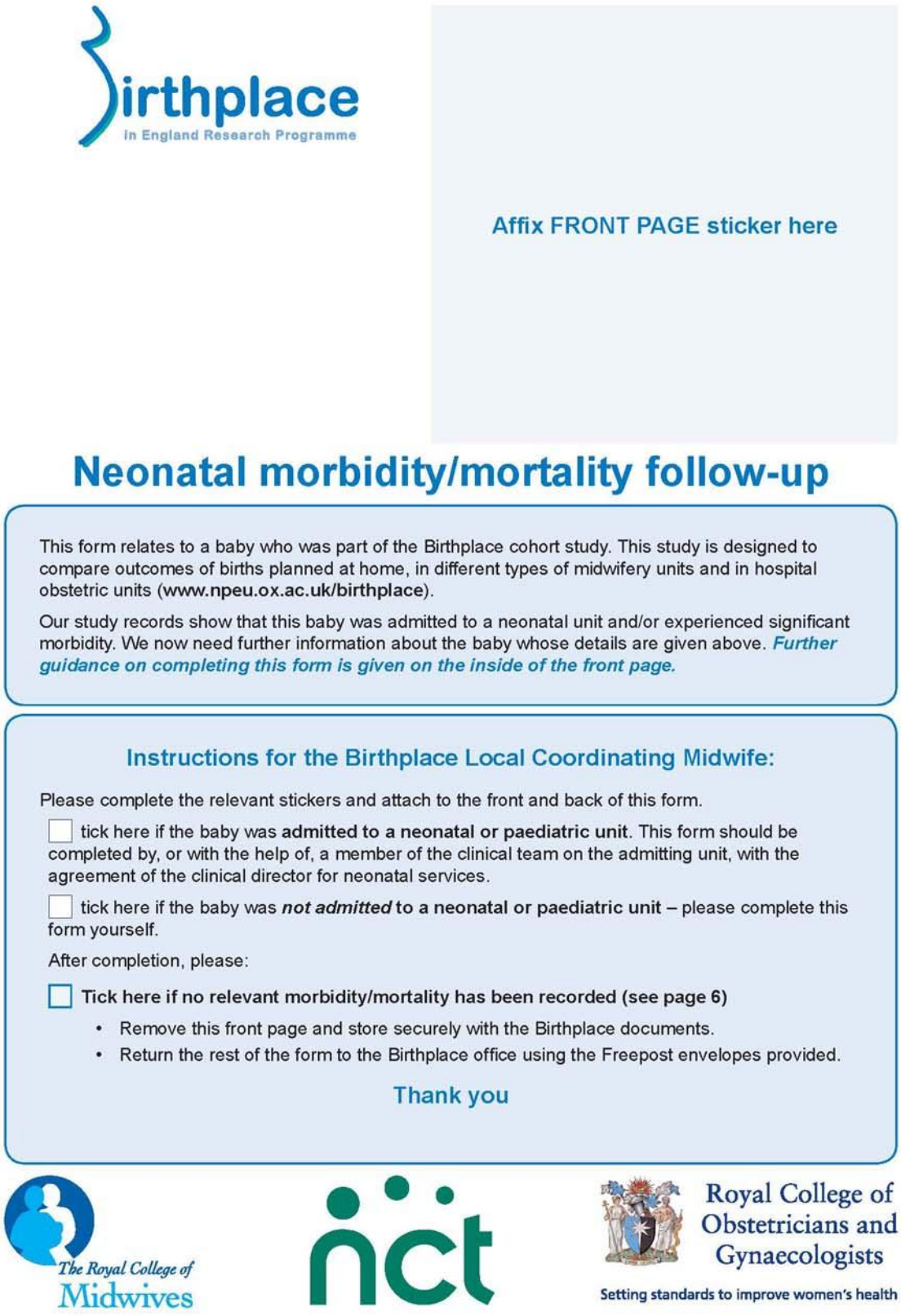
Completed by: _____

Thank you for completing this form.
Please return this form to the Birthplace Co-ordinating Office.

FREEPOST RRKH-XXAB-JJLK
Birthplace in England Research Programme
NPEU, University of Oxford
Old Road Campus
Oxford, OX3 7LF

MREC reference number: 07/H0505/151
Version 2, March 2010

Figure 6. Neonatal morbidity form



Birthplace
In England Research Programme

Affix FRONT PAGE sticker here

Neonatal morbidity/mortality follow-up

This form relates to a baby who was part of the Birthplace cohort study. This study is designed to compare outcomes of births planned at home, in different types of midwifery units and in hospital obstetric units (**www.npeu.ox.ac.uk/birthplace**).

Our study records show that this baby was admitted to a neonatal unit and/or experienced significant morbidity. We now need further information about the baby whose details are given above. ***Further guidance on completing this form is given on the inside of the front page.***

Instructions for the Birthplace Local Coordinating Midwife:

Please complete the relevant stickers and attach to the front and back of this form.

☐ tick here if the baby was **admitted to a neonatal or paediatric unit**. This form should be completed by, or with the help of, a member of the clinical team on the admitting unit, with the agreement of the clinical director for neonatal services.

☐ tick here if the baby was ***not admitted*** **to a neonatal or paediatric unit** – please complete this form yourself.

After completion, please:

☐ **Tick here if no relevant morbidity/mortality has been recorded (see page 6)**

- Remove this front page and store securely with the Birthplace documents.
- Return the rest of the form to the Birthplace office using the Freepost envelopes provided.

Thank you

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Setting standards to improve women's health

Instructions to the person completing this form

Please complete this form and return to the Birthplace Local Coordinating midwife (LCM). See back page for return address.

Please enter your name and contact details here in case the LCM has any queries.

Name: _____ Phone/email: _____

The LCM will check the completed form and remove the front page and all identifying details before returning to the Birthplace office. The front page will be kept in a secure location by the LCM in the Trust where this baby was born.

Thank you for your help.

If you have any questions about the form or about this study please contact:

- the Birthplace Local Coordinating midwife (LCM) whose address is given on the back page of this form; or
- the Birthplace Project Manager

  Tel: 01865 289748
  Fax: 01865 289758
  Email: birthplace@npeu.ox.ac.uk

MREC reference number: 07/H0505/151

Definitions: Levels of neonatal care

Intensive care: for babies with the most complex problems, receiving any respiratory support via a tracheal tube and in the first 24 hours after its withdrawal; receiving NCPAP for any part of the day and less than five days old; below 1000g current weight and receiving NCPAP for any part of the day and for 24 hours after withdrawal; less than 29 weeks gestational age and less than 48 hours old; requiring major emergency surgery, for the pre-operative period and post-operatively for 24 hours; requiring full exchange transfusion, peritoneal dialysis, infusion of an inotrope, pulmonary vasodilator or prostaglandin and for 24 hours afterwards; any other very unstable baby considered by the nurse-in-charge to need 1:1 nursing; a baby on the day of death.

High dependency care: babies receiving NCPAP for any part of the day and not fulfilling any of the criteria for intensive care; below 1000g current weight and not fulfilling any of the criteria for intensive care; receiving parenteral nutrition; having convulsions; receiving oxygen therapy and below 1500g current weight; requiring treatment for neonatal abstinence syndrome; requiring specified procedures that do not fulfil any criteria for intensive care: care of an intra-arterial catheter or chest drain, partial exchange transfusion, tracheostomy care until supervised by a parent; requiring frequent stimulation for severe apnoea.

Special care: provided for all other babies who could not reasonably be expected to be looked after at home by their mother.

Normal care: provided for babies who themselves have no medical indication to be in hospital.

Section A: Neonatal or paediatric unit admission

1. **Was this baby admitted to a neonatal or paediatric unit for intensive care, high dependency care, special care or transitional care within 48 hours of birth?** Yes ☐ No ☐

   If No, *please go to section B.*

2. **Date of admission:** D D / M M / Y Y

3. **Type of unit**

Neonatal unit	☐
Other	☐

   If Other, please specify unit type: _____

4. **How many days care did the baby receive at each level of care?**
   Include part of any day as 1 day

Intensive care	☐☐☐ days
High dependency care	☐☐☐ days
Special care	☐☐☐ days
Normal care (including on postnatal ward)	☐☐☐ days
Total days:	☐☐☐ days

See definitions of levels of care inside front page of this booklet.

5. **Did this baby have any respiratory support (ventilator or continuous positive airway pressure, CPAP) during their admission?** Yes ☐ No ☐

   If Yes, for how many days? *Include part of any day as 1 day*

Total number of days receiving respiratory support	☐☐☐ days
Total number of days receiving supplemental oxygen	☐☐☐ days

6. **Has the baby been discharged home?** Yes ☐ No ☐

   If Yes, please give date: D D / M M / Y Y

7. **What were the main reasons for admission?**

   _____

   _____

   _____

   _____

Section B: Meconium aspiration

1. **Was this baby diagnosed with meconium aspiration syndrome?** Yes ☐ No ☐

   If No, *please go to section C.*

2. **Date of diagnosis:** D D / M M / Y Y

Project 08/1604/140

3. **Did this baby receive ECMO during admission?** Yes ☐ No ☐

If Yes, please give total number of days baby received ECMO: ☐☐ days

4. **Were any of the following diagnosed at any time during the baby's stay in the unit, in addition to the diagnosis of meconium aspiration syndrome?** *Please tick all that apply*

Pneumonia	☐
Pulmonary air leak	☐
Pulmonary haemorrhage	☐
Pulmonary hypertension	☐

Section C: Encephalopathy

1. **Was this baby diagnosed with neonatal encephalopathy?** Yes ☐ No ☐

If No, *please go to section D.*

2. **Date of diagnosis:** D D / M M / Y Y

3. **What was the most severe grade of encephalopathy recorded?**

Mild	☐
Moderate	☐
Severe	☐

4. **Was a specific cause of the encephalopathy identified?** Yes ☐ No ☐

If Yes, please give details of any causes identified, in addition to presumed perinatal asphyxia.

_____

_____

5. **Did the baby have seizures requiring treatment?** Yes ☐ No ☐

6. **Was the baby treated with hypothermia (cooling)?** Yes ☐ No ☐

Section D: Seizures

1. **Was this baby diagnosed with isolated seizures?** Yes ☐ No ☐

If No, *please go to section E.*

2. **Date of diagnosis:** D D / M M / Y Y

3. **Was a specific cause of the isolated seizures identified?** Yes ☐ No ☐

If Yes, please give details of any causes identified, in addition to presumed perinatal asphyxia.

_____

_____

4. **Was the baby prescribed medication to control seizures at any time?** Yes ☐ No ☐

Section E: Sepsis

1. **Was this baby diagnosed with neonatal sepsis (proven or suspected)?** Yes ☐ No ☐
   If No, *please go to section F.*

2. **Date of diagnosis:** D D / M M / Y Y

3. **Clinical risk factors for infection:**

   Did the mother have a diagnosis of clinical chorioamnionitis? Yes ☐ No ☐

   What was the duration of membrane rupture prior to delivery? ☐☐☐ days ☐☐☐ hours

   OR ☐ Not Known

   Was the mother known to be a carrier of GBS prior to birth? Yes ☐ No ☐

4. **Up to and including the 5th postnatal day, did the baby have?**

   A positive blood culture Yes ☐ No ☐

   If Yes, please specify organism: _____

   Evidence of infection in CSF Yes ☐ No ☐

   If Yes, please specify white cell count: _____

   Please specify organism: _____

   A positive culture from another site (not blood or CSF)? Yes ☐ No ☐

   If Yes, please specify usually sterile site(s) and organism(s): _____

   Bowel perforation or definite necrotising enterocolitis? Yes ☐ No ☐

   Chest X-ray changes consistent with pneumonia? Yes ☐ No ☐

Section F: Cephalhaematoma

1. **Was this baby diagnosed with cephalhaematoma or subaponeurotic bleeding?**

   Cephalhaematoma Yes ☐ No ☐

   Subaponeurotic bleeding Yes ☐ No ☐

   If No to both, *please go to section G.*

2. **Date of diagnosis:** D D / M M / Y Y

Section G: Cerebral haemorrhage

1. **Was this baby diagnosed with an intracranial haemorrhage?** Yes ☐ No ☐
   If No, *please go to section H.*

2. **Date of diagnosis:** D D / M M / Y Y

3. **What kind of intracranial haemorrhage was this?**

Subdural haemorrhage	☐
Subarachnoid haemorrhage	☐
Intracerebral haemorrhage	☐
Intraventricular haemorrhage	☐
Other	☐

If Other, please give details: _____

Section H: Injuries

1. **Was this baby diagnosed with any of the injuries listed below?** Yes ☐ No ☐

If No, *please go to section I.*

Date of diagnosis and cause. *Please tick all that apply.*

Injury	Data of diagnosis	Cause of injury
☐ Brachial plexus injury	D D / M M / Y Y	
☐ Fractured humerus	D D / M M / Y Y	
☐ Fractured clavicle	D D / M M / Y Y	
☐ Fractured skull	D D / M M / Y Y	
☐ Other injury *(give details)* _____	D D / M M / Y Y	

Section I: Kernicterus

1. **Was this baby diagnosed with kernicterus?** Yes ☐ No ☐

If No, *please go to section J.*

2. **Date of diagnosis:** D D / M M / Y Y

3. **What was the maximum SBR recorded for this baby?** ☐☐☐☐ µmol/l

4. **Did the baby require an exchange transfusion?** Yes ☐ No ☐

5. **How many days of phototherapy did the baby receive?**
Include part of any day as 1 day ☐☐ days

Section J: Feeding difficulties

1. **Was this baby diagnosed with feeding difficulties which required admission to a neonatal or paediatric unit for 48 hours or more?** Yes ☐ No ☐

If No, *please go to section K.*

2. **Date of diagnosis:** D D / M M / Y Y

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3. **Did this baby require parenteral feeding?** Yes ☐ No ☐

If Yes, please give the total number of days: ☐☐☐ days

4. **Did this baby require tube (orogastric or nasogastric) feeding?** Yes ☐ No ☐

If Yes, please give the total number of days: ☐☐☐ days

5. **How was the baby being fed at time of discharge (or current method of feeding if not yet discharged)?**

Please tick all that apply.

Intravenously	☐
Naso-gastric	☐
Oro-gastric route	☐
Oral sucking feeding	☐

Section K: Neonatal death

1. **Was the baby known to have died at the time this form was completed?** Yes ☐ No ☐

If No, *please go to section L.*

2. **Date and time of baby's death:** D D M M Y Y H H : m m (24hr)

3. **Was this baby registered as a neonatal death?** Yes ☐ No ☐

4. **If this was a neonatal death, where did the baby die?**

Obstetric unit postnatal room	☐
Alongside midwifery unit labour room	☐
Alongside midwifery unit postnatal room	☐
Freestanding midwifery unit labour room	☐
Home	☐
Neonatal unit	☐
Paediatric unit	☐
Other	☐

If Other, please give details: _____

5. **Has a cause of death been identified?** Yes ☐ No ☐

If Yes, please provide details:

_____

_____

_____

6. **Has a postmortem been performed?** Yes ☐ No ☐

Section L: Other details

For all babies: please check all sections and add any additional information that you think might be relevant regarding this baby's condition:

_____

_____

_____

_____

Confirmation of significant neonatal morbidity or mortality

1. Have at least one of the outcomes listed below been identified for this baby? Yes ☐ No ☐

- Neonatal or paediatric unit admission (Section A)
- Meconium aspiration (Section B)
- Encephalopathy (Section C)
- Seizures (Section D)
- Sepsis (Section E)
- Cephalhaematoma (Section F)
- Cerebral haemorrhage (Section G)
- Injuries (Section H)
- Kernicterus (Section I)
- Feeding difficulties (Section J)
- Neonatal death (Section K)

If No, were any of the above conditions suspected but not confirmed on investigation? Yes ☐ No ☐

If Yes, please give details

_____

_____

_____

If No, please tick the **blue** box on the front page and give any relevant details below

_____

_____

_____

Job title of person completing this form _____

Date form completed D D M M Y Y

Please return this form to the Birthplace Local Coordinating Midwife (see back cover for the address details)

Project 08/1604/140

Affix BACK PAGE sticker here

Return instructions for the person completing this form

Please return this form to the Birthplace Local Coordinating Midwife at the above address. ***Do NOT return to the Birthplace office.***

Thank you very much for completing this form.

