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Perinatal and maternal outcomes in planned home and obstetric unit births in women at 'higher risk' of complications: secondary analysis of the Birthplace national prospective cohort study

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Objective To explore and compare perinatal and maternal outcomes in women at 'higher risk' of complications planning home versus obstetric unit (OU) birth.

Design Prospective cohort study.

Setting OUs and planned home births in England.

Population 8180 'higher risk' women in the Birthplace cohort.

Methods We used Poisson regression to calculate relative risks adjusted for maternal characteristics. Sensitivity analyses explored possible effects of differences in risk between groups and alternative outcome measures.

Main outcome measures Composite perinatal outcome measure encompassing 'intrapartum related mortality and morbidity' (intrapartum stillbirth, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle) and neonatal admission within 48 hours for more than 48 hours. Two composite maternal outcome measures capturing intrapartum interventions/adverse maternal outcomes and straightforward birth.

Results The risk of 'intrapartum related mortality and morbidity' or neonatal admission for more than 48 hours was lower in planned home births than planned OU births [adjusted relative risks (RR) 0.50, 95% CI 0.31–0.81]. Adjustment for clinical risk factors did not materially affect this finding. The direction of effect was reversed for the more restricted outcome measure 'intrapartum related mortality and morbidity' (RR adjusted for parity 1.92, 95% CI 0.97–3.80). Maternal interventions were lower in planned home births.

Conclusions The babies of 'higher risk' women who plan birth in an OU appear more likely to be admitted to neonatal care than those whose mothers plan birth at home, but it is unclear if this reflects a real difference in morbidity. Rates of intrapartum related morbidity and mortality did not differ statistically significantly between settings at the 5% level but a larger study would be required to rule out a clinically important difference between the groups.

Keywords Adverse maternal outcomes, adverse perinatal outcomes, home birth, intrapartum interventions, obstetric risk factors, obstetric unit, planned place of birth, spontaneous labour, straightforward vaginal birth.

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Introduction

National guidance on intrapartum care in England and Wales recommends that women with certain pre-existing medical or obstetric conditions should be advised that these conditions are associated with an increased risk to the mother or baby during labour or shortly after birth and that care in an obstetric unit (OU) would be expected to reduce the risk.^{1,2}

Most 'higher risk' women plan birth in an OU, but the Birthplace study found that around 7% of women who

planned home birth, 4% of those who planned birth in an alongside midwifery unit (AMU), and 3% planning birth in a freestanding midwifery unit (FMU) had known risk factors.³

For 'low risk' women available evidence suggests that women who plan birth at home or in a midwifery unit have a higher likelihood of a normal birth with less intervention and that, apart from nulliparous women planning birth at home, outcomes for their babies are comparable with those for women planning OU birth.^{3,4} For some groups of 'higher risk' women, such as those with diabetes, there is good evidence that maternal or neonatal outcomes can be improved through monitoring, treatment or other interventions not normally provided outside an OU. 5 However, the guidance on conditions indicating birth in an OU was based on consensus rather than high-quality evidence² and for many 'higher risk' conditions, the risks and benefits of planning birth in a non-OU setting are not well documented. The aim of this study was to explore the clinical characteristics and outcomes of 'higher risk' women in the Birthplace cohort. The sample of 'higher risk' women planning birth in a midwifery unit was small, so the study focused on planned home birth versus planned OU birth. The primary objective was to evaluate the risk of adverse perinatal outcomes in planned home births in 'higher risk' women compared with planned OU births. Secondary objectives were: to describe and compare the clinical characteristics of 'higher risk' women in these two settings; to compare perinatal outcomes in 'higher risk' women planning home birth with outcomes in 'low risk' women planning home birth; and to compare maternal interventions and outcomes in 'higher risk' women planning birth at home and in OUs.

Methods

Setting and participants

This study used data from the Birthplace in England national prospective cohort study.3,4 The Birthplace study collected data on 79 774 'low' and 'higher risk' births between April 2008 and April 2010 from 142 NHS trusts (97% of all trusts providing home birth services across England), 53 FMUs, 43 AMUs and a stratified random sample of 36 OUs. Women were eligible for inclusion in the Birthplace cohort if they planned a vaginal birth and received some labour care from an NHS midwife during established labour³ in their planned birth settings. Women who had an elective caesarean section (CS) or CS before the onset of labour, presented in preterm labour (<37 weeks' gestation), had a multiple pregnancy, had an unplanned home birth, or who were 'unbooked' (received no antenatal care) were excluded. Stillbirths occurring before the start of care in labour were also excluded. The study had a high response rate and low levels of missing data.3,4

Planned place of birth was based on the woman's intended place of birth at the start of care in labour regardless of whether she was transferred during labour or immediately after the birth. The study population of 'higher risk' women consisted of women planning birth at home or in an OU in the Birthplace cohort who according to clinical guidelines in place at the time of the study had risk factors 'indicating increased risk suggesting planned birth in an obstetric unit' (see guideline for full list²). That is, 'higher risk' women were those with specified medical or obstetric risk factors known prior to the onset of labour² or with post-term pregnancies (gestational age 42⁺¹ weeks or more). Women were defined as 'low risk' if they were giving birth at term and were not known to have any of these pre-existing risk factors. We excluded women with planned induction of labour because this was almost exclusively carried out in OUs so there were no comparable 'higher risk' women in the home birth group. Records were excluded from the analyses reported here if parity was unknown.

Study data

As described elsewhere, 3,4,6 maternal characteristics and medical or obstetric risk factors known prior to the onset of labour were extracted from the woman's medical records by the midwife attending the birth. Risk factors were recorded using a checklist of risk factors listed on the data collection form. 'Complicating conditions' noted by the midwife at the start of care in labour (for example, prolonged rupture of membranes and meconium-stained liquor), intrapartum interventions, and adverse maternal and perinatal outcomes were recorded by the attending midwife using a data collection form started during labour and completed on or after the fifth postnatal day. Additional data on babies admitted to a neonatal unit were collected in a follow-up survey. The methods and data are described more fully elsewhere. 3,4

All analyses comparing outcomes in 'higher risk' women were conducted in the full group of 'higher risk' women (referred to as 'population 1') and in the restricted population of 'higher risk' women without 'complicating conditions' identified at the start of care in labour ('population 2'). For analyses of planned home births in which we compared outcomes for 'higher risk' and 'low risk' women planning home birth, we used 'low risk' women planning home birth as the reference group.