If you have any questions, please contact the Birthplace office:

Birthplace Project Manager
Birthplace in England Research Programme
National Perinatal Epidemiology Unit
University of Oxford
Old Road Campus
Oxford
OX3 7LF

Tel: 01865 289748
Fax: 01865 289758
Email: birthplace@npeu.ox.ac.uk

MREC ref: 07/H0505/151
V1 01/2010

Figure 7. Maternal morbidity form

Birthplace in England Research Programme

Affix FRONT PAGE sticker here

Maternal morbidity/mortality follow-up

The Birthplace data collection form for this woman indicates that significant maternal morbidity or mortality may have occurred, or that the baby was stillborn.

Please complete this form to provide additional details about these events.

If you are not sure how to answer any of the questions, please contact the Birthplace office (tel: 01865 289748; email: birthplace@npeu.ox.ac.uk; fax: 01865 289758).

Instructions for completing this form:

Please complete the relevant stickers and attach to the front and back of this form.

After completion, please:

☐ **Tick here if no relevant morbidity/mortality has been recorded (see page 4)**

- Before returning, remove this front page and store securely with the Birthplace documents.
- Return the rest of the form to the Birthplace office using the Freepost envelopes provided.

Thank you

The Royal College of Midwives

nct

Royal College of Obstetricians and Gynaecologists

Setting standards to improve women's health

Section A: Blood transfusion

1. **Did this woman receive a blood transfusion within 48 hours of the birth?** Yes ☐ No ☐

   If No, *please go to section B.*

2. **When was the first blood transfusion given?**

   Was this? *Please tick one box*

Intrapartum	☐
End of third stage – 23 hours after birth	☐
24 – 48 hours after birth	☐

3. **How many units of whole blood or packed cells did this woman receive?** ☐☐

4. **Was a cell saver used?** Yes ☐ No ☐

   If Yes, please give the volume of patient's blood transfused: ☐☐☐☐ ml

5. **What was the lowest postnatal haemoglobin recorded for this woman?** ☐☐.☐ g/dl

6. **What was the primary reason for the blood transfusion?** *Please tick one only*

Uterine atony	☐
Genital tract trauma	☐
Morbidly adherent placenta	☐
Infection	☐
Anaemia	☐
Retained products	☐
Other	☐

   If Other, please give details _____

Section B: High dependency, intensive or specialist care

1. **Within the first 48 hours after the birth was this woman admitted to a higher level of care?** Yes ☐ No ☐

   If No, *please go to section C.*

2. **What type of higher level care did this woman receive?** *Please tick all that apply*

High dependency unit or area	☐
Intensive care unit	☐
Specialist unit e.g. dialysis unit	☐

   Type of specialist unit _____

   If you have ticked any of the above boxes, *please continue completing this section.*

   If Not, *please go to next section.*

3. Please give details of length of stay and reasons for admission to higher level care:

Type of unit	Date of admission	Date of discharge	Main reason for admission	Treatment(s) received
	D D / M M / Y Y	D D / M M / Y Y		
	D D / M M / Y Y	D D / M M / Y Y		
	D D / M M / Y Y	D D / M M / Y Y		
	D D / M M / Y Y	D D / M M / Y Y		
	D D / M M / Y Y	D D / M M / Y Y		

Section C: Maternal mortality

1. Was this woman registered as a maternal death (within 42 days of giving birth)? Yes ☐ No ☐

   If No, *please go to section D.*

2. Date and time of maternal death D D / M M / Y Y h h m m

3. Where did this woman die?

- Obstetric unit ☐
- Alongside midwifery unit ☐
- Freestanding midwifery unit ☐
- Home ☐
- High dependency unit/area ☐
- Intensive care unit ☐
- Other hospital ward or department ☐

If Other, please give details _____

4. Has a cause of death been identified? Yes ☐ No ☐

   If Yes, please provide details:

   _____

   _____

   _____

5. Has a postmortem been performed? Yes ☐ No ☐

Section D: Stillbirth

1. **Was this baby registered as a stillbirth?** Yes ☐ No ☐
   If No, *please go to section E.*

2. **Was a fetal heartbeat heard at labour onset?** Yes ☐ No ☐

3. **If this was an intrapartum stillbirth, was stillbirth diagnosed in?**
   - First stage of labour ☐
   - Second stage of labour ☐
   - Other ☐

   If Other, please give details: _____

4. **Has a cause of death been identified?** Yes ☐ No ☐
   If Yes, please provide details:

   _____

   _____

   _____

5. **Has a postmortem been performed?** Yes ☐ No ☐

Section E: Other details

Please check the form and add any additional information that you think might be relevant about this delivery, the mother or the fetus/baby.

_____

_____

_____

_____

Form continues on next page. P.T.O.

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Confirmation of significant maternal morbidity or mortality

1. **Have at least one of the outcomes listed below been identified for this woman or baby?** Yes ☐ No ☐
   - Blood transfusion (Section A)
   - Maternal admission or mortality (Sections B & C)
   - Stillbirth (Section D)

   If No, were any of the above conditions suspected but not confirmed on investigation? Yes ☐ No ☐

   If Yes, please give details

   _____

   _____

   _____

   If No, please tick the **blue** box on the front page and give any relevant details below

   _____

   _____

   _____

Job title of person completing this form _____

Date form completed D D M M Y Y

Affix BACK PAGE sticker here

Thank you very much for completing this form.

If you have any questions, please contact the Birthplace office:

Birthplace Project Manager
FREEPOST RRKH-XXAB-JJLK
Birthplace in England Research Programme
National Perinatal Epidemiology Unit
University of Oxford
Old Road Campus
Oxford
OX3 7LF

Tel: 01865 289748
Fax: 01865 289758
Email: birthplace@npeu.ox.ac.uk

MREC ref: 07/H0505/151
V1 01/2010

Appendix 3 'Other risk factors': coding of free text risk factor data

Conditions recorded as free text under 'other' at question C3 of the DCF were reviewed. Conditions which already appeared in the coding list on page 4 of the DCF (the 'NICE' risk factors) were recoded. Conditions which were not classifiable under any of the listed risk factors were recoded into the following categories:

- Other higher risk suggesting planned birth in an obstetric unit (coded 11A or 16A).
- Lower risk NOT considered to suggest planned birth in an obstetric unit (coded 11B or 16B).
- Unclassifiable (Coded 11C or 16C).

The process for reviewing and classifying conditions was as follows:

The free text entries were reviewed and a provisional list of the more commonly occurring categories and/or conditions requiring review by an obstetrician was produced.

- The Birthplace lead researcher (JH) and chief investigator (PB) reviewed the list and agreed the classification of the conditions on the list and discussed general principles for classification of conditions .
- JH provisionally coded the conditions where possible and compiled a list of queries .
- JH and PB reviewed the query cases and agreed the final coding.
- The coding was reviewed by the study research midwife (MS) and final revisions agreed by discussion (PB, JH, MS).

All coding was carried out blind to the woman's planned place of birth.

Results

There were 3,055 observations (4% of all eligible women) where free-text information was recorded which did not correspond to a NICE 'risk factor'. The majority of this information related to conditions which were not judged to put the woman or baby at 'higher risk' (n=2180) and were coded as 'other not a risk factor'. There were only nine observations with 'unclassifiable' free-text information recorded.

327 observations had an 'other medical condition' and 648 had an 'other obstetric condition' which were classified as 'other risk factors'. There were 14,785 'higher risk' women in the sample and 547 of these women (0.7% of all eligible women) were classified as 'higher risk' based on having an 'other risk factor' where no NICE 'risk factors' were recorded.

The 'other higher risk' conditions which were considered to indicate an increased risk suggesting planned birth in an OU are listed in Table 43.

Table 43. 'Other higher risk': medical and obstetric conditions not included as NICE guideline 'risk factors' which were used to classify women as 'higher risk'

Free-text recorded at C3 by midwife	Frequency
ABNORMAL ECG	1
ACUTE DEMYELINATING ENCEPHALOMYELITIS	1
ACUTE PANCREATITIS	2
ADAMS OLIVER SYNDROME	1
ADDISONS DISEASE	2
ADRENAL HYPERPLASIA	1
ANGIOPLASTY	1
ANTI LEWIS ANTIBODIES	1
ANTI PHOSPHOLIPID SYNDROME	7
ANTI-M ANTIBODIES	1
AUTOSOMAL RECESSIVE GLYCOGEN STORAGE DISEASE	1
AVM	1
BABY HAS 1 KIDNEY ON SCAN	1
BABY HAS MULTI CYSTIC DYSPLASTIC KIDNEY	1
BABY MILD L VENTRICULOMEGALY	1
BABY VENTRICULOMEGALY - RESOLVED BY 32/40	1
BALANCED TRANSLOCATION OF CHROMOSOME 6-14	1
BEHCETS SYNDROME	3
BEHCETS SYNDROME (MEMBRANES CAN ULCERATE) TREATED WITH CALCIUM & PREDNISOLONE	1
BENIGN INTRACRANIAL HYPERTENSION	2
BENIGN INTRACRANIAL HYPERTENSION AS A CHILD	1
BICORNUATE UTERUS	3
BIL RENAL PELVIC DILATION (BABY	1
BLACKOUTS HEART & HYPOTENSIVE DISORDER LOSS OF BLADDER SENSATION SELF CATHETERISED TWICE DAILY	1
BLADDER SURGERY AGE 9 - REQUIRED INDWELLING CATHETER FOR LABOUR	1
BLEEDING - WAS TWIN PREGNANCY BUT MISCARRIED TWIN 1 AT 13 WEEKS PREGNANT	1
BRANCHIOTORENCIL SYNDROME	1
BREAST CANCER - LUMPECTOMY + RADIO / CHEMOTHERAPHY	1
BRONCHOPULMONARY DYSPLASIA AS A BABY TRACHESTOMY / LARYNGOPLASTY FOR SUBGLOTTIC STENOSIS. *CONT*	1
C1 INHIBITOR DEFICIENCY (HERIDITORY ANGIOEDEMA)	1
CALCIFICATION OF PLACENTA NOTED ON SCAN @ 37 WEEKS. SCAN INITIALLY SMALL FOR DATES BUT GROWTH GOOD.	1
CEREBELLA ATAXIA CALISING LOSS OF BALANCE	1
CEREBRAL ANEURYSM	1
CEREBRAL MENINGIOMA/CRANIOTOMY 2004	1
CEREBRAL PALSY	6
CEREBRAL PALSY LEARNING DISABILITY	1
CERVICAL FIBROID	1
CERVICAL FIBROID - LUMBAR REGION	1
CERVICAL SUTURE	1
CHARCOT - MARIE - TOOTH DISEASE	1
CHIARI MALFORMATION - (NEUROLOGICAL)	1
CHOLESTASIS	5

CHOLESTASIS OF PREGNANCY	3
CHOLINESTERASE DEFICIENCY	1
CLEFT LIP & PALATE	1
COLITIS	1
COLORECTAL CANCER HEREDITARY NON-POLYPOSIS	1
CONGENITAL HEART BLOCK ANTIBODY	1
CONN'S SYNDROME R ADRENAL GLAND REMOVED	1
CONVULSION SYNCOPY	1
CPT 2 DEFICIENCY	1
CROHNS DISEASE	32
CROHNS DISEASE - ANALFISTULAS ++ PAST PERIANAL ABSCESS X 3	1
CROHNS DISEASE & VIT B12 DEFICIENCY	1
ECHOGENIC BOWEL (FETAL)	1
EHLER DANLOS SYNDROME - HYPER MOBILITY TYPE.	1
EPISODE OF SENSORY LOSS AT 20/40? MIGRAINE?? THA?? ANTIPHOSPHOID LIPID SYNDROME	1
ESBC URINE INFECTION EARLY IN PREGNANCY	1
EVACUATION OF PERINEAL HAEMATOMA IN THEATRE UNDER SPINAL	1
FEBRILE CONSULSIONS / PERNICIOUS ANAEMIA / OBSTETRIC CHOLEASTASIS	1
FEMALE CIRCUMCISION	3
FEMALE CIRCUMCISION (CORRECTED SURGERY)	1
FEMALE GENITAL MUTILATION	9
FEMALE GENITAL MUTILATION GRADE 1 MATERNAL VIT D DEFICIENCY	1
FETAL DIAGNOSIS OF GASTROSCHISIS	1
FETAL MULTICYSTIC KIDNEY	1
FETAL PERIMENTRANOUS VSD BEEN GREAT ORMOND STREET	1
FETAL SCAR VENTRICULOMEGLY BOTH SIDES & HYPOPLASTIC CEREBELLUM	1
FETUS DIAGNOSED WITH DILATED RENAL PELVIS BOTH SIDES	1
FGM AND PREVIOUS 3RD DEGREE TEAR	1
FREQUENT UTIs	1
GILBERTS DISEASE	1
GILBERTS SYNDROME	5
GRAND MULTIP	2
GRAND MULTIP G7 P4 + 2	1
GRAND MULTIPARITY	1
GYPUPLASTIC IT HEART SGD	1
H / O FACTURED PELVIS DUE TO A CAR ACCIDENT. WAS TOLD SHE COULD NOT HAVE A NORMAL DELIVERY *CONT*	1
HAEMOCUROMOTOSIS	1
HAMOCYSTINUMA	1
HEART MURMUR OBSTETRIC CHOLESTASIS	1
HIGH BILE ACIDS - GALL STONE & ? OC	1
HIGH URIC ACID	1
HODGKINS DISEASE 2001 HYPOTHYHROIDISM SINCE 2001.	1
HYPERCALCAEMIA SECONDARY TO HYPERPARATHYROIDISM	1
HYPERMOBILITY SYNDROME (EHLERS DANLOS SYNDROME)	1
IGA NEPHROPATHY - NO TREATMENT REQUIRED IN PREGNANCY OR PRIOR TO PREGNANCY	1
II PELVIS - SPD	1
ILEOSTOMY - CROHNS DISEASE	1
IOL FOR INITIAL POLYHYDRAMNIOS THEN LOW LIQUOR VOL	1
JEHOVAH'S WITNESS	2
LARGE FOR DATES	1
LICHEN SCLEROSIS	1
LICHIN SCLEROSIS AT ATROPHICUS	1

LOW FETAL MOVEMENTS	2
LOW HB & VERRITIN DECLINED ALL BLOOD TESTS IN EARLY PREGNANCY. POST MATURE TERM + 21 DECLINED *CONT*	1
LOW LEVEL ANTI-CARDIOTIPIN ANTIBODY	1
LOW LV	1
LOW LYING PLACENTA	1
LOW LYING PLACENTA 4 CM AWAY FROM OS	1
MASTOCYTOSIS	1
METHYLENETE TROHYDRALATE (MTHFR) PRONE TO BLOOD CLOTTING	1
MILD VENTRICULOMEGALY SEEN IN BABY ON USS AT 38+ WEEJS GESTATUS	1
MULTICYSTIC DYSPLASTIC KIDNEYS	1
MULTIPLE SCLEROSIS	1
NEURALGIA PARAESTHETICA	1
NEUROFIBROMATOSIS TYPE 1	1
NO FETAL MOVEMENT SEEN ON USS	1
OBSTETRIC CHOLESTASIS	42
OBSTETRIC CHOLESTASIS - RESOLVED	1
ON MEDICATION REQUIRING 48 HOUR OBSERVATIONS OF BABY P.N. HOME BIRTH AGAINST MEDICAL ADVICE.	1
OSTEOGENESIS IMPERFECTA TYPE I MALIGNANT HYPETHEMIA	1
OVERDOSE AT 20 WEEKS	1
PERIODIC PARALYSIS - ?FORM OF EPILEPSY	1
PITUARY CYST	1
PITUITARY PROBLEMS	1
PLACENTA ACENETA - CONSERVATIVE MANAGEMENT. PLACENTA EXPLELLED @ 10WKS P / N	1
PLACENTA ACRETTA	1
PLUMMER - VINSON SYNDROME	1
POLYCYSTIC KIDNEYS ON BABY FOUND ON USS	1
PREVIOUS 3RD DEGREE TEAR	10
PREVIOUS 4TH DEGREE TEAR	2
PREVIOUS ABO INCOMPATABILITY	1
PREVIOUS BRAIN ANEURYSM	1
PREVIOUS EPISIOTOMY BREAKDOWN / PP HB 7.0 GLDL	1
PRIMARY NON-HODGKINSONS LYMPHOMA TREATED SUCCESSFULLY WITH CHEMO AND RADIOTHERAPY	1
PROLACTINUMA	1
PROLONGED RUPTURE OF MEMBRANES	3
PROLONGED RUPTURE OF MEMBRANES > 92 HOURS.	1
PROTHOOMBOTIC STATUS OF BLOOD	1
PULMONARY SARCOIDOSIS	1
PYLONEPHRITIS	1
RAISED BILE ACIDS	1
RECEIVING TREATMENT FOR MALARIA	1
RECENT INPT: DOUBLE PNEUMONIA ON ABs & FRAGMIN (FRAGMIN STOPPED PRIOR TO LABOUR)	1
RECURRENT UTIs	1
RECURRENT UTIs & PYLONEPHRITIS	1
RECURRENT UTIs (URINARY TRACT INFECTIONS) AND PYELONEPHRITIS	1
REDUCED FETAL MOVEMENTS	1
REDUCED FETAL MOVEMENTS FOR 24 HOURS	1
REDUCED FETAL MOVEMENTS OVER SEVERAL WEEKS	1
REMOVAL OF MALIGNANT MELANOMA	1
RENAL THROMBOCYTHAEMIS	1
RHESUS INCOMPATABILITY BILIVOLAN HIGH AT DELIVERY	1