Outcome measures

The main study outcome was a composite encompassing both the adverse perinatal outcomes included in the original Birthplace primary outcome ('intrapartum composite' defined as any of: stillbirth after the start of care in labour, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured

humerus or clavicle) and admission to a neonatal unit within 48 hours of birth for more than 48 hours. A minimum length of stay of 48 hours was used to exclude short admissions for more minor problems, e.g. transient respiratory problems associated with CS, and those where a lower threshold of admission might apply due to onsite availability of neonatal care. Duration of neonatal unit admission was not directly recorded in Birthplace and had to be derived from a number of variables that included date of admission and discharge, number of days at 'intensive', high dependency', 'special' and 'normal' level care and free text notes. In most cases, the duration of admission was unambiguously classifiable as more or less than 48 hours. In borderline cases, two reviewers blinded to planned place of birth independently reviewed all available data (including free text) to determine whether the admission was for more than 48 hours.

For comparability with previous analyses, we also considered the original Birthplace composite primary outcome ('intrapartum composite' defined above), which was designed to capture the adverse perinatal outcomes that may be related to the quality of intrapartum care.^{3,4}

We considered two composite maternal outcomes. The first, designed to capture intrapartum interventions and adverse maternal outcomes requiring obstetric care, was defined as one or more of: augmentation, instrumental delivery, intrapartum CS, general anaesthesia, maternal blood transfusion, 3rd/4th degree perineal tear, maternal admission for higher level care. The second composite measure ('straightforward vaginal birth') aimed to capture birth without complications that might affect future pregnancies and was defined as birth without intrapartum CS, instrumental delivery, 3rd/4th degree perineal trauma or blood transfusion.

Statistical analysis

All analyses were conducted separately by parity. We tested for interactions between planned place of birth and parity using the Wald test and where we did not find a significant interaction, we carried out a pooled analysis for nulliparous and parous women combined.

Robust variance estimation was used to allow for the clustered nature of the data and, as described elsewhere, ^{3,4} probability weights were incorporated to account for differences in the probability of a woman being selected for inclusion in the study arising from differences in each unit/ trust's period of participation and the stratum-specific probabilities of selection of OUs.

For all outcomes we calculated the weighted event rate with 95% confidence intervals (CIs) and used log Poisson regression with robust standard errors⁷ to calculate relative risks (RRs) and confidence intervals and adjust for maternal characteristics [maternal age, ethnicity, marital status,

body mass index (BMI), index of multiple deprivation, gestational age, and parity where appropriate, see Table S1 for categorisation]. Adjusted relative risks were not calculated where the number of events was too small to perform a reliable adjusted analysis.

The main analyses were conducted in the whole study population ('population 1'). Additionally, because previous analyses had shown that women in the OU group were more likely to have 'complicating conditions' at the start of care in labour³ we repeated the main analyses in the restricted population of women without complicating conditions at the start of care in labour ('population 2').

Finally, because the main analyses only controlled for differences in maternal characteristics and not for possible differences in risk, we conducted sensitivity analyses of the 'main composite' outcome in which we frequency 'matched' women in the OU and home groups on individual risk factor. Matching was only feasible on a single 'risk' variable so the sensitivity analyses were conducted in women without 'complicating conditions' at the start of care in labour and with only one risk factor, excluding women with 'other' medical or obstetric risk factors ('population 3'). Women with 'other' risk factors were excluded, as these categories included diverse conditions that were not necessarily comparable in the two settings.

Sensitivity analyses were conducted as follows. First, we repeated the analysis of the 'main composite' in population 3 and compared the findings with the main analyses to see to what extent progressively restricting the populations had an effect on the estimated relative risks. Secondly, we used logistic regression to conduct a risk-adjusted analysis in population 3. Prior to conducting the risk-adjusted analyses, we used chi-squared automatic interaction detection (CHAID)⁸ to explore whether there were significant interactions between maternal characteristics (age, parity, BMI) and risk factors that needed to be incorporated in the matching. This identified that parity and level of obesity varied by setting in parous women with BMI >35 kg/m² and that parity varied by setting in parous women with a previous CS. We therefore created more detailed matching criteria (see Table S2) for parous women with either of these two risk factors to reflect these interactions.

We planned to use conditional logistic regression to carry out a matched analysis but found that this method did not enable us to apply weights. However, exploratory analyses comparing unconditional and conditional models indicated that conditional and unconditional models yielded similar results. For comparability with the main weighted analyses we therefore used weighted unconditional logistic regression for the risk-adjusted sensitivity analysis. Because the outcome of interest is uncommon, odds ratios (ORs) and relative risks are similar.

We conducted an additional *post hoc* sensitivity analysis to explore whether the cut-off of more than 48 hours length of stay used in our main composite outcome measure affected the findings. For this we used a 'modified composite' encompassing the 'intrapartum composite' (as before) and admission to a neonatal unit within 48 hours of birth for more than 4 days.

CHAID analysis was performed using SPSS version 20.0.9 All other analyses were carried out using STATA version 13.¹⁰ We assessed statistical significance at the 5% level.

In the results which follow we first describe the characteristics of the study sample of 'higher risk' women. We then present results of our main analyses comparing adverse perinatal outcomes in 'higher risk' women planning home birth with those planning OU birth, and in 'low risk' and 'higher risk' women planning home birth. These are followed by results comparing interventions and maternal outcomes in 'higher risk' women in both settings. Finally, we describe results of our series of sensitivity analyses using the 'main composite' outcome.

Results

The 'higher risk' study population consisted of 8180 eligible 'higher risk' women: 6691 planned OU births and 1489 planned home births (see Figure S1 for study inclusion flow chart). For analyses comparing outcomes in 'higher risk' and 'low risk' home births, the 'low risk' group consisted of 16 619 'low risk' women planning home birth (Figure S2).

Maternal and clinical characteristics of the study sample of 'higher risk' women

Women in the planned home birth group were more likely to be older, white, married/living with partner and living in less deprived areas than were women in the planned OU group. Women in the planned home birth group were also more likely to be parous (81.0% versus 62.5%) and to have had more than one previous pregnancy. The proportion of women who gave birth at 42 weeks' gestation or more was higher in the planned home birth group (Table 1).

The proportion of 'higher risk' women with multiple risk factors and the proportion with a medical (as opposed to obstetric) risk factor was higher in the planned OU group. The prevalence of obstetric or fetal risk factors was broadly similar in 'higher risk' women in the two settings (Table 2).

The distribution of individual risk factors differed between birth settings and by parity (see Table 2 for the most prevalent risk factors, Table S3 for full details). In nulliparous women, BMI >35 kg/m² was a common risk factor in both settings; post-term pregnancy was more prevalent in the planned home birth group, and pre-eclampsia or pregnancy-induced hypertension in the current preg-

nancy and known carriage of group B streptococcus (GBS) were both more common in the planned OU group. In parous women, more common risk factors in both settings included BMI >35 kg/m², previous CS, post-term pregnancy and known carriage of GBS; BMI >35 kg/m² and post-term pregnancy were more common in the planned home birth group, while previous CS and known carriage of GBS were more common in the planned OU group.

The proportion of the women who had 'complicating conditions' noted at the start of care in labour was higher in the planned OU group (38.4% versus 13.0% in nulliparous women and 22.6% versus 8.7% in parous women) and the proportion of women with multiple 'complicating conditions' was also higher in the planned OU group (10.8% versus 2.9% in nulliparous women and 3.5% versus 0.5% in parous women). Table S4 shows the prevalence of 'complicating conditions' in each planned birth setting.

Transfers were more common in nulliparous women: 39% of the nulliparous women who planned home birth transferred to an OU before birth compared with 14% of parous women (weighted percentages). More detailed analyses of transfers are reported elsewhere.¹¹

Adverse perinatal outcomes

Planned home birth versus planned OU birth in 'higher risk' women – 'intrapartum composite' outcome

In both nulliparous and parous women the proportion of births with an adverse perinatal outcome as measured by the more restrictive of our two perinatal outcome measures (the 'intrapartum composite') was higher in planned home births (Table 3), but the number of events was small (n=41) and the difference was not statistically significant (RR adjusted for parity 1.92, 95% CI 0.97–3.80). Findings were similar when the analysis was restricted to women without 'complicating conditions' at the start of care in labour (Table 3).

Planned home birth versus planned OU birth in 'higher risk' women – 'main composite' outcome

When the measure of adverse perinatal outcome was extended by including neonatal unit admissions for more than 48 hours ('main composite'), the number of adverse outcomes increased to 240: 41 of these were events included in the 'intrapartum composite' and 199 involved neonatal unit admissions for more than 48 hours for other reasons. In the latter group, hypoglycaemia and/or sepsis or suspected sepsis were mentioned as reasons for admission in 50% of admissions where a reason was available (n = 188, data not shown). The composition of adverse outcomes differed by setting. In planned OU births, events included in the 'intrapartum composite' constituted 12.4% of the 'main composite' outcomes (29 of 215 events), with neonatal unit

Table 1. Characteristics of 'higher risk' women and their babies by planned place of birth

| | | Nullip | arous | | Parous | | | | |
|--------------------------------|------------|--------|-------|------|----------|------|----------|------|--|
| | 0 | U | Но | ome | 0 | U | Но | me | |
| | n = 2 | 2524 | n = | 288 | n = 4167 | | n = 1201 | | |
| | n | %* | n | %* | n | %* | n | %* | |
| Maternal age, years | | | | | | | | | |
| Under 20 | 279 | 11.0 | 7 | 3.1 | 78 | 1.7 | 6 | 0.5 | |
| 20–24 | 645 | 25.2 | 33 | 11.4 | 650 | 15.1 | 105 | 8.7 | |
| 25–29 | 694 | 27.4 | 75 | 26.3 | 1146 | 27.2 | 270 | 22.2 | |
| 30–34 | 588 | 23.7 | 106 | 37.2 | 1220 | 29.5 | 374 | 31.5 | |
| 35–39 | 262 | 10.6 | 58 | 19.3 | 856 | 21.1 | 346 | 28.8 | |
| 40+ | 51 | 2.0 | 9 | 2.7 | 211 | 5.4 | 100 | 8.2 | |
| Missing | 5 | 2.0 | 0 | 2.7 | 6 | 5.4 | 0 | 0.2 | |
| Ethnic group | J | | O | | O | | O | | |
| White | 2099 | 81.7 | 275 | 93.2 | 3205 | 74.9 | 1124 | 93.4 | |
| Non-white | 423 | | | | | | | | |
| | | 18.3 | 13 | 6.8 | 956 | 25.1 | 76 | 6.6 | |
| Missing | 2 | | 0 | | 6 | | 1 | | |
| Understanding of English | 2222 | 02.2 | 205 | 00.6 | 2764 | 00.3 | 4404 | 00.4 | |
| Fluent | 2323 | 92.2 | 286 | 99.6 | 3764 | 90.3 | 1194 | 99.4 | |
| Not fluent | 189 | 7.8 | 1 | 0.4 | 358 | 9.7 | 7 | 0.6 | |
| Missing | 12 | | 1 | | 45 | | 0 | | |
| Marital/Partner status | | | | | | | | | |
| Married/Living together | 2077 | 82.7 | 270 | 95.0 | 3731 | 90.1 | 1139 | 95.6 | |
| Single/Unsupported by partner | 413 | 17.3 | 16 | 5.0 | 376 | 9.9 | 53 | 4.4 | |
| Missing | 34 | | 2 | | 60 | | 9 | | |
| Body mass index (kg/m²) | | | | | | | | | |
| Not recorded | 325 | 13.3 | 43 | 13.9 | 540 | 13.6 | 161 | 12.8 | |
| <18.5 | 74 | 2.9 | 3 | 0.8 | 80 | 1.9 | 26 | 2.0 | |
| 18.5–24.9 | 847 | 33.9 | 114 | 39.3 | 1335 | 31.8 | 387 | 32.8 | |
| 25.0–29.9 | 485 | 18.7 | 43 | 14.9 | 896 | 21.8 | 217 | 17.5 | |
| 30.0–34.9 | 213 | 8.3 | 13 | 6.1 | 442 | 10.6 | 84 | 7.9 | |
| 35.0–39.9 | 368 | 14.7 | 51 | 18.5 | 542 | 13.0 | 242 | 20.3 | |
| 40.0+ | 204 | 8.2 | 20 | 6.6 | 324 | 7.4 | 81 | 6.7 | |
| Missing | 8 | | 1 | | 8 | | 3 | | |
| IMD quintiles | | | | | | | | | |
| 1st Least deprived | 383 | 15.0 | 54 | 21.5 | 633 | 14.9 | 253 | 21.5 | |
| 2nd | 425 | 16.5 | 64 | 21.8 | 680 | 16.0 | 246 | 20.1 | |
| 3rd | 465 | 18.1 | 65 | 21.2 | 718 | 16.9 | 220 | 18.2 | |
| 4th | 574 | 22.9 | 63 | 23.5 | 830 | 19.7 | 243 | 20.4 | |
| 5th Most deprived | 651 | 27.5 | 37 | 12.1 | 1266 | 32.6 | 231 | 19.8 | |
| Missing | 26 | | 5 | | 40 | | 8 | | |
| Previous pregnancies ≥24 compl | eted weeks | | | | | | | | |
| 1 previous | _ | _ | _ | _ | 2384 | 56.8 | 562 | 45.8 | |
| 2 previous | _ | _ | _ | _ | 1032 | 24.8 | 349 | 29.4 | |
| 3+ previous | _ | _ | _ | _ | 751 | 18.4 | 290 | 24.8 | |
| Missing | _ | | _ | | 0 | | 0 | | |
| Gestation (completed weeks) | | | | | - J | | _ | | |
| 37 | 159 | 6.4 | 5 | 1.7 | 265 | 6.5 | 37 | 2.9 | |
| 38 | 352 | 14.0 | 20 | 6.3 | 614 | 14.4 | 124 | 10.9 | |
| 39 | 553 | 21.8 | 59 | 20.3 | 1012 | 24.6 | 247 | 19.6 | |
| 40 | 715 | 28.3 | 73 | 25.6 | 1337 | 32.3 | 436 | 37.1 | |
| 41 | 516 | 20.2 | 47 | 17.7 | 761 | 18.4 | 225 | 19.5 | |
| 42 | | 8.7 | 80 | | | | | | |
| 42 | 211 | 0.7 | 00 | 27.5 | 155 | 3.6 | 113 | 8.7 | |