RHEUMATIC FEVER AS A CHILD	2
RIGHT RENAL PELVIS DILATION	1
SARCOIDOSIS	1
SARCOIDOSIS - (DISCHARGED FROM CLINIC)	1
SARCOIDOSIS ON STEROIDS	1
SELECTIVE REDUCTION OF TWIN 1 DUE TO EDWARDS SYNDROME	1
SIGNIFICANT UTERINE FIBROIDS	1
SINGLE UMBILICAL ARTERY	1
SNEDDONS SYNDROME	1
SPD	10
SPD (ADMISSION X 1)	1
SPD SYMPHYSIS PUBIC DYSFUNCTION	1
SPD, Asthma	1
SPINAL CHORD INJURY CAUSING INCOMPLETE TETRAPLEGIA	1
SPLENOMEGALY	2
SPONTANEOUS PNEUMOTHORAX	1
STICKLERS SYNDROME	1
SUB-CHORIONIC HEAMATOMA	1
SUPRA PUBIC DYSFUNCTION	3
SUPRA PUBIC PAIN ++	1
SUXAMETHONIUM - LIKELY ADVERSE REACTION	1
SVT - NOT UNDER MEDICAL SUPERVISION / ON MEDICATION PALPATIONS + KNOWN TACCYCARDIA	1
SYMPHISIS PUBIS DISCOMFORT.	1
SYMPHYSIS PUBIS 'FRACTURE'	1
SYSTEMIC VASCULITIS	1
TARLOR CYST ON SPINE - SEEN BY ANAESTHESTIC	1
TECTAL PLATE GLYOMA	1
Third degree tear following birth of first baby	1
TIA	1
TRAIT HB TYGARD	1
TREATED FOR CA BREAST 2008. LUMPECTOMY HAD RADIOTHERAPY & CHEMOTHERAPY	1
TRISOMY 13	1
TURNERS SYNDROME IN FETUS	1
TVT SLING	1
TYPE 4 FEMALE GENITAL MUTILATION	1
ULCERATIVE COLITIS	3
ULCERATIVE COLLITAS	1
UNILATERAL CLEFT LIP	1
URINARY RETENTION	1
UTERINE FIBROIDS AND SPD	1
VAGINAL PROLAPSE	1
VAN DER WOUDE SYNDROME	1
VENTRICULAR PERITONEAL SHUNT DUE TO HYDROCEPHALUS AS CHILD	1
VISCERAL HYPERALGIA	1
VP SHUNT	1
VULAL VERICOSITIES	1
WOLFF PARKINSON WHITE SYNDROME	3
X2 PNEUMOTHORAX	1

Appendix 4 Summary of missing data

Risk status

Only 451 women in the sample (0.6% of all eligible women included) had missing 'risk status' and these data were missing for fewer than 1% of women in each setting (Table 44).

Table 44. Summary of missing 'risk status' data for all women by planned place of birth

Unit type	Risk status missing		Total births
	n	%	n
OU	177	0.5	32257
Home	83	0.5	18269
FMU	95	0.8	11666
AMU	96	0.5	17582
Total	451	0.6	79774

Primary outcome and confounders

The primary outcome was coded as missing where at least one component of the primary outcome was missing and no other components were recorded as having occurred. Three questions on the data collection forms contributed to the primary outcome: a question listing 13 neonatal morbidities with an option 'no morbidity identified', a Yes/No question about death at the time the form was completed, and a Yes/No question about whether there was a stillbirth. The majority of births where the primary outcome was missing had the neonatal morbidity question left blank (0.9%, 583 observations), fewer observations had the death question left blank (0.4%, 246 observations), and the stillbirth question was missing for 3 observations (Table 45). Both the neonatal morbidity question and death question were in a section of the form relating to adverse outcomes and it may be that where no morbidity was observed these questions were more likely to be left incomplete.

Women's marital or partner status was the confounder with the most missing data, 1.2% overall for 'low risk' women. The OU (1.6% missing) and AMU (1.5% missing) groups had the highest proportion of missing data for this variable. All other potential confounders had fewer than 1.0% missing data both overall and for each planned place of birth (Table 46).

Table 45. Missing primary outcome data for 'low risk' women by planned place of birth

	Missing component of the primary outcome								
	A neonatal morbidity		Early neonatal death		Stillbirth		Primary outcome data complete		All 'low risk'
	n	%	n	%	n	%	n	%	n
OU	119	0.6	69	0.4	0	-	19551	99.2	19706
Home	251	1.5	81	0.5	1	0.0	16553	98.3	16840
FMU	72	0.6	19	0.2	0	-	11199	99.3	11282
AMU	141	0.8	77	0.5	2	0.0	16524	98.9	16710
Total	583	0.9	246	0.4	3	0.0	63827	98.9	64538

Table 46. Missing data for potential confounders for 'low risk' women by planned place of birth

	Missing data for potential confounders									
	OU n=19706		Home n=16840		FMU n=11282		AMU n=16710		Total n=64538	
Potential confounders	n	%	n	%	n	%	n	%	n	%
Maternal age	25	0.1	34	0.2	14	0.1	38	0.2	111	0.2
Ethnicity	27	0.1	21	0.1	5	0	37	0.2	90	0.1
Understanding of English	152	0.8	26	0.2	27	0.2	64	0.4	269	0.4
Marital or partner status	320	1.6	111	0.7	120	1.1	243	1.5	794	1.2
BMI in pregnancy	55	0.3	94	0.6	17	0.2	66	0.4	232	0.4
Index of multiple deprivation score	126	0.6	118	0.7	31	0.3	48	0.3	323	0.5
Parity	31	0.2	16	0.1	17	0.2	37	0.2	101	0.2
Gestation	56	0.3	41	0.2	27	0.2	55	0.3	179	0.3

The proportion of births with missing primary outcome data was less than 2% for every potential confounder variable overall and within each category of the potential confounders (Table 47). There was a much higher proportion of missing primary outcome data for births that also had missing confounder data.

Table 47. Distribution of missing primary outcome data for 'low risk' women by baseline characteristic

Potential confounders	Primary outcome				Total births
	Not missing		Missing		
	n	%	n	%	n
All 'low risk' women	63827	98.9	711	1.1	64538
Maternal age					
Under 20	3434	99.0	36	1.0	3470
20-24	11477	99.1	101	0.9	11578
25-29	18138	99.0	177	1.0	18315
30-34	18525	98.8	216	1.2	18741
35-39	10446	98.7	133	1.3	10579
40+	1716	98.4	28	1.6	1744
Missing	91	82.0	20	18.0	111
Ethnic group					
White	55185	98.9	634	1.1	55819
Indian or Bangladeshi	1714	99.2	14	0.8	1728
Pakistani	1379	99.5	7	0.5	1386
Black Caribbean	633	99.2	5	0.8	638
Black African	1385	99.2	11	0.8	1396
Mixed	1016	99.1	9	0.9	1025
Other	2434	99.1	22	0.9	2456
Missing	81	90.0	9	10.0	90
Understanding of English					
Fluent	60216	98.9	675	1.1	60891
Some	2633	99.2	21	0.8	2654
None	719	99.3	5	0.7	724
Missing	259	96.3	10	3.7	269
Marital/partner status					
Married/living with partner	57965	98.9	646	1.1	58611
Single or unsupported by partner	5094	99.2	39	0.8	5133
Missing	768	96.7	26	3.3	794
Body mass index in pregnancy (kg/m^2)					
Not recorded	11505	99.0	117	1.0	11622
Less than 18.5	1547	99.0	16	1.0	1563
18.5-24.9	30516	99.0	318	1.0	30834
25.0-29.9	14774	98.8	175	1.2	14949
30.0-35.0	5285	99.0	53	1.0	5338
Missing	200	86.2	32	13.8	232

Table 47 (continued): Distribution of missing primary outcome data for 'low risk' women by baseline characteristic

Potential confounders	Primary outcome				Total births
	Not missing		Missing		
	n	%	n	%	n
Index of Multiple Deprivation score (quintile)					
1st Least deprived	11724	98.7	152	1.3	11876
2nd	12179	98.8	152	1.2	12331
3rd	12756	98.9	141	1.1	12897
4th	13221	99.0	131	1.0	13352
5th Most deprived	13655	99.2	104	0.8	13759
Missing	292	90.4	31	9.6	323
Previous pregnancies >=24 completed weeks					
Nulliparous	28443	99.0	288	1.0	28731
Multiparous	35289	98.8	417	1.2	35706
Missing	95	94.1	6	5.9	101
Gestation (completed weeks)					
37	1866	99.0	18	1.0	1884
38	6025	99.1	55	0.9	6080
39	15269	98.8	178	1.2	15447
40	24157	98.9	271	1.1	24428
41	15220	98.9	172	1.1	15392
42+	1117	99.0	11	1.0	1128
Missing	173	96.6	6	3.4	179

Appendix 5 Supplementary tables and figures for analyses of 'low risk' births

Detailed breakdown of primary outcome events by planned place of birth

Table 48. Contribution of individual outcome events to the primary outcome in 'low risk' women by planned place of birth

	OU		Home		FMU		AMU	
	n	%	n	%	n	%	n	%
Stillbirth	3	3.7	6	8.6	4	9.8	1	1.7
Early neonatal death (within 7 days)	5	6.2	5	7.1	5	12.2	3	5.2
Neonatal encephalopathy (clinical)	32	39.5	32	45.7	16	39.0	16	27.6
Neonatal encephalopathy (signs)	8	9.9	4	5.7	2	4.9	4	6.9
Meconium aspiration syndrome	24	29.6	15	21.4	11	26.8	25	43.1
Brachial plexus injury	6	7.4	5	7.1	2	4.9	7	12.1
Fractured humerus	1	1.2	1	1.4	0	0.0	0	0.0
Fractured clavicle	2	2.5	2	2.9	1	2.4	2	3.4
Total	81	100	70	100	41	100	58	100

Each of the categories above are mutually exclusive and outcomes listed higher in the table take precedence over outcomes listed lower down. For example, if a baby with neonatal encephalopathy died within 7 days the outcome is classified as an early neonatal death.

Table 49. Contribution of individual outcome events to the primary outcome in 'low risk' women without complicating conditions at the start of care in labour by planned place of birth

	OU		Home		FMU		AMU	
	n	%	n	%	n	%	n	%
Stillbirth	3	6.3	6	9.7	3	8.6	0	0.0
Early neonatal death (within 7 days)	2	4.2	4	6.5	3	8.6	3	5.6
Neonatal encephalopathy (clinical)	20	41.7	28	45.2	15	42.9	15	27.8
Neonatal encephalopathy (signs)	7	14.6	3	4.8	2	5.7	4	7.4
Meconium aspiration syndrome	11	22.9	13	21.0	9	25.7	25	46.3
Brachial plexus injury	3	6.3	5	8.1	2	5.7	7	13.0
Fractured humerus	1	2.1	1	1.6	0	0.0	0	0.0
Fractured clavicle	1	2.1	2	3.2	1	2.9	0	0.0
Total	48	100	62	100	35	100	54	100

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Subgroup analysis: outcomes for 'low risk' women without complicating conditions at the start of care in labour by parity and planned place of birth

Figure 8. Home vs. OU: Primary outcome for 'low risk' women without complicating conditions at the start of care in labour by parity

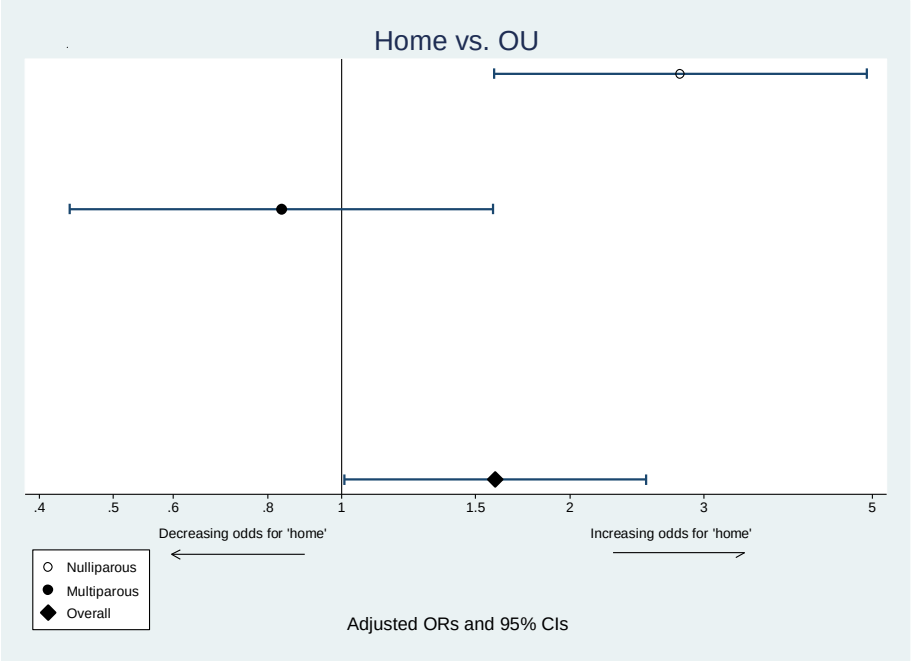

Figure 9. FMU vs. OU: Primary outcome for 'low risk' women without complicating conditions at the start of care in labour by parity

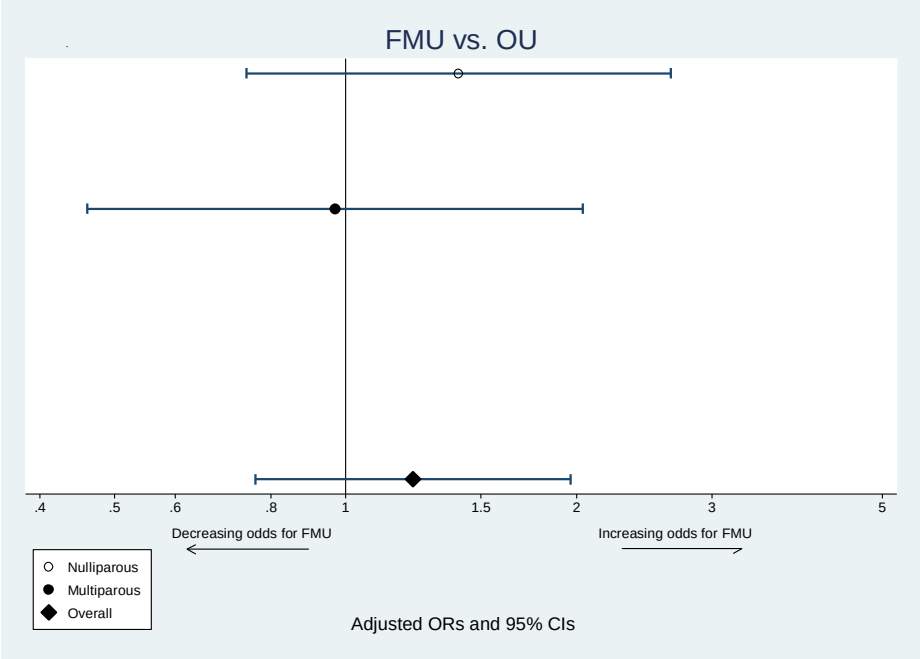

Figure 10. AMU vs. OU: Primary outcome for 'low risk' women without complicating conditions at the start of care in labour by parity

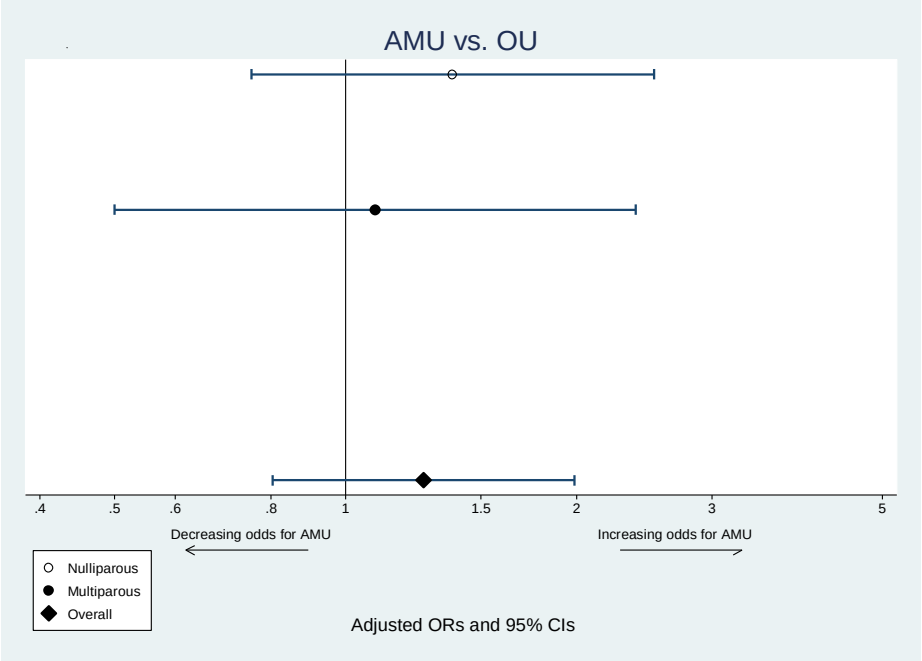

Figure 11. Home vs. OU: Perinatal secondary outcomes for 'low risk' women without complicating conditions at the start of care in labour by parity

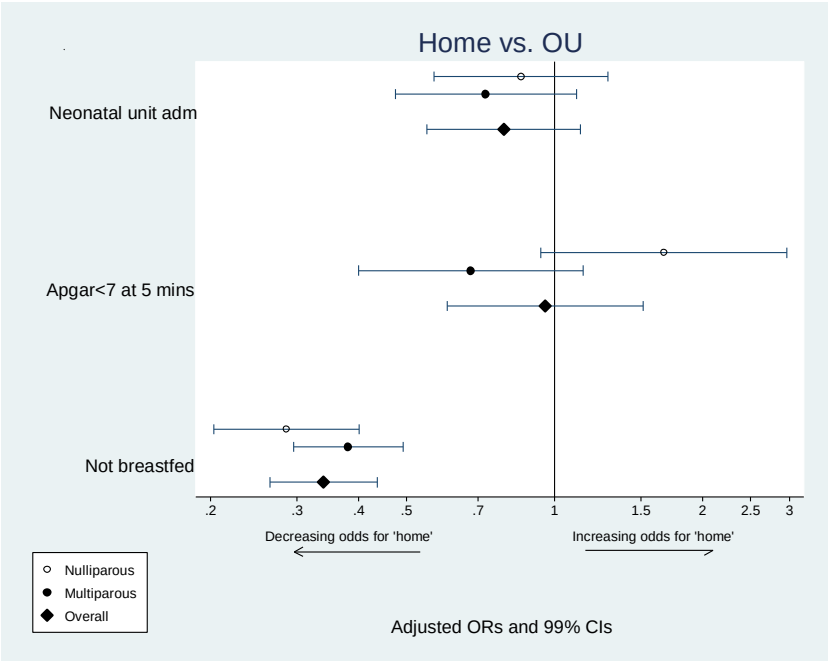

Figure 12. FMU vs. OU: Perinatal secondary outcomes for 'low risk' women without complicating conditions at the start of care in labour by parity

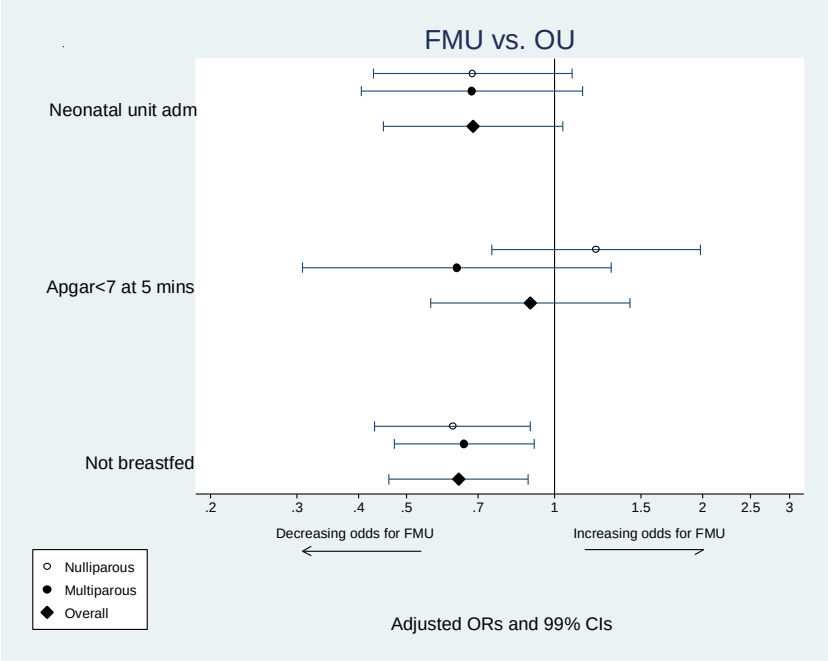

Figure 13. AMU vs. OU: Perinatal secondary outcomes for 'low risk' women without complicating conditions at the start of care in labour by parity

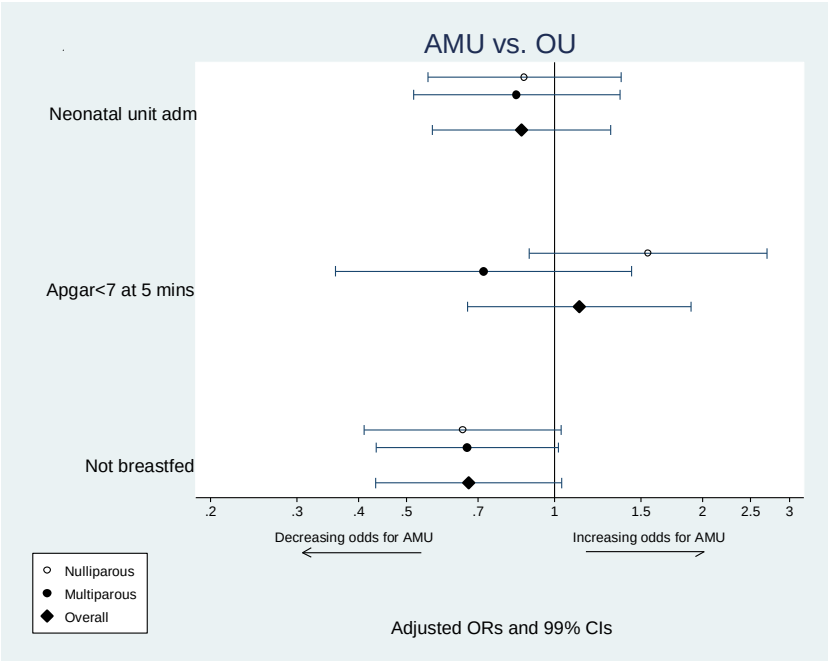

Figure 14. Home vs. OU: Maternal secondary outcomes for 'low risk' women without complicating conditions at the start of care in labour by parity

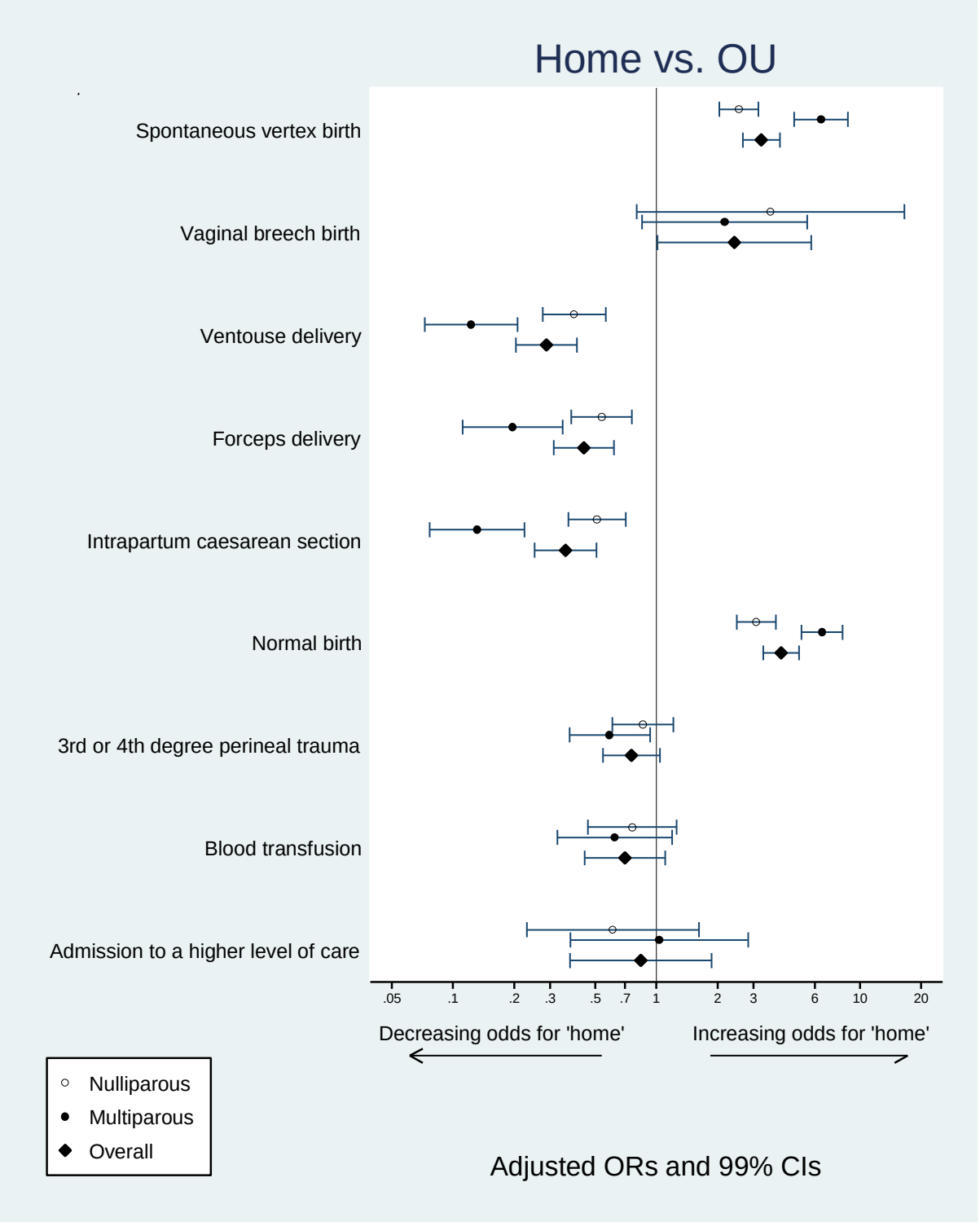

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Figure 15. FMU vs. OU: Maternal secondary outcomes for 'low risk' women without complicating conditions at the start of care in labour by parity

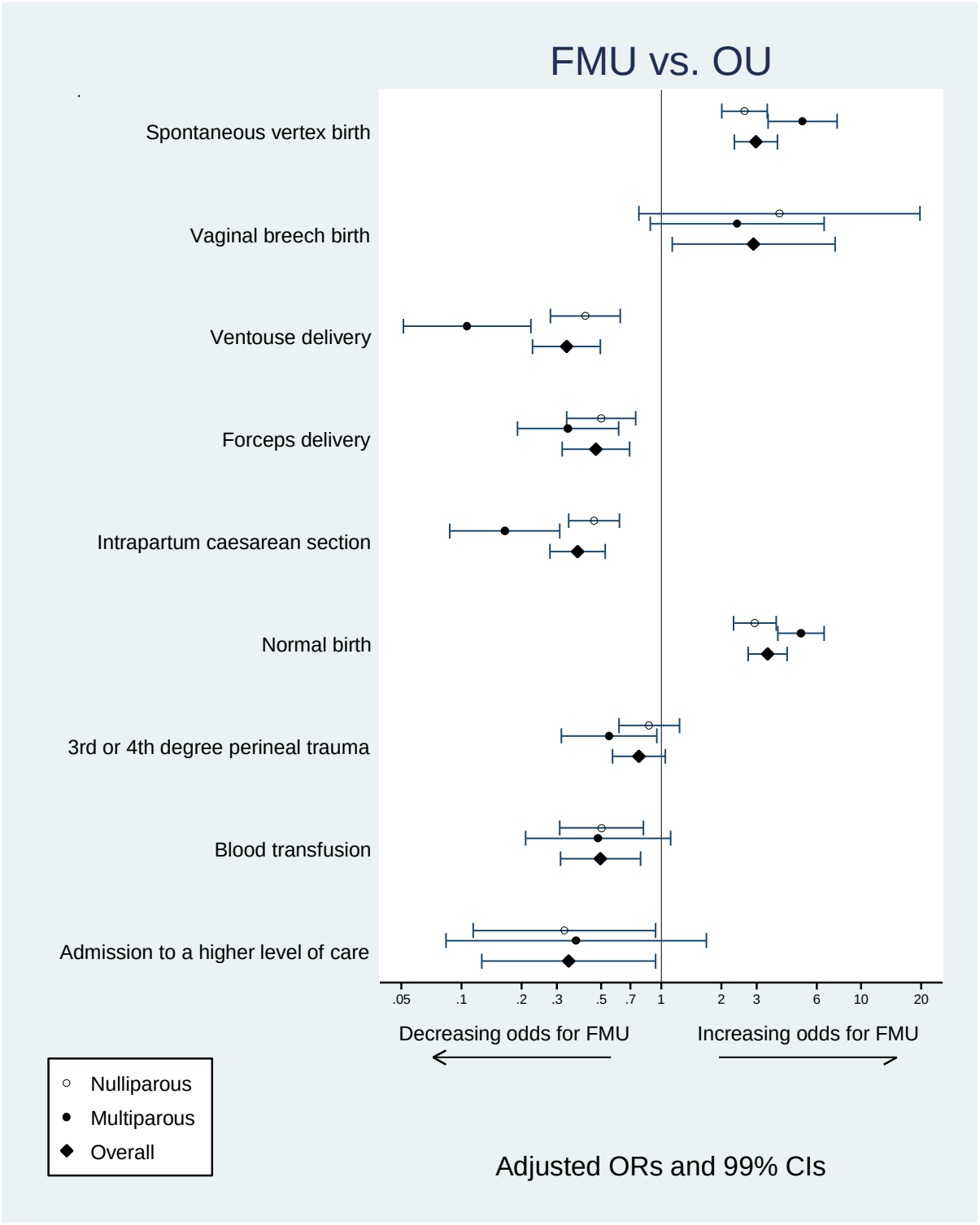

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Figure 16. AMU vs. OU: Maternal secondary outcomes for 'low risk' women without complicating conditions at the start of care in labour by parity