Table 1. (Continued)

| | | Nullip | arous | | | Parous | | | | |
|-------------------------|-------|----------------|-------|--------------|------|----------|------|----------|--|--|
| | 0 | OU n = 2524 | | Home n = 288 | | U | Home | | | |
| | n = 2 | | | | | n = 4167 | | n = 1201 | | |
| | n | %* | n | %* | n | %* | n | %* | | |
| 43–44 ⁺⁰ day | 14 | 0.6 | 3 | 0.9 | 8 | 0.2 | 15 | 1.3 | | |
| Missing | 4 | | 1 | | 15 | | 4 | | | |
| Birthweight (g) | | | | | | | | | | |
| <2500 | 96 | 3.9 | 3 | 1.1 | 88 | 2.2 | 13 | 1.0 | | |
| 2500–2999 | 449 | 17.5 | 32 | 9.7 | 628 | 15.0 | 97 | 8.5 | | |
| 3000–3499 | 936 | 37.8 | 101 | 34.8 | 1548 | 37.3 | 362 | 30.9 | | |
| 3500–3999 | 757 | 29.8 | 106 | 40.0 | 1306 | 31.2 | 431 | 35.2 | | |
| 4000–4499 | 239 | 9.6 | 43 | 13.5 | 490 | 11.8 | 243 | 20.2 | | |
| ≥4500 | 42 | 1.5 | 3 | 0.9 | 103 | 2.5 | 49 | 4.2 | | |
| Missing | 5 | | 0 | | 4 | | 6 | | | |

^{*}Probability weights are incorporated to account for differences in the probability of a woman being selected for inclusion in the study arising from differences in each unit/trust's period of participation and the stratum-specific probabilities of selection of OUs.

admissions for more than 48 hours for other reasons accounting for the vast majority (87.6%) of events. In contrast, among planned home births the 'intrapartum composite' outcomes constituted 46.7% of the 'main composite' outcomes (12 of 25 events), and neonatal unit admissions for more than 48 hours for other reasons accounted for 53.3% of events (Table S5).

In both nulliparous and parous 'higher risk' women, the risk of an adverse perinatal outcome ('main composite') was lower in planned home births than in planned OU births (nulliparous women: 27.7 per 1000 planned home births versus 46.0 per 1000 planned OU births; parous women: 12.3 per 1000 planned home births versus 26.8 per 1000 planned OU births). Absolute event rates were higher in nulliparous women but there was no evidence that the relative decrease in the risk of an adverse event ('main composite') in planned home births differed by parity. Overall, the risk of the 'main composite' outcome was significantly lower in planned home births than in planned OU births (adjusted RR 0.50, 95% CI 0.31-0.81) (Table 4). A similar pattern was observed when the analysis was restricted to 'higher risk' women without 'complicating conditions', indicating that the risk of neonatal unit admission was higher in planned OU births even in the absence of complications such as prolonged rupture of membranes and meconium staining.

'Higher risk' versus 'low risk' women planning birth at home – 'main composite' outcome

In planned home births, the absolute risk of an adverse perinatal outcome ('main composite') was significantly higher in 'higher risk' women than in 'low risk' women planning birth in the same setting (adjusted RR 1.89, 95% CI 1.23–2.90, Table 5). Adjusted relative risks did not differ significantly by parity. The excess risk in 'higher risk' versus 'low risk' planned home births was not statistically significant when the analysis was restricted to women without 'complicating conditions' at the start of care in labour (adjusted RR 1.66, 95% CI 0.95–2.91).

Interventions and maternal outcomes

Compared with planned OU birth, planned home birth was associated with a significantly lower risk of intrapartum interventions and adverse maternal outcomes requiring obstetric care in both nulliparous and parous 'higher risk' women and a significantly higher probability of straightforward vaginal birth in both nulliparous and parous 'higher risk' women (Table 6).

Adverse perinatal outcomes - sensitivity analyses

Restricted analyses and controlling for differences in risk Restricting the analyses of the 'main composite' to women without 'complicating conditions' ('population 2', Table 4) and to women without 'complicating conditions' and with only one specified risk factor ('population 3', Table S6) did not reveal any clear differences from the unrestricted analysis (adjusted RR 0.50, 0.42 and 0.48 in populations 1–3, respectively). Adjustment for maternal characteristics and controlling for differences in risk did not materially affect the risk of the 'main composite' outcome (Table S7).