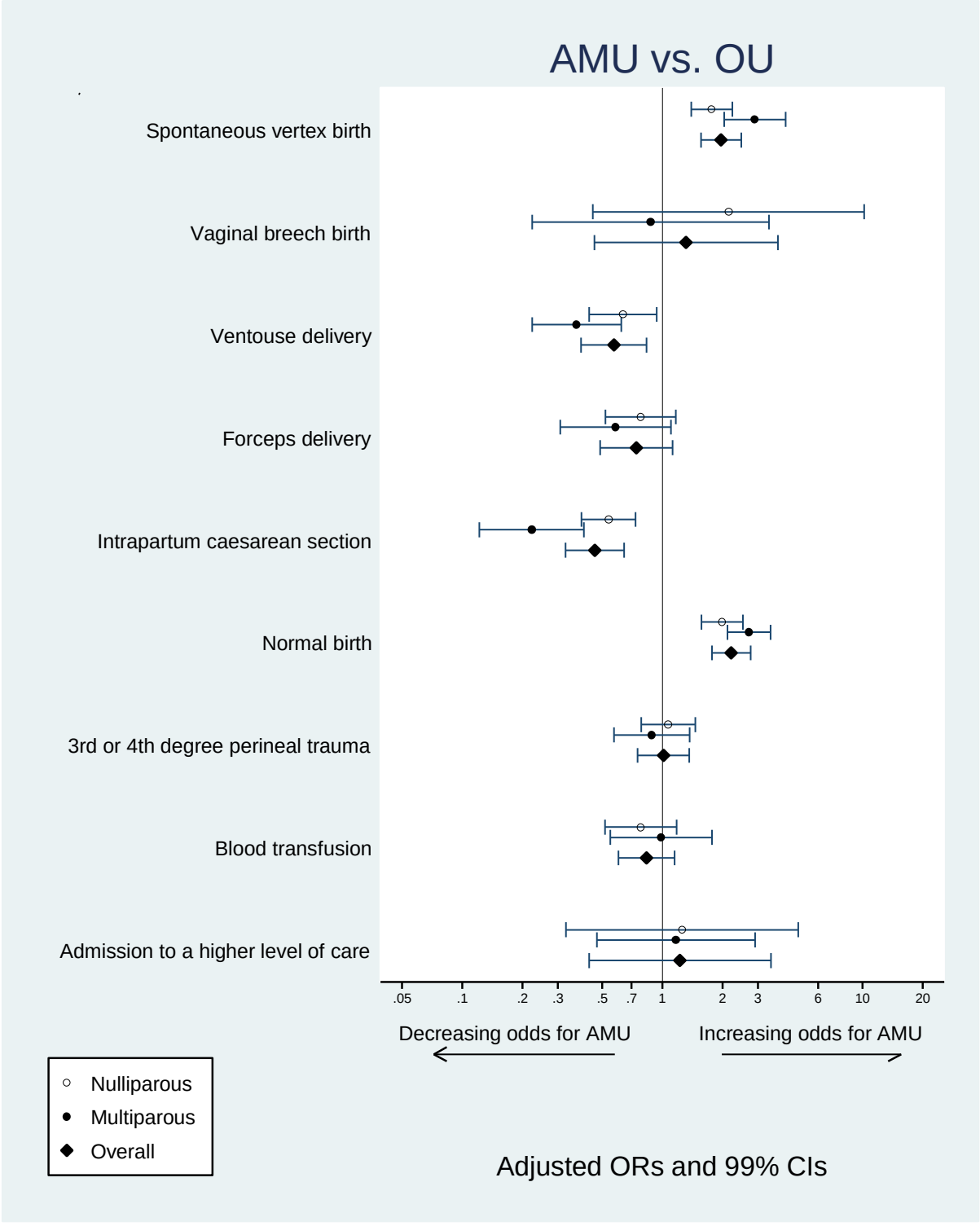


Figure 17. Home vs. OU: Maternal interventions for 'low risk' women without complicating conditions at the start of care in labour by parity

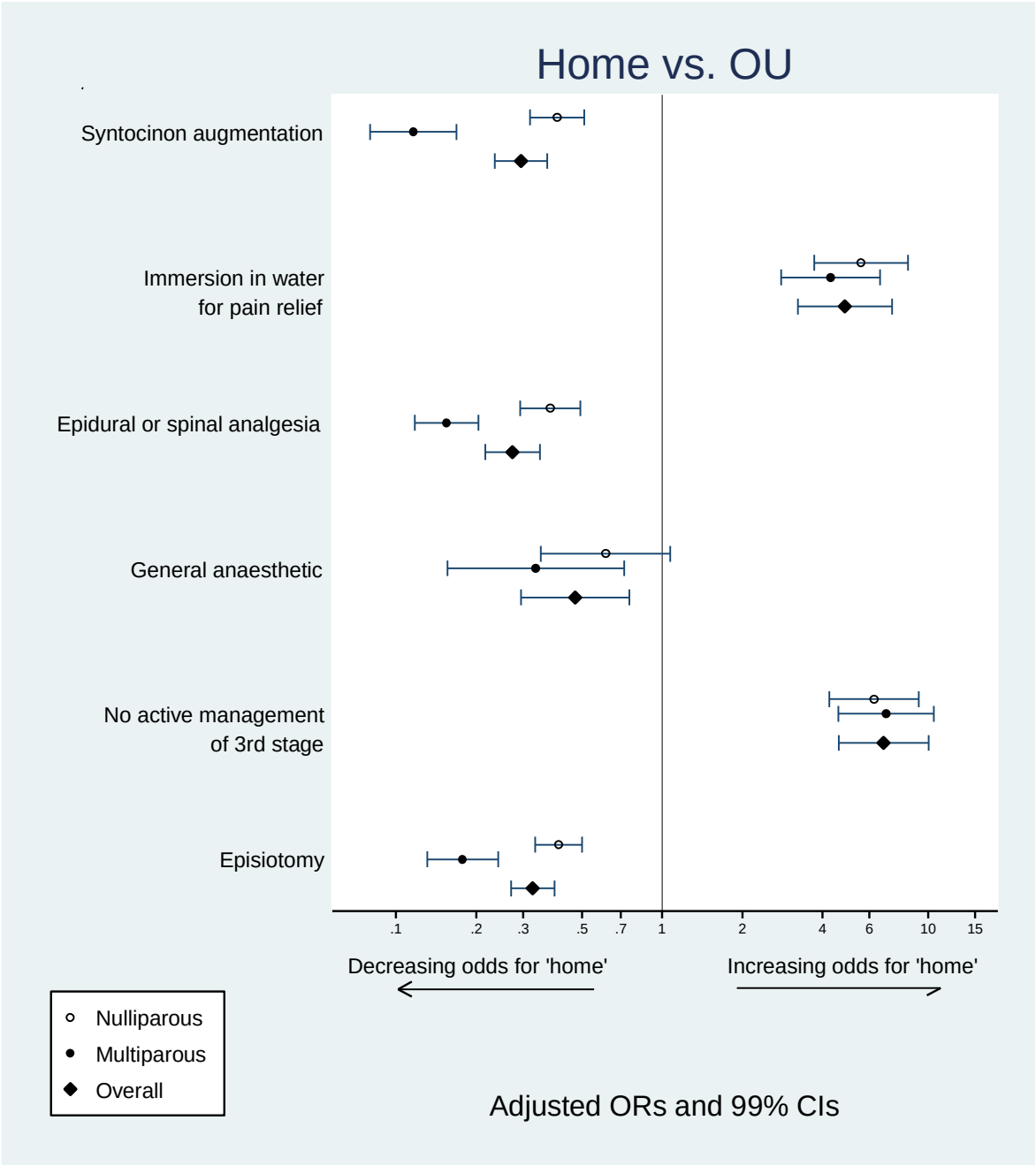


Figure 18. FMU vs. OU: Maternal interventions for 'low risk' women without complicating conditions at the start of care in labour by parity

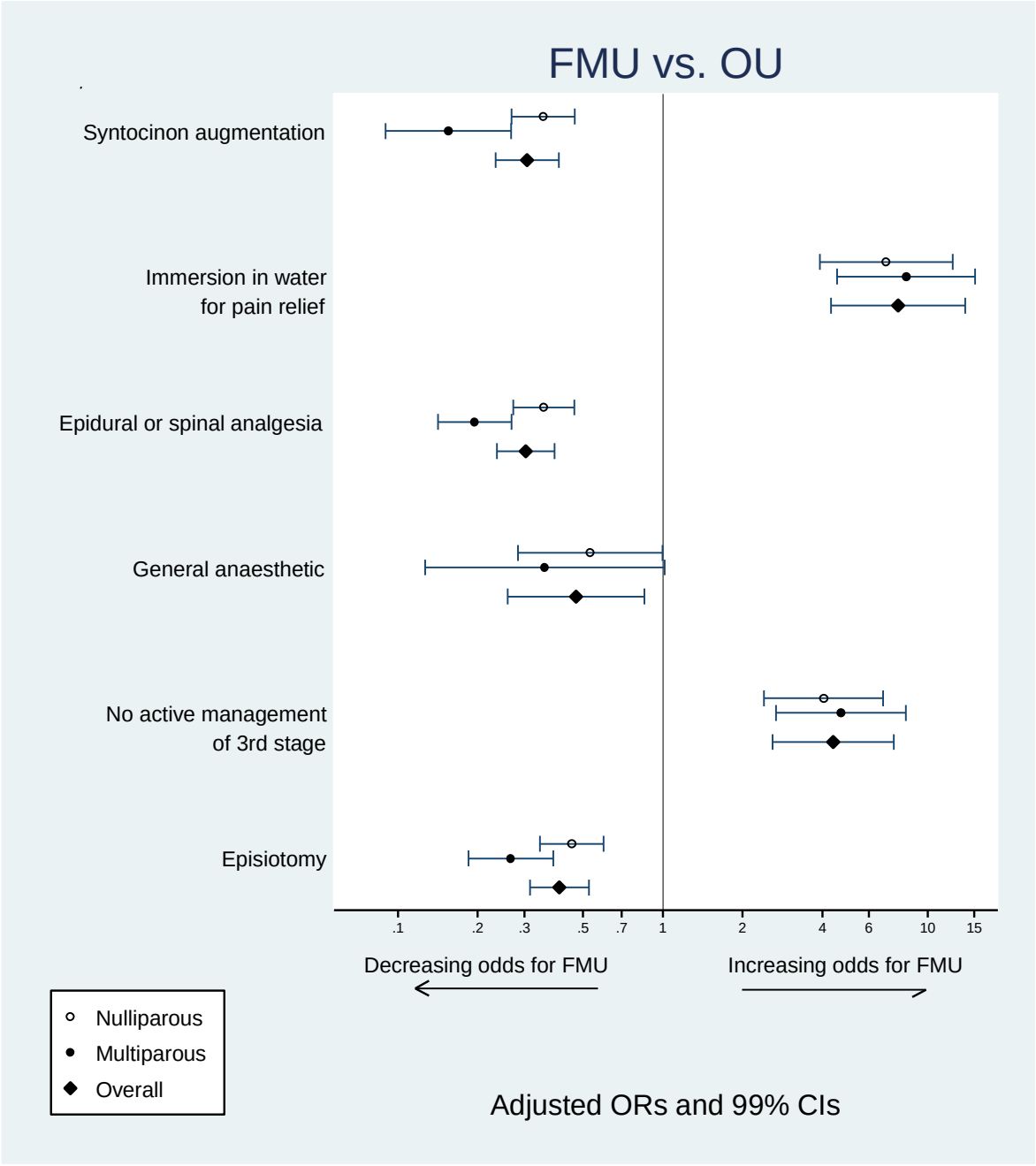


Figure 19. AMU vs. OU: Maternal interventions for 'low risk' women without complicating conditions at the start of care in labour

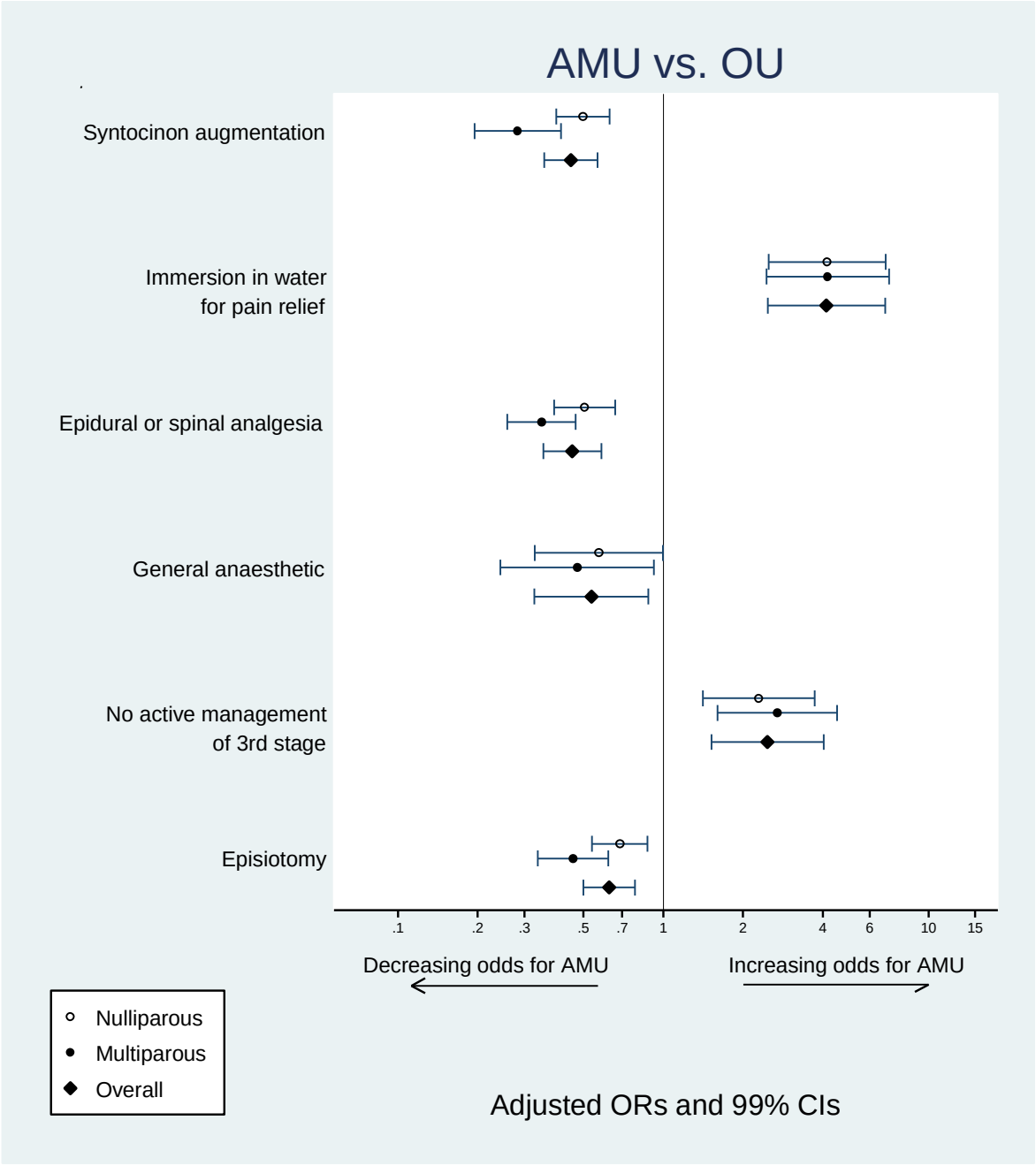


Table 50. Perinatal secondary outcomes for 'low risk' women without complicating conditions at the start of care in labour by parity and planned place of birth

	Events[1]	Births[1]	Weighted[1]	Adjusted[2]	
	n	n	n/1000	OR	(99% CI)
Neonatal unit admission	1014	55797		Interaction test p = 0.776	
Nulliparous women					
OU	228	7781	29.4	1	-
Home	101	4007	25.4	0.86	(0.57-1.28)
FMU	106	4712	20.6	0.68	(0.43-1.09)
AMU	163	7340	24.3	0.87	(0.55-1.36)
Total	598	23840	28.4		
Multiparous women					
OU	122	7417	16.5	1	-
Home	134	11258	12.0	0.73	(0.47-1.11)
FMU	64	5700	11.4	0.68	(0.41-1.14)
AMU	96	7582	13.0	0.84	(0.52-1.36)
Total	416	31957	15.6		
Apgar<7 at 5 mins.	417	55930		Interaction test p = 0.002	
Nulliparous women					
OU	60	7761	8.0	1	-
Home	51	4022	12.9	1.67	(0.94-2.97)
FMU	50	4708	9.1	1.21	(0.75-1.98)
AMU	74	7374	11.8	1.55	(0.89-2.70)
Total	235	23865	8.5		
Multiparous women					
OU	54	7413	8.0	1	-
Home	62	11326	5.6	0.68	(0.40-1.14)
FMU	30	5704	5.2	0.63	(0.31-1.30)
AMU	36	7622	5.9	0.72	(0.36-1.44)
Total	182	32065	7.5		
Not breastfed	10809	54880		Interaction test p = 0.021	
Nulliparous women					
OU	1890	7762	23.1	1	-
Home	239	3984	5.9	0.29	(0.20-0.40)
FMU	751	4683	16.1	0.62	(0.43-0.89)
AMU	1269	7324	15.9	0.65	(0.41-1.03)
Total	4149	23753	21.6		
Multiparous women					
OU	2202	7398	28.7	1	-
Home	1533	11168	13.6	0.38	(0.29-0.49)
FMU	1210	5671	21.4	0.66	(0.47-0.91)
AMU	1715	7574	21.2	0.66	(0.43-1.02)
Total	6660	31811	26.6		

1 Restricted to women included in the adjusted analysis

2 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks and gestation (completed weeks)

Table 51. Maternal secondary outcomes for 'low risk' women without complicating conditions at the start of care in labour by parity and planned place of birth

	Events[1]	Births[1]	Weighted[1]	Adjusted[2]	
	n	n	%	OR	(99% CI)
Spontaneous vertex birth	48793	56026		Interaction test p < 0.001	
Nulliparous women					
OU	5171	7791	65.7	1	-
Home	3216	4033	80.1	2.54	(2.04-3.16)
FMU	3858	4714	83.1	2.61	(2.01-3.39)
AMU	5694	7378	76.9	1.77	(1.39-2.24)
Total	17939	23916	67.9		
Multiparous women					
OU	6737	7429	90.6	1	-
Home	11141	11338	98.3	6.44	(4.75-8.74)
FMU	5595	5714	98.0	5.10	(3.43-7.60)
AMU	7381	7629	96.6	2.90	(2.04-4.12)
Total	30854	32110	92.1		
Vaginal breech birth	106	56026		Interaction test p = 0.648	
Nulliparous women					
OU	6	7791	0.1	1	-
Home	8	4033	0.2	3.63	(0.80-16.52)
FMU	11	4714	0.3	3.90	(0.77-19.66)
AMU	12	7378	0.2	2.14	(0.45-10.19)
Total	37	23916	0.1		
Multiparous women					
OU	13	7429	0.2	1	-
Home	34	11338	0.3	2.16	(0.85-5.51)
FMU	15	5714	0.3	2.40	(0.88-6.53)
AMU	7	7629	0.1	0.87	(0.22-3.41)
Total	69	32110	0.2		
Ventouse delivery	2364	56026		Interaction test p < 0.001	
Nulliparous women					
OU	866	7791	11.5	1	-
Home	241	4033	5.8	0.39	(0.28-0.56)
FMU	270	4714	5.4	0.42	(0.28-0.62)
AMU	570	7378	8.0	0.64	(0.43-0.94)
Total	1947	23916	10.8		
Multiparous women					
OU	250	7429	3.4	1	-
Home	52	11338	0.5	0.12	(0.07-0.21)
FMU	24	5714	0.4	0.11	(0.05-0.22)
AMU	91	7629	1.3	0.37	(0.22-0.62)
Total	417	32110	2.9		

1 Restricted to women included in the adjusted analysis

2 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks and gestation (completed weeks)

Table 51 continued: Maternal secondary outcomes for 'low risk' women without complicating conditions at the start of care in labour by parity and planned place of birth

	Events[1]	Births[1]	Weighted[1]	Adjusted[2]	
	n	n	%	OR	(99% CI)
Forceps delivery	2183	56026		Interaction test p < 0.001	
Nulliparous women					
OU	754	7791	9.8	1	-
Home	268	4033	6.3	0.54	(0.38-0.76)
FMU	276	4714	5.3	0.50	(0.34-0.74)
AMU	582	7378	7.8	0.78	(0.52-1.17)
Total	1880	23916	9.3		
Multiparous women					
OU	135	7429	1.9	1	-
Home	46	11338	0.4	0.20	(0.11-0.35)
FMU	42	5714	0.7	0.34	(0.19-0.61)
AMU	80	7629	1.1	0.58	(0.31-1.11)
Total	303	32110	1.6		
Intrapartum caesarean section	2580	56026		Interaction test p < 0.001	
Nulliparous women					
OU	994	7791	13.0	1	-
Home	300	4033	7.7	0.51	(0.37-0.71)
FMU	299	4714	6.1	0.46	(0.34-0.62)
AMU	520	7378	7.1	0.54	(0.39-0.73)
Total	2113	23916	11.9		
Multiparous women					
OU	294	7429	4.0	1	-
Home	65	11338	0.5	0.13	(0.08-0.22)
FMU	38	5714	0.6	0.16	(0.09-0.31)
AMU	70	7629	0.9	0.22	(0.12-0.41)
Total	467	32110	3.2		
'Normal birth'	43435	55849		Interaction test p < 0.001	
Nulliparous women					
OU	3645	7758	46.4	1	-
Home	2750	4014	69.3	3.10	(2.48-3.87)
FMU	3315	4706	71.1	2.94	(2.30-3.75)
AMU	4667	7372	62.9	1.99	(1.56-2.53)
Total	14377	23850	49.7		
Multiparous women					
OU	5860	7384	79.0	1	-
Home	10821	11297	95.9	6.52	(5.17-8.23)
FMU	5401	5703	94.7	5.00	(3.82-6.54)
AMU	6976	7615	91.1	2.71	(2.12-3.48)
Total	29058	31999	82.2		

1 Restricted to women included in the adjusted analysis

2 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks and gestation (completed weeks)

Table 51 (continued): Maternal secondary outcomes for 'low risk' women without complicating conditions at the start of care in labour by parity and planned place of birth

	Events[1]	Births[1]	Weighted[1]	Adjusted[2]	
	n	n	%	OR	(99% CI)
Third or fourth degree perineal trauma	1487	55935		Interaction test p = 0.121	
Nulliparous women					
OU	363	7773	4.6	1	-
Home	176	4023	4.4	0.86	(0.61-1.21)
FMU	190	4706	4.1	0.87	(0.61-1.24)
AMU	362	7369	4.9	1.07	(0.78-1.46)
Total	1091	23871	4.6		
Multiparous women					
OU	123	7424	1.7	1	-
Home	112	11325	1.0	0.59	(0.37-0.93)
FMU	50	5704	0.9	0.55	(0.32-0.95)
AMU	111	7611	1.5	0.89	(0.57-1.37)
Total	396	32064	1.6		
Blood transfusion	437	55689		Interaction test p = 0.552	
Nulliparous women					
OU	121	7755	1.6	1	-
Home	44	4014	1.1	0.76	(0.46-1.26)
FMU	36	4704	0.7	0.50	(0.31-0.82)
AMU	78	7321	1.2	0.78	(0.52-1.18)
Total	279	23794	1.5		
Multiparous women					
OU	48	7386	0.6	1	-
Home	44	11256	0.4	0.62	(0.33-1.19)
FMU	24	5678	0.3	0.48	(0.21-1.12)
AMU	42	7575	0.6	0.99	(0.55-1.77)
Total	158	31895	0.6		
Admission to a higher level of care	225	56063		Interaction test p = 0.595	
Nulliparous women					
OU	59	7795	0.8	1	-
Home	21	4034	0.5	0.61	(0.23-1.61)
FMU	13	4715	0.2	0.33	(0.11-0.94)
AMU	40	7389	1.0	1.26	(0.33-4.78)
Total	133	23933	0.8		
Multiparous women					
OU	24	7436	0.3	1	-
Home	31	11345	0.3	1.03	(0.38-2.82)
FMU	9	5714	0.1	0.38	(0.08-1.68)
AMU	28	7635	0.4	1.17	(0.47-2.91)
Total	92	32130	0.3		

1 Restricted to women included in the adjusted analysis

2 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks and gestation (completed weeks)

Table 52. Maternal interventions during labour for 'low risk' women without complicating conditions at the start of care in labour by parity and planned place of birth

	Events[1]	Births[1]	Weighted[1]	Adjusted[2]	
	n	n	%	OR	(99% CI)
Syntocinon augmentation	5758	55786		Interaction test p < 0.001	
Nulliparous women					
OU	2262	7692	29.5	1	-
Home	661	4019	15.7	0.40	(0.32-0.51)
FMU	673	4690	13.0	0.35	(0.27-0.47)
AMU	1258	7363	16.9	0.50	(0.39-0.63)
Total	4854	23764	27.1		
Multiparous women					
OU	547	7367	7.4	1	-
Home	110	11332	0.9	0.12	(0.08-0.17)
FMU	82	5702	1.2	0.16	(0.09-0.27)
AMU	165	7621	2.2	0.28	(0.19-0.41)
Total	904	32022	6.1		
Immersion in water for pain relief	16352	55800		Interaction test p < 0.001	
Nulliparous women					
OU	1068	7787	13.3	1	-
Home	2000	3969	50.4	5.60	(3.73-8.40)
FMU	2561	4707	53.7	6.97	(3.91-12.43)
AMU	2811	7379	38.5	4.15	(2.50-6.90)
Total	8440	23842	18.4		
Multiparous women					
OU	547	7427	7.1	1	-
Home	3121	11188	27.7	4.30	(2.80-6.59)
FMU	2405	5712	41.2	8.29	(4.55-15.11)
AMU	1839	7631	23.6	4.17	(2.45-7.10)
Total	7912	31958	11.8		
Epidural or spinal analgesia	8296	55903		Interaction test p < 0.001	
Nulliparous women					
OU	2838	7753	37.9	1	-
Home	868	4022	21.1	0.38	(0.29-0.49)
FMU	893	4698	18.1	0.36	(0.27-0.46)
AMU	1699	7367	23.6	0.51	(0.39-0.66)
Total	6298	23840	35.2		
Multiparous women					
OU	1061	7403	14.8	1	-
Home	320	11333	2.8	0.16	(0.12-0.20)
FMU	201	5705	3.4	0.20	(0.14-0.27)
AMU	416	7622	5.7	0.35	(0.26-0.47)
Total	1998	32063	12.5		

1 Restricted to women included in the adjusted analysis. 2 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks and gestation (completed weeks)

Table 52 continued: Maternal interventions during labour for 'low risk' women without complicating conditions at the start of care in labour by parity and planned place of birth

	Events[1]	Births[1]	Weighted[1]	Adjusted[2]	
	n	n	%	OR	(99% CI)
General anaesthetic	387	55722		Interaction test p = 0.343	
Nulliparous women					
OU	124	7684	1.6	1	-
Home	43	3985	1.0	0.61	(0.35-1.07)
FMU	37	4692	0.8	0.53	(0.28-1.00)
AMU	62	7347	0.9	0.57	(0.33-1.00)
Total	266	23708	1.4		
Multiparous women					
OU	53	7369	0.7	1	-
Home	26	11317	0.2	0.34	(0.16-0.72)
FMU	17	5704	0.3	0.36	(0.13-1.02)
AMU	25	7624	0.3	0.47	(0.24-0.92)
Total	121	32014	0.6		
No active management of the 3rd stage of labour	10504	55796		Interaction test p < 0.297	
Nulliparous women					
OU	478	7785	6.3	1	-
Home	1179	3966	30.1	6.25	(4.25-9.21)
FMU	983	4708	21.0	4.04	(2.41-6.80)
AMU	1054	7377	13.3	2.29	(1.41-3.72)
Total	3694	23836	8.1		
Multiparous women					
OU	471	7432	6.5	1	-
Home	3575	11184	32.3	6.94	(4.59-10.49)
FMU	1433	5712	24.0	4.70	(2.67-8.26)
AMU	1331	7632	15.7	2.69	(1.60-4.52)
Total	6810	31960	10.0		
Episiotomy	6241	55992		Interaction test p < 0.001	
Nulliparous women					
OU	2180	7783	28.0	1	-
Home	645	4026	15.3	0.41	(0.33-0.50)
FMU	762	4712	15.6	0.45	(0.34-0.60)
AMU	1573	7377	21.7	0.69	(0.54-0.87)
Total	5160	23898	26.6		
Multiparous women					
OU	553	7432	7.4	1	-
Home	161	11322	1.5	0.18	(0.13-0.24)
FMU	118	5712	2.2	0.27	(0.18-0.39)
AMU	249	7628	3.6	0.46	(0.34-0.62)
Total	1081	32094	6.3		

1 Restricted to women included in the adjusted analysis

2 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks and gestation (completed weeks)

Appendix 6 Sensitivity analysis: Restricted analysis for units/trusts with a response rate of at least 85%

74% of participating units and trusts included 85% or more of eligible women (Table 53). This sensitivity analysis was restricted to the 203 units and trusts that included 85% or more of eligible women.

Table 53. Proportion of units and trusts with a response rate >=85% by planned place of birth

	Response rate				Poor or missing denominator		Total
	<85%		>=85%				
	n	%	n	%	n	%	n
OU	11	31	24	67	1	3	36
Home	16	11	113	80	13	9	142
FMU	13	25	35	66	5	9	53
AMU	7	16	31	72	5	12	43
Total	47	17	203	74	24	9	274

Units/trusts that provided denominator data, which enabled a response rate to be calculated, included a higher proportion of women than units with 'poor or missing' denominator data. The 9% of units/trusts (n=24) with 'poor or missing' denominator data contributed only 3% of births (n=2587) to the study sample (Table 54).

Table 54. Proportion of women included by response rate and planned place of birth

	Response rate				Poor or missing denominator		Total
	<85%		>=85%				
	n	%	n	%	n	%	n
OU	8513	26	23230	72	514	2	32257
Home	1446	8	15883	87	940	5	18269
FMU	1479	13	9858	85	329	3	11666
AMU	3077	18	13701	78	804	5	17582
Total	14515	18	62672	79	2587	3	79774

The 203 units with a response rate of at least 85% also had higher return rates for the neonatal and maternal morbidity forms compared with all participating units and trusts (96% vs. 94% neonatal forms returned; 96% vs. 93% maternal forms returned, Table 55 and Table 56; cf. Table 10 and Table 11 in the main report).

Table 55. Neonatal morbidity form return rates for units/trusts with response rate of at least 85%

	Neonatal morbidity forms				
	Returned		Not returned		Total
	n	%	n	%	n
OU	1054	98	17	2	1071
Home	423	97	14	3	437
FMU	265	95	15	5	280
AMU	343	92	30	8	373
Total	2085	96	76	4	2161

Table 56. Maternal morbidity form return rates for units/trusts with response rate of at least 85%

	Maternal morbidity forms				
	Returned		Not returned		Total
	n	%	n	%	n
OU	578	98	10	2	588
Home	192	94	12	6	204
FMU	134	94	9	6	143
AMU	211	93	17	7	228
Total	1115	96	48	4	1163

The effect of planned place of birth on the primary outcome in this restricted subset of units/trusts with a response rate of at least 85% was consistent with the results of the primary analysis of all 'low risk' women.

The weighted event rates were similar to the primary analysis for both the all 'low risk' women analysis and the analysis of 'low risk' women without complicating conditions at the start of care in labour (Table 57, Table 58, and Table 59).

Overall for all 'low risk' women, there were no statistically significant differences in the odds of a primary outcome event by planned place of birth. For the restricted analysis of 'low risk' women without complicating conditions at the start of care in labour, there was an increase in the odds of a primary outcome event in the planned home birth group (adjusted OR 1.90, 95% CI 1.11 to 3.25, Table 57).

When stratified by parity, the apparent increased odds of a primary outcome event for nulliparous women in the planned home birth group remained in the analysis of all 'low risk' women (adjusted OR 2.18, 95% CI 1.27 to 3.76, Table 58) and the analysis of 'low risk' women without complicating conditions (adjusted OR 4.65, 95% CI 2.42-8.92, Table 59).

In this analysis restricted to centres with a response rate of at least 85%, there was an apparent increase in the odds of a primary outcome event for nulliparous 'low risk' women without complicating conditions in the planned FMU group (adjusted OR 2.29, 95% CI 1.17 to 4.47, Table 59).

Table 57. Primary outcome for babies of 'low risk' women by planned place of birth restricted to units/trusts with a response rate of ≥85%

	Events	Births	Weighted[1]		Unadjusted[1]		Unadjusted[1, 2]		Adjusted[1, 3]	
	n	n	n/1000	(95% CI)	OR	(95% CI)	OR	(95% CI)	OR	(95% CI)
Planned place of birth						n=51123		n=49886		n=49886
OU	62	14253	4.6	(3.3-6.4)	1	-	1	-	1	-
Home	67	14504	4.8	(3.7-6.1)	1.04	(0.68-1.59)	1.05	(0.69-1.60)	1.33	(0.84-2.10)
FMU	37	9475	4.1	(2.9-5.7)	0.89	(0.55-1.43)	0.91	(0.57-1.46)	1.09	(0.69-1.73)
AMU	44	12891	3.4	(2.4-4.7)	0.74	(0.46-1.18)	0.76	(0.48-1.21)	0.86	(0.56-1.31)
Total	210	51123	4.4	(3.3-5.9)						
Planned place of birth (restricted to women with no complicating conditions at the start of care in labour)										
						n=46116		n=45006		n=45006
OU	35	11505	3.0	(2.0-4.4)	1	-	1	-	1	-
Home	59	13620	4.5	(3.4-5.9)	1.51	(0.94-2.45)	1.58	(0.98-2.56)	1.90	(1.11-3.25)
FMU	31	8950	3.6	(2.5-5.1)	1.21	(0.72-2.06)	1.29	(0.77-2.18)	1.52	(0.91-2.52)
AMU	41	12041	3.1	(2.2-4.5)	1.05	(0.62-1.79)	1.13	(0.66-1.92)	1.25	(0.76-2.04)
Total	166	46116	3.1	(2.3-4.2)						

1 Weighted to reflect each unit's duration of participation, the sampling of OUs and take the clustered nature of the data into account.
2 Restricted to women included in the adjusted analysis.
3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index,
index of multiple deprivation score quintile, previous pregnancies >=24 weeks, and gestation (completed weeks).