Table 2. Most common medical and obstetric risk factors known prior to the onset of labour in 'higher risk' women by planned place of birth

| | | Nullip | arous | | | Par | ous | |
|--|----------|--------|-------|-------|----------|-------|----------|-------|
| | | υ | Н | ome | | OU | | ome |
| | n = 2524 | | n = | = 288 | n = 4167 | | n = 1201 | |
| | n | %* | n | %* | n | %* | n | %* |
| Medical condition** | | | | | | | | |
| Confirmed cardiac disease | 49 | 2.00 | 5 | 1.54 | 44 | 1.05 | 10 | 0.75 |
| Hypertensive disorders | 225 | 8.59 | 7 | 2.17 | 150 | 3.50 | 16 | 1.26 |
| Asthma*** | 64 | 2.40 | 9 | 3.55 | 50 | 1.19 | 26 | 2.40 |
| Group B strep*** | 337 | 13.07 | 22 | 7.43 | 495 | 11.95 | 81 | 6.17 |
| Hyperthyroidism | 45 | 1.72 | 12 | 4.14 | 69 | 1.63 | 35 | 2.87 |
| Diabetes | 89 | 3.62 | 1 | 0.27 | 95 | 2.19 | 4 | 0.32 |
| Epilepsy | 60 | 2.27 | 3 | 0.67 | 81 | 1.80 | 24 | 1.96 |
| 'Other' medical**** | 78 | 3.10 | 20 | 7.84 | 76 | 1.73 | 55 | 4.30 |
| Any medical | 1102 | 43.29 | 108 | 37.93 | 1273 | 30.21 | 310 | 24.81 |
| Obstetric or fetal factors** | | | | | | | | |
| Complications in previous pregnancies | | | | | | | | |
| PPH with treatment/ transfusion | 0 | _ | 0 | _ | 179 | 4.43 | 61 | 4.86 |
| Retained placenta*** | 0 | _ | 0 | _ | 123 | 3.14 | 66 | 5.87 |
| Caesarean section | 0 | _ | 0 | _ | 1227 | 30.35 | 209 | 18.21 |
| Current pregnancy | | | | | | | | |
| Pre-eclampsia or pregnancy-induced hypertension | 369 | 14.60 | 6 | 2.37 | 176 | 4.13 | 16 | 1.20 |
| Gestational diabetes | 119 | 4.68 | 8 | 2.63 | 175 | 4.33 | 33 | 3.14 |
| BMI at booking >35 kg/m ² | 557 | 22.24 | 70 | 24.60 | 828 | 19.48 | 314 | 26.23 |
| Post-term (42 ⁺¹ –44 weeks) | 198 | 8.20 | 78 | 26.80 | 132 | 3.11 | 114 | 8.92 |
| Small for gestational age*** | 107 | 4.11 | 5 | 1.67 | 136 | 2.96 | 18 | 1.58 |
| 'Other' obstetric/fetal**** | 120 | 4.84 | 15 | 4.62 | 143 | 3.55 | 78 | 6.56 |
| Any obstetric/fetal | 1570 | 62.64 | 187 | 64.36 | 3213 | 77.44 | 936 | 78.93 |
| Medical and obstetric/fetal risk factors per women | | | | | | | | |
| 1 | 2222 | 88.20 | 272 | 95.05 | 3415 | 82.00 | 1079 | 90.23 |
| 2+ | 302 | 11.80 | 16 | 4.95 | 752 | 18.00 | 122 | 9.77 |

^{*}Percentages are weighted to account for differences in the probability of a woman being selected for inclusion in the study arising from differences in each unit/trust's period of participation and the stratum-specific probabilities of selection of OUs.

Changing length of neonatal unit admission in the 'main composite 'outcome

In a post hoc sensitivity analysis in which we explored the effect of changing the cut-off for length of stay in the 'main composite' from 48 hours to 4 days, we found that the proportion of births with an adverse outcome decreased from 34.0 per 1000 births (95% CI 26.7–43.2) to 20.4 per 1000 births (95% CI 15.8–26.3) in the planned OU group and from 15.2 per 1000 births (95% CI 9.9–23.2) to 12.3 per 1000 births (95% CI 7.4–20.4) in the planned home birth group. Overall, the difference in outcomes between settings was no longer statistically significant (adjusted RR

0.63, 95% CI 0.35–1.12), although the 'direction of effect' was unchanged (Table S8).

Discussion

Main findings

In 'higher risk' women, compared with planned OU birth, planned home birth was associated with a significantly reduced risk of 'intrapartum related mortality and morbidity' or neonatal admission within 48 hours for more than 48 hours. The difference reflected a higher neonatal admission rate in planned OU births. This finding was not

^{**}Prevalence >2% for medical condition and prevalence >3% for obstetric/fetal factors.

^{***}Asthma = Asthma requiring an increase in treatment or hospital treatment. Group B strep = Risk factors associated with group B streptococcus whereby antibiotics in labour would be recommended. Retained placenta = Retained placenta requiring manual removal in theatre. Small for gestational age = Small for gestational age in this pregnancy (<5th centile or reduced growth velocity on ultrasound).

^{****&#}x27;Risk factors' recorded in free text by the midwife. See Table S3 for further details.

Table 3. Adverse perinatal outcomes ('intrapartum composite') for babies of 'higher risk' women by parity and planned place of birth

| | Events | Births | Wei | ghted* | Una | adjusted* | Adjusted** | |
|----------------|----------------------|------------------|-----------------|---------------|------|-----------|------------|-----------|
| | n | n | n/1000 | 95% CI | RR | 95% CI | RR | 95% CI |
| All 'higher ri | sk' women ('po | pulation 1') | | | | | | |
| Overall (Wald | test for interaction | on $P = 0.88***$ | | | | | | |
| OU | 29 | 6648 | 4.2 | 2.9-6.1 | 1 | - | | |
| Home | 12 | 1471 | 7.1 | 4.1-12.2 | 1.68 | 0.87-3.25 | 1.92 | 0.97-3.80 |
| Nulliparous | | | | | | | | |
| OU | 15 | 2508 | 6.0 | 3.7–9.7 | 1 | _ | | |
| Home | 4 | 284 | 10.6 | 4.2-26.8 | 1.77 | 0.62-5.05 | | |
| Parous | | | | | | | | |
| OU | 14 | 4140 | 3.1 | 1.8–5.5 | 1 | - | | |
| Home | 8 | 1187 | 6.2 | 3.0-12.9 | 1.99 | 0.79-5.00 | | |
| 'Higher risk' | women withou | t 'complicating | conditions' ('p | opulation 2') | | | | |
| Overall (Wald | test for interaction | on $P = 0.53***$ | | | | | | |
| OU | 18 | 4715 | 3.8 | 2.6–5.6 | 1 | - | | |
| Home | 10 | 1312 | 6.7 | 3.6–12.4 | 1.75 | 0.84-3.62 | 2.05 | 0.98-4.29 |
| Nulliparous | | | | | | | | |
| OU | 10 | 1528 | 6.5 | 3.7–11.5 | 1 | - | | |
| Home | 3 | 249 | 9.2 | 3.0–27.6 | 1.41 | 0.41-4.87 | | |
| Parous | | | | | | | | |
| OU | 8 | 3187 | 2.5 | 1.3–4.8 | 1 | - | | |
| Home | 7 | 1063 | 6.1 | 2.8-13.4 | 2.43 | 0.88-6.71 | | |

^{*}Probability weights are incorporated to account for differences in the probability of a woman being selected for inclusion in the study arising from differences in each unit/trust's period of participation and the stratum-specific probabilities of selection of OUs.

materially altered by adjusting for maternal characteristics or risk factors, and remained of the same order when the definition of the neonatal admission component of the outcome measure was changed to admission for more than 4 days.

When the measure of adverse perinatal outcome was restricted to include only 'intrapartum related mortality and morbidity', a measure that encompassed intrapartum stillbirth, early neonatal death and specific intrapartum related morbidities, the direction of effect was reversed, with a higher proportion of adverse outcomes in planned home births, but this apparent difference in risk compared with planned OU birth was not statistically significant and confidence intervals were wide and compatible with a range of effects. Because of the small sample size it was not possible to adjust for maternal characteristics other than parity.

Compared with 'low risk' women planning home birth, 'higher risk' women who planned a home birth had a significantly higher risk of an adverse perinatal outcome.

Planned home birth was associated with lower intervention rates and an increased probability of having a straightforward vaginal birth compared with planned OU birth.

Strengths and limitations

A strength of the study is that we were able to evaluate outcomes in a nationally representative sample of 'higher risk' women planning vaginal birth in an OU or at home using high quality data from a cohort study with a low risk of bias due to non-response.³ We controlled for potential confounders, including gestational age which has a strong association with neonatal unit admission even in term births.¹²

The number of 'higher risk' women planning a home birth in our sample was small so that we had limited statistical power to detect clinically important differences in uncommon adverse outcomes between birth settings and were unable to adjust for maternal characteristics other than parity in our analysis of the 'intrapartum composite'. It is possible that a clinically important difference in intrapartum related morbidity and mortality may exist between the two settings which our study had insufficient power to detect. To increase statistical power, we used a composite measure of perinatal mortality and morbidity that included admission to a neonatal unit within 48 hours for more than 48 hours. This will have excluded short admissions for observation or for transient problems, but neonatal unit

^{**}Adjusted for parity.

^{***}P-value for interaction between parity and planned place of birth.

Table 4. Adverse perinatal outcomes ('main composite') for babies of 'higher risk' women by parity and planned place of birth

| | Events | Total | Wei | ighted* | Una | adjusted* | Adjusted*' ** | |
|----------------|----------------------|------------------|-------------------|----------------|------|-----------|---------------|-----------|
| | n | n n | n/1000 | 95% CI | RR | 95% CI | RR | 95% CI |
| All 'higher ri | sk' women ('po | pulation 1') | | | | | | |
| Overall (Wald | test for interaction | on $P = 0.64***$ |) | | | | | |
| OU | 215 | 6636 | 34.0 | 26.7-43.2 | 1 | _ | 1 | _ |
| Home | 25 | 1469 | 15.2 | 9.9-23.2 | 0.45 | 0.27-0.73 | 0.50 | 0.31-0.81 |
| Nulliparous | | | | | | | | |
| OU | 107 | 2503 | 46.0 | 33.2-63.4 | 1 | - | 1 | _ |
| Home | 9 | 283 | 27.7 | 12.5–60.3 | 0.60 | 0.26-1.41 | 0.60 | 0.25-1.43 |
| Parous | | | | | | | | |
| OU | 108 | 4133 | 26.8 | 21.6–33.1 | 1 | - | 1 | _ |
| Home | 16 | 1186 | 12.3 | 6.8–22.2 | 0.46 | 0.24-0.86 | 0.47 | 0.25–0.88 |
| 'Higher risk' | women withou | t 'complicating | g conditions' ('ہ | population 2') | | | | |
| Overall (Wald | test for interaction | on $P = 0.91***$ |) | | | | | |
| OU | 139 | 4711 | 31.1 | 24.3–39.7 | 1 | - | 1 | _ |
| Home | 18 | 1310 | 12.4 | 7.3–21.2 | 0.40 | 0.22-0.72 | 0.42 | 0.23-0.76 |
| Nulliparous | | | | | | | | |
| OU | 64 | 1528 | 44.7 | 31.1–63.9 | 1 | - | 1 | _ |
| Home | 6 | 248 | 21.1 | 8.5–51.1 | 0.47 | 0.18–1.24 | 0.43 | 0.16–1.16 |
| Parous | | | | | | | | |
| OU | 75 | 3183 | 24.6 | 19.4–31.0 | 1 | _ | 1 | _ |
| Home | 12 | 1062 | 10.5 | 5.1–21.9 | 0.43 | 0.20-0.93 | 0.41 | 0.18-0.89 |

^{*}Probability weights are incorporated to account for differences in the probability of a woman being selected for inclusion in the study arising from differences in each unit/trust's period of participation and the stratum-specific probabilities of selection of OUs.

admissions may potentially be influenced by access or other factors unrelated to the severity of neonatal morbidity. ¹³ Neonatal unit admission for more than 48 hours was substantially more common in planned OU births and we have no means of determining whether this reflects a real difference in morbidity as opposed to a difference in admission criteria and/or admission threshold.