Table 58. Primary outcome for babies of 'low risk' women by parity and planned place of birth restricted to units/trusts with response rate of at least 85%

	Events	Births	Weighted[1]		Unadjusted[1]		Unadjusted[1, 2]		Adjusted[1, 3]	
	n	n	n/1000	(95% CI)	OR	(95% CI)	OR	(95% CI)	OR	(95% CI)
Planned place of birth										
Nulliparous women						n=22604		n=22078		n=22078
OU	38	7740	5.3	(3.6-7.7)	1	-	1	-	1	-
Home	38	3983	10.6	(7.5-15.0)	2.01	(1.20-3.38)	2.04	(1.24-3.36)	2.18	(1.27-3.76)
FMU	22	4384	5.2	(3.4-8.0)	0.98	(0.55-1.76)	0.99	(0.56-1.74)	1.15	(0.66-2.02)
AMU	27	6497	4.0	(2.7-6.0)	0.75	(0.43-1.31)	0.77	(0.45-1.33)	0.87	(0.52-1.45)
Total	125	22604	5.3	(3.8-7.3)						
Multiparous women						n=28457		n=27808		n=27808
OU	24	6503	3.7	(2.4-5.8)	1	-	1	-	1	-
Home	29	10509	2.5	(1.8-3.6)	0.68	(0.38-1.20)	0.68	(0.38-1.22)	0.75	(0.41-1.36)
FMU	15	5077	3.1	(1.8-5.3)	0.84	(0.41-1.70)	0.88	(0.43-1.79)	0.99	(0.49-2.00)
AMU	17	6368	2.7	(1.5-5.1)	0.74	(0.34-1.59)	0.78	(0.36-1.69)	0.83	(0.39-1.74)
Total	85	28457	3.5	(2.4-5.1)						

Adjusted regression test of heterogeneity p-values: Home 0.005 ; FMU 0.72 ; AMU 0.92 ; Overall 0.02
1 Weighted to reflect each unit's duration of participation, the sampling of OUs and take the clustered nature of the data into account.
2 Restricted to women included in the adjusted analysis.
3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index,
index of multiple deprivation score quintile, previous pregnancies >=24 weeks, and gestation (completed weeks).

Table 59. Primary outcome for babies of 'low risk' women without complicating conditions at the start of labour care by parity and planned place of birth restricted to units/trusts with response rate of at least 85%

	Events	Births	Weighted[1]		Unadjusted[1]		Unadjusted[1, 2]		Adjusted[1, 3]	
	n	n	n/1000	(95% CI)	OR	(95% CI)	OR	(95% CI)	OR	(95% CI)
Planned place of birth (restricted to women with no complicating conditions at the start of care in labour)										
Nulliparous women						n=19577		n=19119		n=19119
OU	17	5947	2.8	(1.7-4.5)	1	-	1	-	1	-
Home	35	3611	10.8	(7.5-15.6)	3.88	(2.12-7.12)	4.10	(2.28-7.38)	4.65	(2.42-8.92)
FMU	20	4074	5.2	(3.3-8.3)	1.85	(0.95-3.63)	1.95	(1.01-3.75)	2.29	(1.17-4.47)
AMU	24	5945	3.4	(2.2-5.2)	1.21	(0.64-2.29)	1.29	(0.69-2.40)	1.47	(0.79-2.73)
Total	96	19577	3.2	(2.2-4.5)						
Multiparous women						n=26484		n=25887		n=25887
OU	18	5552	3.2	(1.8-5.5)	1	-	1	-	1	-
Home	24	9998	2.2	(1.5-3.2)	0.69	(0.35-1.36)	0.70	(0.35-1.39)	0.78	(0.40-1.54)
FMU	11	4864	2.3	(1.3-4.0)	0.73	(0.33-1.60)	0.78	(0.36-1.72)	0.89	(0.42-1.88)
AMU	17	6070	2.9	(1.5-5.3)	0.91	(0.39-2.09)	0.98	(0.43-2.27)	1.05	(0.47-2.37)
Total	70	26484	3.0	(1.9-4.8)						

Adjusted regression test of heterogeneity p-values: Home <0.001 ; FMU 0.07 ; AMU 0.53; Overall <0.001

1 Weighted to reflect each unit's duration of participation, the sampling of OUs and take the clustered nature of the data into account.

2 Restricted to women included in the adjusted analysis.

3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >=24 weeks, and gestation (completed weeks).

Appendix 7 Sensitivity analysis: propensity score analysis

In the 'low risk' group of women, a sensitivity analysis was carried out using propensity scores to examine in more detail the impact on the results of the differences in the characteristics of the women in the different groups. These analyses were carried out separately for each non-OU setting compared with the OU group.

We summarised the imbalance in baseline characteristics (maternal characteristics and individual complicating conditions identified at the start of care in labour) between the non-OU groups and OU group using standardised differences (Figure 20, Figure 21, and Figure 22). Categorical variables were collapsed into binary variables and standardised differences in proportions were calculated. For continuous variables, standardised differences in means were calculated. A standardised difference of more than 10% indicates serious imbalance.[42] There were a higher proportion of women with complicating conditions identified at the start of care in labour in the OU group compared with all other planned places of birth. In particular, a higher proportion of women in the OU group had prolonged rupture of membranes (for longer than 18 hours) and meconium stained liquor. There were also large differences in the socio-demographic characteristics of women who planned to give birth in an FMU or at home compared with the OU group. Women in the planned home and FMU groups were more likely to be White, have a fluent understanding of English, to live in a more socioeconomically advantaged area, to be older, and married or living with their partner. The most striking differences were in the age and parity of women in the home group compared with the women in the OU group: they tended to be older and more likely to have given birth previously.

For each non-OU/OU comparison, a propensity score was calculated for each woman which represents the probability that the woman would plan to give birth in the non-OU setting, based on her maternal characteristics and individual complicating conditions identified at the start of care in labour. The distribution of the propensity scores for the three non-OU/OU comparisons are presented in (Figure 23, Figure 24, and 0). For each figure, a low propensity score indicates a low propensity to plan birth in the non-OU setting. Conversely, a high propensity score indicates a high propensity to plan birth in the non-OU setting. Most of the women in the OU group had a low propensity to plan a home birth, and most of the women in the home group had a high propensity to plan a home birth. The distributions of propensity scores for the midwifery units were more similar to the OU group, particularly in the AMU group which reflects the similar characteristics of the women in the AMU and OU groups.

Figure 20. Covariate imbalance between planned home births and planned OU births

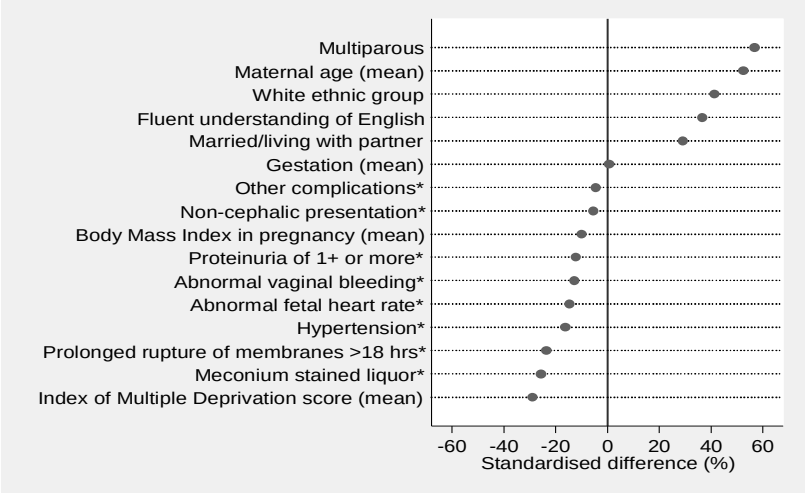


Figure 21. Covariate imbalance between planned AMU births and planned OU births

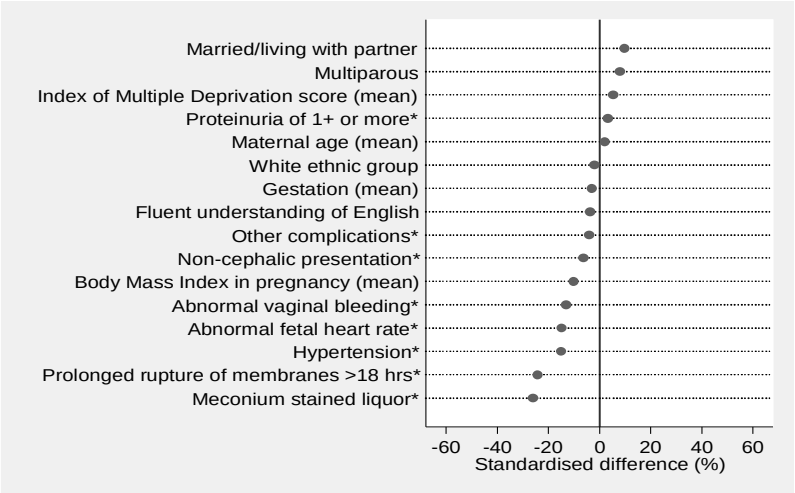
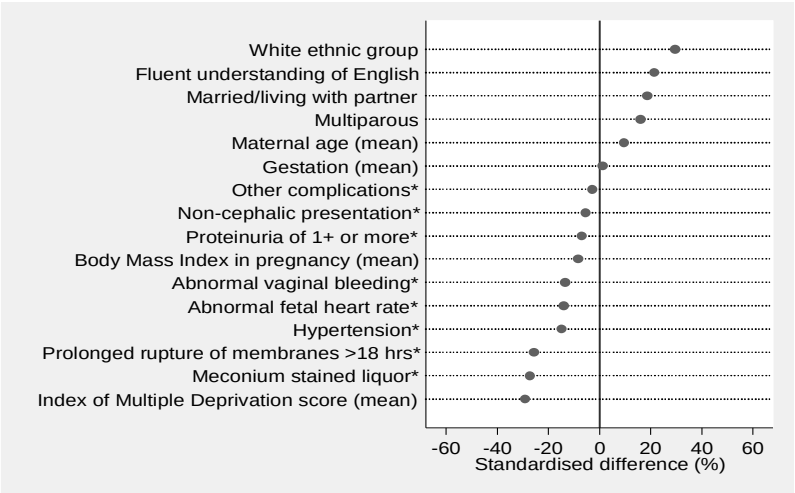


Figure 22. Covariate imbalance between planned FMU births and planned OU births



*

Figure 23. Distribution of propensity scores for planned home births and planned OU births

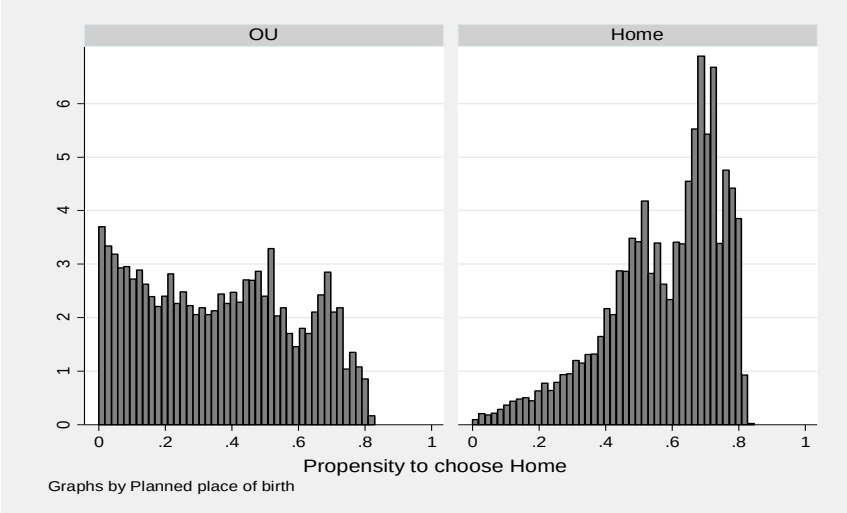
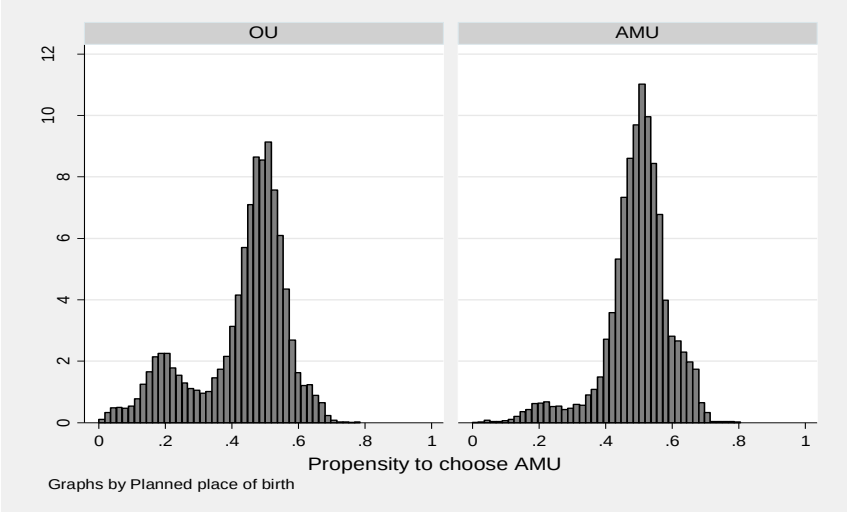
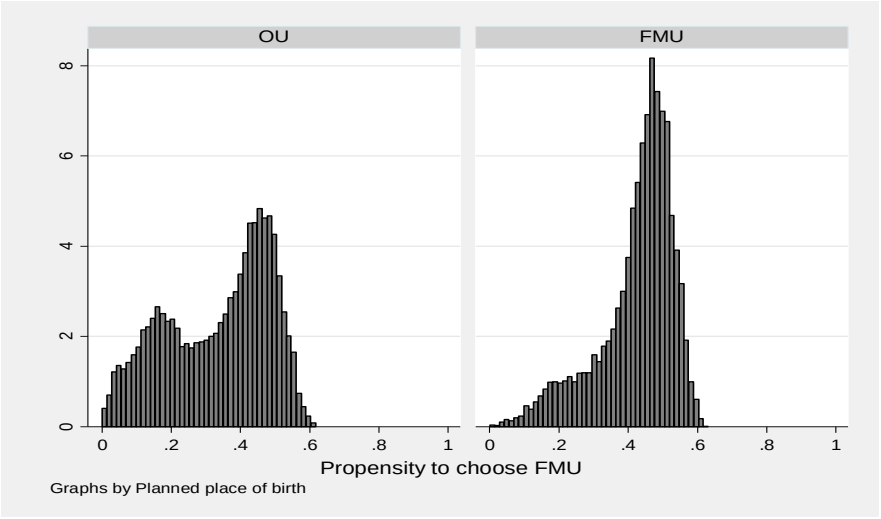


Figure 24. Distribution of propensity scores for AMU births and planned OU births



Complicating conditions identified at the start of care in labour

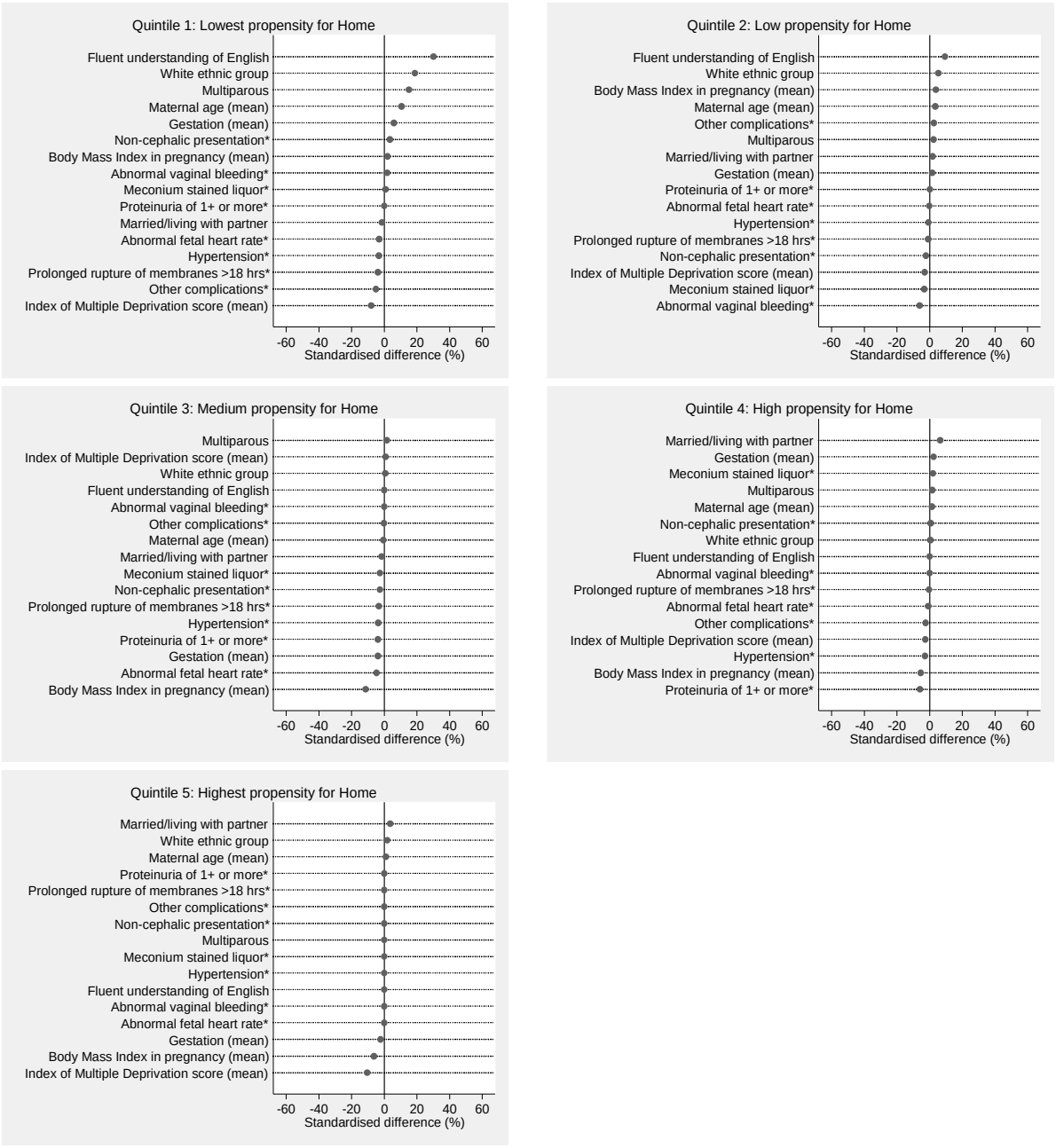
Figure 25. Distribution of propensity scores for FMU births and planned OU births



Women were divided into quintiles based on the rank of their propensity scores. The covariate imbalance was compared within each propensity score quintile (Figure 26, Figure 27, and Figure 28). Good balance was achieved in quintiles 2 to 5 for each comparison. Quintile 1, which contains women with the lowest propensity to plan birth in the non-OU setting, was still not well-balanced for some covariates after stratification by propensity score quintile. For planned home births, the remaining imbalance in quintile 1 was due to socio-demographic characteristics. For both types of midwifery unit, the remaining imbalance in quintile 1 was due to complicating conditions identified at the start of care in labour.

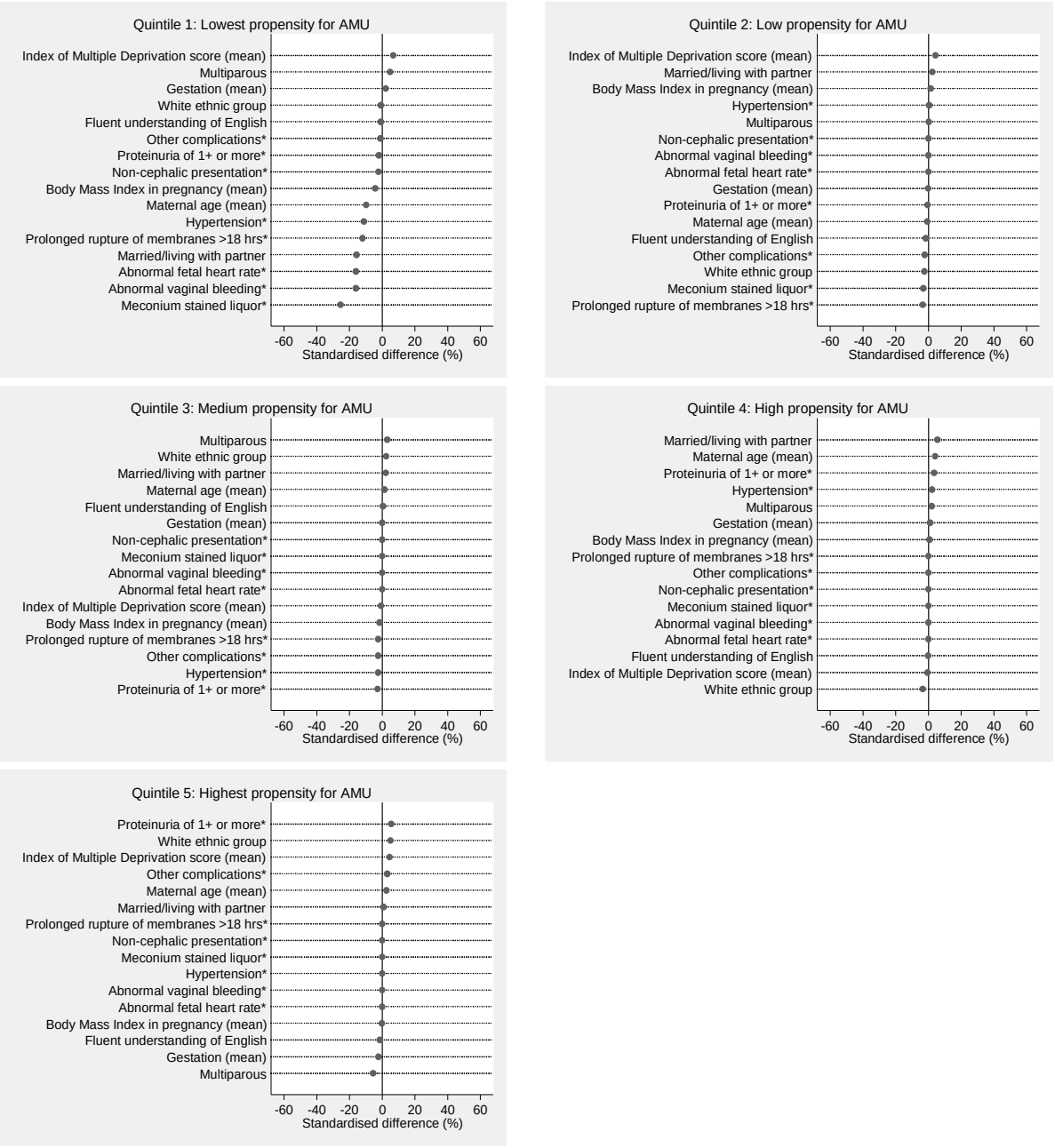
The analysis of the primary outcome was repeated within each propensity score quintile for each non-OU/OU comparison (0, Table 61, and Table 62). Unadjusted odds ratios are presented, as the numbers of events in each quintile were too small to perform a reliable adjusted analysis. The incidence of the primary outcome was lower for women whose characteristics were consistent with a high probability of planning birth in a non-OU setting. The quintile containing women with the lowest propensity to plan birth outside of an OU had the highest incidence of the primary outcome. This was observed for all planned places of birth, including OUs. There were no discernable patterns or trends evident in the quintile specific odds ratios. Tests for heterogeneity showed no evidence of a difference between the quintile specific odds ratios for each planned place of birth.

Figure 26. Covariate imbalance between planned home births and planned OU births within propensity score quintile



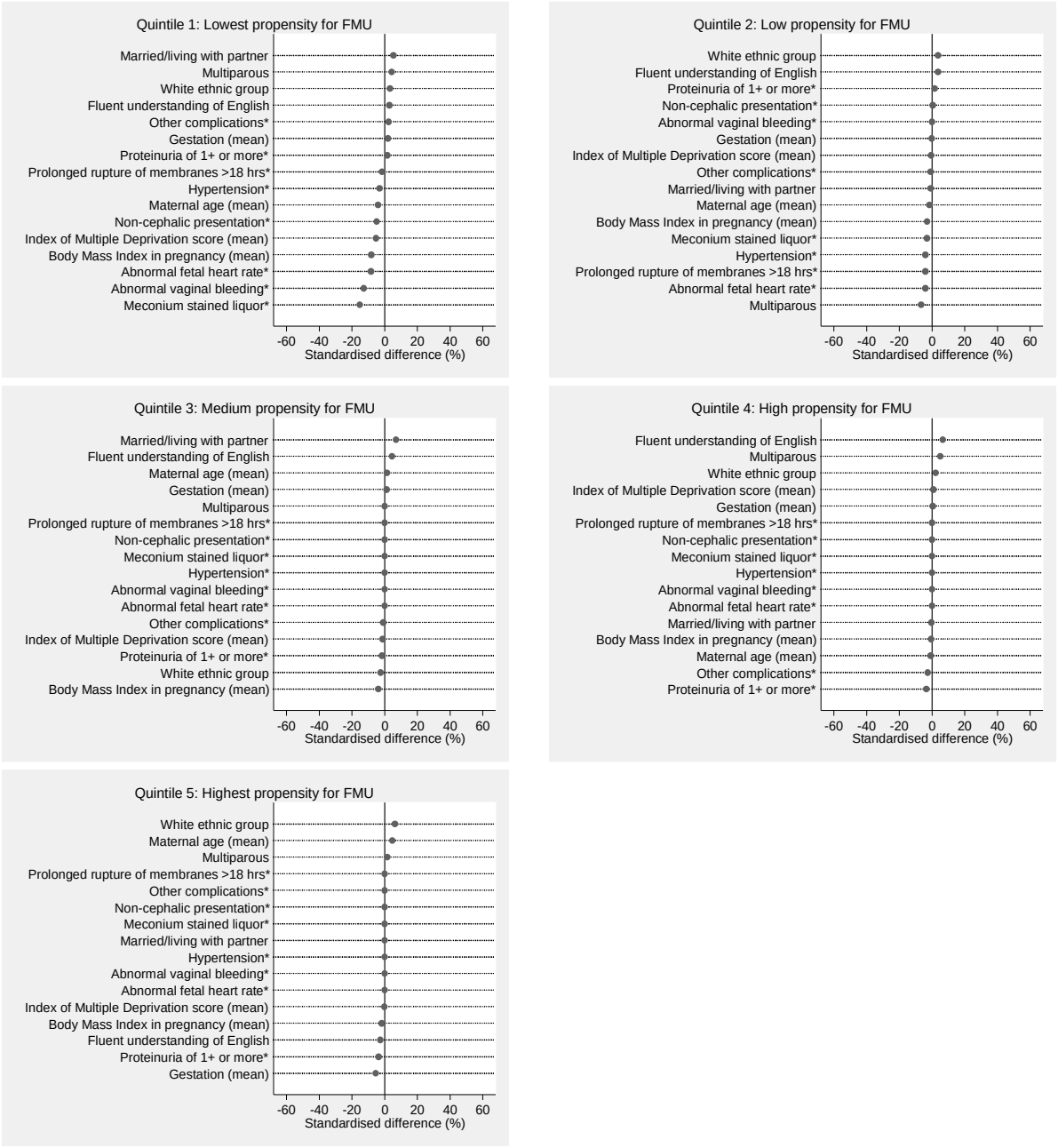
* *Complicating conditions identified at the start of care in labour*

Figure 27. Covariate imbalance between planned AMU and planned OU births within propensity score quintile



* *Complicating conditions identified at the start of care in labour.*

Figure 28. Covariate imbalance between planned FMU births and planned OU births within propensity score quintile



* *Complicating conditions identified at the start of care in labour.*

Table 60. Primary outcome for babies of 'low risk' women for planned home births compared with planned OU births by propensity score quintile

Propensity to plan birth at home		OU			Home			Unadjusted*
Propensity score quintile	median [range]	Events n	Births n	Incidence* n/1000	Events n	Births n	Incidence* n/1000	OR (95% CI)
1 Lowest	0.11 [0.00, 0.22]	37	6291	6.5	6	696	7.1	1.09 (0.42 to 2.83)
2 Low	0.34 [0.22, 0.43]	17	4734	3.9	12	2258	7.7	1.98 (0.77 to 5.09)
3 Medium	0.49 [0.43, 0.56]	17	3354	4.9	26	3604	5.9	1.22 (0.65 to 2.27)
4 High	0.64 [0.56, 0.69]	5	2595	1.7	13	4358	3.4	2.00 (0.74 to 5.42)
5 Highest	0.74 [0.69, 0.85]	3	1820	1.4	12	5149	1.9	1.34 (0.37 to 4.79)
Overall	0.49 [0.00, 0.85]	79	18,794	4.4	69	16,065	4.3	1.50 (0.99 to 2.27)[†]

** Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.*

[†] Overall OR, weighted and adjusted for quintile. Test of heterogeneity across quintiles

p value = 0.84 (Wald test).

Table 61. Primary outcome for babies of 'low risk' women for planned AMU births compared with planned OU births by propensity score quintile

Propensity to plan birth at an AMU		OU			AMU			Unadjusted*
Propensity score quintile	median [range]	Events n	Births n	Incidence* n/1000	Events n	Births n	Incidence* n/1000	OR (95% CI)
1 Lowest	0.24 [0.00, 0.40]	39	5245	8.4	11	1726	7.4	0.88 (0.35 to 2.18)
2 Low	0.44 [0.40, 0.47]	18	3851	4.4	15	3109	4.9	1.14 (0.53 to 2.46)
3 Medium	0.49 [0.47, 0.51]	7	3580	1.9	12	3378	3.2	1.72 (0.70 to 4.21)
4 High	0.53 [0.51, 0.55]	9	3327	2.9	8	3618	1.3	0.43 (0.13 to 1.39)
5 Highest	0.58 [0.55, 0.80]	6	2791	2.3	12	4171	3.8	1.68 (0.50 to 5.61)
Overall	0.49 [0.00, 0.80]	79	18,794	4.4	58	16,002	3.7	1.09 (0.69 to 1.72)[†]

** Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.*

[†] Overall OR, weighted and adjusted for quintile. Test of heterogeneity across quintiles

p value = 0.34 (Wald test).

Table 62. Primary outcome for babies of 'low risk' women for planned FMU births compared with planned OU births by propensity score quintile

Propensity to plan birth at an FMU		OU			FMU			Unadjusted*
Propensity score quintile	median [range]	Events n	Births n	Incidence* n/1000	Events n	Births n	Incidence* n/1000	OR (95% CI)
1 Lowest	0.14 [0.00, 0.22]	38	5169	8.0	8	789	9.3	1.17 (0.62 to 2.19)
2 Low	0.30 [0.22, 0.37]	14	4169	3.4	9	1791	5.5	1.61 (0.69 to 3.76)
3 Medium	0.41 [0.37, 0.44]	11	3566	3.5	6	2397	2.1	0.58 (0.22 to 1.52)
4 High	0.47 [0.44, 0.49]	12	3100	3.6	13	2844	3.9	1.09 (0.47 to 2.52)
5 Highest	0.52 [0.49, 0.62]	4	2790	1.2	5	3139	2.0	1.67 (0.44 to 6.40)
Overall	0.41 [0.00, 0.62]	79	18,794	4.4	41	10,960	3.6	1.14 (0.73 to 1.77)[†]

** Weighted to reflect each unit's duration of participation, the sampling of OUs and to take the clustered nature of the data into account.*

[†] Overall OR, weighted and adjusted for quintile. Test of heterogeneity across quintiles

p value = 0.31 (Wald test).

Addendum

The Birthplace in England Research Programme combines the Evaluation of Maternity Units in England (EMU) study funded in 2006 by the National Institute for Health Research Service Delivery and Organisation (NIHR SDO) programme, and the Birth at Home study in England, funded in 2007 by the Department of Health Policy Research Programme (DH PRP). This document is part of a suite of reports representing the combined output from this jointly funded research. Should you have any queries please contact Sdoedit@southampton.ac.uk

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