Interpretation

The few studies that have evaluated perinatal outcomes in women with known risk factors planning home birth have identified poorer outcomes in this group compared with 'low risk' women planning birth at home, but have not compared outcomes with comparable women planning OU birth. ^{14–16} A UK study comparing outcomes in women attended by independent midwives (IM) with a matched group in NHS care, in which 66% of the IM group planned home birth, found higher perinatal mortality rates for 'higher risk' women in the IM group, but their 'higher risk' group included preterm births and twin pregnancies. ¹⁷

In our sample, more women in the planned OU birth group had multiple risk factors and complicating conditions

at the start of labour care than the women who planned home birth, suggesting possible differences in risk. Differences in some combinations of maternal characteristics and risk factors (particularly maternal age, parity, BMI >35 kg/m² and previous caesarean section) were also evident in exploratory analyses of the two groups (J. Hollowell, unpublished observation). Our sensitivity analyses did not suggest that known differences in the risk profiles of the two groups explained the observed differences in perinatal outcomes between birth settings, but it is possible that the severity of the recorded risk factors or other unmeasured factors affecting risk may have differed in the two settings.

Admission to a neonatal unit involves separation of mother and baby, which may have negative consequences and is therefore an important outcome to consider. However, we cannot determine whether the higher admission rate in planned OU births represents a true difference in neonatal morbidity, increased precautionary treatment or extended observation of babies born in an OU, or 'under-treatment' of babies born (or planned to be born) at home. We do not know to what extent the babies of 'higher risk' women born at home are monitored for early

^{**}Adjusted for maternal age, ethnic group, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery and parity where appropriate.

^{***}P-value for interaction between parity (nulliparous versus parous) and planned place of birth.

Table 5. Adverse perinatal outcomes ('main composite') in planned home births ('higher risk' versus 'low risk' women)

| | Events | Total | Wei | ghted* | Una | adjusted* | Adjusted*'** | | |
|--------------------|-------------------|--------------|-----------------|---------------------|-------|-----------|--------------|-----------|--|
| | n | n | n/1000 | 95% CI | RR | 95% CI | RR | 95% CI | |
| All planned hom | e births ('popu | ılation 1') | | | | | | | |
| Overall (Wald test | for interaction F | P = 0.93***) | | | | | | | |
| Low risk | 177 | 16 309 | 10.7 | 9.0-12.8 | 1 | _ | 1 | _ | |
| Higher risk | 25 | 1469 | 15.2 | 9.9-23.2 | 1.42 | 0.94-2.14 | 1.89 | 1.23-2.90 | |
| Nulliparous | | | | | | | | | |
| Low risk | 84 | 4399 | 19.3 | 15.2-24.4 | 1 | _ | 1 | _ | |
| Higher risk | 9 | 283 | 27.7 | 12.5-60.2 | 1.44 | 0.61-3.37 | 1.82 | 0.89-3.72 | |
| Parous | | | | | | | | | |
| Low risk | 93 | 11 910 | 7.5 | 6.1–9.3 | 1 | - | 1 | - | |
| Higher risk | 16 | 1186 | 12.3 | 6.8–22.2 | 1.63 | 0.88-3.03 | 1.92 | 1.02-3.64 | |
| Planned home bi | irths in womer | without 'com | plicating condi | tions' ('population | າ 2') | | | | |
| Overall (Wald test | for interaction F | P = 0.83***) | | | | | | | |
| Low risk | 151 | 15 318 | 9.9 | 8.1–12.0 | 1 | - | 1 | _ | |
| Higher risk | 18 | 1310 | 12.4 | 7.3–21.3 | 1.26 | 0.75–2.13 | 1.66 | 0.95–2.91 | |
| Nulliparous | | | | | | | | | |
| Low risk | 69 | 3983 | 17.8 | 13.5–23.5 | 1 | _ | 1 | _ | |
| Higher risk | 6 | 248 | 21.1 | 8.5–51.0 | 1.18 | 0.45–3.13 | 1.69 | 0.73–3.89 | |
| Parous | | | | | | | | | |
| Low risk | 82 | 11 335 | 7.1 | 5.6-8.8 | 1 | - | 1 | - | |
| Higher risk | 12 | 1062 | 10.5 | 5.0-21.9 | 1.49 | 0.71-3.12 | 1.69 | 0.79-3.61 | |

^{*}Probability weights are incorporated to account for differences in the probability of a woman being selected for inclusion in the study arising from differences in each unit/trust's period of participation and the stratum-specific probabilities of selection of OUs.

signs of complications requiring treatment or whether some conditions resulting in admission of OU-born babies are safely managed at home. It is possible that there is increased medical and midwifery monitoring of babies born in hospital, leading to more screening for conditions such a low blood sugars and infection. Once a baby is admitted, intervention and monitoring may be continued until uncertainty about the baby's condition has been resolved.

The higher rate of adverse perinatal outcomes seen in 'higher risk' women who planned a home birth compared with 'low risk' women in the same setting indicates that the recommended criteria for defining 'higher risk' do identify women whose babies are at increased risk, but our sample size was too small even in this national study to assess the risks associated with most individual risk factors.

It remains unclear why 'higher risk' women choose home birth, although there is some evidence that many are motivated by the desire to avoid intervention in hospital.¹⁹ Midwifery unit admission criteria typically exclude women with 'risk factors',²⁰ so many 'higher risk' women who want to avoid OU birth may only be able to opt for home birth. Further research is required into whether some

groups of 'higher risk' women might be safely looked after in other midwifery-led settings. For example, recent research suggests that otherwise healthy parous women with a BMI of 35–40 kg/m² may have relatively low intrapartum risks,²¹ and a Dutch study found that extremely obese women achieved good outcomes in midwifery-led care.²²

Conclusions

In planned home births, the babies of women classified as 'higher risk' according to current guidelines are at increased risk of an adverse intrapartum related outcome or neonatal unit admission for more than 48 hours compared with 'low risk' women who plan birth at home. Guidelines state that it may be safer for this group of women to plan birth in an OU, but the risk of an adverse perinatal outcome associated with planned home birth versus planned OU birth appears to depend on the measure used. The babies of 'higher risk' women who plan birth in an OU are more likely to be admitted to a neonatal unit for more than 48 hours than are the babies of 'higher risk'

^{**}Adjusted for maternal age, ethnic group, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery and parity where appropriate.

^{***}P-value for interaction between parity (nulliparous versus parous) and planned place of birth.

Table 6. Interventions and maternal outcomes for 'higher risk' women by parity and planned place of birth

| | Events | Total | We | eighted* | Una | adjusted* | Adj | usted*'** | |
|-------------------|------------------|----------------|-----------------|-----------------------|---------------|-----------|------|-----------|--|
| | n | n | % | 95% CI | RR | 95% CI | RR | 95% CI | |
| All 'higher risk' | women ('popu | ılation 1') | | | | | | | |
| Interventions and | l adverse matern | al outcomes re | quiring obstetr | ic care (maternal cor | mposite outco | me) | | | |
| Nulliparous | | | | | | | | | |
| OU | 1599 | 2491 | 64.6 | 61.5-67.6 | 1 | _ | 1 | _ | |
| Home | 103 | 282 | 33.8 | 27.7-40.4 | 0.52 | 0.43-0.64 | 0.48 | 0.40-0.58 | |
| Parous | | | | | | | | | |
| OU | 1463 | 4102 | 35.7 | 33.6–38.0 | 1 | _ | 1 | _ | |
| Home | 108 | 1186 | 8.9 | 7.3–10.9 | 0.25 | 0.20-0.31 | 0.26 | 0.21-0.32 | |
| Straightforward | aginal birth | | | | | | | | |
| Nulliparous | 3 | | | | | | | | |
| οŪ | 1305 | 2504 | 51.7 | 48.9–54.4 | 1 | _ | 1 | _ | |
| Home | 201 | 284 | 73.5 | 66.8–79.2 | 1.42 | 1.29–1.57 | 1.63 | 1.47–1.81 | |
| Parous | | | | | | | | | |
| OU | 3109 | 4138 | 74.7 | 72.9–76.4 | 1 | _ | 1 | _ | |
| Home | 1101 | 1189 | 92.7 | 91.1–94.1 | 1.24 | 1.21–1.28 | 1.20 | 1.16–1.23 | |
| 'Higher risk' wo | men without ' | complicating | conditions' ('i | oopulation 2') | | | | | |
| | | | | ic care (maternal co | mposite outco | me) | | | |
| Nulliparous | | | . 3 | | • | | | | |
| οŪ | 841 | 1510 | 56.6 | 52.8–60.3 | 1 | _ | 1 | _ | |
| Home | 85 | 247 | 31.4 | 24.7–39.0 | 0.55 | 0.44-0.70 | 0.50 | 0.40-0.63 | |
| Parous wome | n | | | | | | | | |
| OU | 969 | 3154 | 30.7 | 28.7–32.8 | 1 | _ | 1 | _ | |
| Home | 86 | 1064 | 7.9 | 6.3–9.8 | 0.26 | 0.20-0.32 | 0.26 | 0.21-0.34 | |
| Straightforward v | aginal birth | | | | | | | | |
| Nulliparous | - | | | | | | | | |
| OU | 906 | 1523 | 59.0 | 55.9–62.0 | 1 | _ | 1 | _ | |
| Home | 180 | 247 | 75.9 | 68.8–81.8 | 1.29 | 1.17–1.42 | 1.43 | 1.29–1.58 | |
| Parous wome | n | | | | | | | | |
| OU | 2484 | 3181 | 77.7 | 76.0–79.4 | 1 | _ | 1 | _ | |
| Home | 992 | 1065 | 93.4 | 91.5–94.8 | 1.20 | 1.17–1.24 | 1.17 | 1.13–1.20 | |

^{*}Probability weights are incorporated to account for differences in the probability of a woman being selected for inclusion in the study arising from differences in each unit/trust's period of participation and the stratum-specific probabilities of selection of OUs.

women who plan birth at home, but it is uncertain whether this reflects a real difference in morbidity. A larger study would be required to determine whether there is a statistically significant increase in uncommon intrapartum related adverse perinatal outcomes in 'higher risk' women who plan birth at home compared with 'higher risk' women who plan birth in an OU.

Obstetric intervention rates are lower in 'higher risk' women who plan home birth compared with those who plan OU birth.

No change in the guidelines on planned place of birth for 'higher risk' women can be recommended on the basis of the results reported here, but further evaluation of outcomes in some groups of 'higher risk' women who plan birth in a non-OU setting would be merited to strengthen the evidence informing guidelines on planned place of birth.

Disclosure of interests

The authors declare that they have no competing interests.

Contribution to authorship

This study is part of a programme of work, the research questions and protocol for which were developed by a co-investigator group including JH, RR, PB, MK, LL, AM, CM, NM, MN, MR, JS and LS. JH and RR conceived and developed the outline for this study; YL and JH developed the protocol and analysis plan with input from JT, RR, MK and DP; YL conducted the analysis; JT and LL provided

^{**}Adjusted for maternal age, ethnic group, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery and parity where appropriate.

statistical advice; YL and JH drafted the manuscript with input from all authors. All authors were involved in interpretation of data, review and revision of the draft manuscript and approval of the final version.

Details of ethics approval

Research ethics committee approval for the Birthplace study was obtained from the Berkshire Research Ethics Committee (MREC ref 07/H0505/151) and did not require consent to be sought from participants as no personally identifiable data were collected.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Figure S1. Study inclusion flow chart ('higher risk' women).

Figure S2. Study inclusion flow chart ('low risk' women planning a home birth).

Table S1. Categorisation of potential confounders.

Table S2. Categorisation of risk factors used for risk adjustment.

Table S3. Medical and obstetric risk factors known prior to the onset of lavour in 'higher risk' women by planned place of birth.

Table S4. 'Complicating conditions' identified at the start of care in labour in 'higher risk' women by planned place of birth.

Table S5. Contribution of individual outcome events to the adverse perinatal outcomes ('main composite') by planned place of birth in 'higher risk' women.

Table S6. Perinatal and maternal outcomes in 'higher risk' women without 'complicating conditions' identified at the start of care in labour and with only one risk factor but no 'other' medical or 'other obstetric' risk factors (population 3).

Table S7. Sensitivity analysis controlling for risk factors: adverse perinatal outcomes ('main composite') for planned home birth versus planned OU birth (population 3).

Table S8. *Post hoc* sensitivity analysis with modified perinatal outcome. Adverse perinatal outcomes ('modified composite') for babies of 'higher risk' women by planned place of birth. ■

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