The Birthplace in England Research Programme: further analyses to enhance policy and service delivery decision-making for planned place of birth

Protocol

Chief Investigator:

Dr Jennifer Hollowell

National Perinatal Epidemiology Unit (NPEU)

University of Oxford

Old Road Campus

Headington

Oxford

OX3 7LF

Tel: 01865 289700

Email: jennifer.hollowell@npeu.ox.ac.uk

1. Aims and Objectives

The aim of this follow-on project is to support the development and delivery of safe, equitable and effective maternity services by strengthening the evidence-base relating to planned place of birth. In particular it will:

- Describe and explore the impact of service configuration and other variations in the organisation and delivery of services on birth outcomes, with a particular focus on maternal outcomes which impact on future pregnancies, such as caesarean section or complicated vaginal delivery (objectives 1 and 2).
- Further describe intrapartum transfer rates and explore the possible impact of factors relating to the organisation and delivery of services on transfers (objective 3).
- Explore the clinical characteristics, management and outcomes of 'higher' risk women who opt for a non-OU birth (objective 4).

The following specific research questions will be addressed:

1. The impact of service configuration and organisation on maternal interventions and outcomes

1.1. Is there evidence to suggest that maternal interventions and outcomes differ for planned births in OUs with an attached AMU compared with OUs without an AMU?

1.2. Is there evidence to suggest that maternal outcomes in planned obstetric unit births differ in trusts with high/low proportion of non-OU births (home/FMU/AMU combined or home/FMU births)?

1.3. Is there any evidence to suggest that outcomes (maternal and neonatal) in planned home births differ in trusts with a high/low volume of planned home births?

1.4. Is there any evidence to suggest that outcomes (maternal and neonatal) in planned AMU births are affected by size/throughput or other known characteristics of the AMU?

1.5. Is there any evidence to suggest that outcomes (maternal and neonatal) in planned FMU births are affected by the size/throughput or other known characteristics of the FMU including distance and/or average travel time to the nearest OU?

2. Factors affecting variability in maternal interventions and outcomes

2.1. What is the variation between individual units and trusts (for home births) in maternal interventions (operative and instrumental deliveries) and outcomes (third/fourth degree perineal trauma)?

2.2. Does the effect of planned place of birth on maternal interventions and outcomes vary for specific sub-groups of women, particularly those defined by parity, age, ethnicity and the level of deprivation of their area of residence?

2.3. Do maternal interventions and outcomes vary by time of day and day of the week in births planned in each setting?

2.4. *For OUs, AMUs and FMUs, what is the variation in maternity staffing levels, and are these measures associated with differences in maternal interventions and outcomes?*

3. Factors affecting intrapartum transfers of women and the transfer process

3.1. What maternal characteristics known at the start of care in labour are most strongly associated with intrapartum transfer?

3.2. For women planning a birth outside a hospital obstetric unit, what variation exits between units and trusts (home births) in the proportion of women who are transferred from their planned place of birth during or immediately after labour?

3.3. To what extent can any differences in transfer rates between units and trusts (home births) be explained by the characteristics of the unit (e.g. size, midwifery staffing levels, distance to the nearest OU, age of the unit) or other aspects of the organisation and delivery of services?

3.4. Do intrapartum transfers vary by time of day and day of the week in births planned in each setting?

3.5. In planned home and FMU births, does the time from decision to transfer to start of transfer and total time from decision to transfer to assessment in OU vary in women transferred for reasons likely to require more urgent transfer (e.g. for fetal distress in 2nd stage)?

4. The characteristics and management of 'higher risk' women in non-OU settings

4.1. What are the maternal demographic and clinical characteristics of women known to be at 'higher risk' of complications prior to the onset of labour who plan to give birth in each of the non-OU settings?

4.2. Is there any evidence that in 'higher risk' women, the increased risk of adverse perinatal outcomes observed in planned home births relative to planned OU births is attributable to the planned delivery setting as opposed to differences in the clinical characteristics of the two groups?

4.3. How are 'higher risk' women who present for planned birth in a non-OU setting managed with respect to transfer? For example, for women who are transferred, what is the distribution of time to decision to transfer and time to start of transfer? Does the decision to transfer and timing of transfer depend on maternal characteristics or the presence of other medical/obstetric risk factors?

4.4. How are 'low risk' women (i.e. those without known medical or obstetric risk factors prior to the onset of labour) managed with respect to transfer from non-OU settings when they are found to have complicating conditions (breech presentation, prolonged rupture of membranes, etc) at the start of care in labour?

2. Background

Since the early 1990s, government maternity care policy has moved away from consultant-led care for women with straightforward pregnancies towards policies designed to give women a choice of settings for birth. Other initiatives that have also driven changes in the organisation and delivery of maternity care include the introduction of support workers, changed roles and professional boundaries for midwifery and medical staff, and the recent expansion in the number of midwifery-led units (MUs).

Against this policy and organisational background, the Birthplace Research Programme was commissioned in order to fill a number of important gaps in the evidence supporting the provision of high-quality intrapartum maternity care in England. At the time there was little reliable evidence about the nature, geographical location and distribution of MUs. Evidence was also lacking about the number and characteristics of women planning birth in different settings, the staffing structures

within MUs and their position within and relationship with the wider organisation and provision of maternity care, including obstetric and home birth services.

Evidence from the Birthplace mapping study shows that in 2010 there were 53 Alongside Midwifery Units (AMUs) and 59 Freestanding Midwifery Units (FMUs) in operation in England, representing around 39% of all available maternity units (1). Of the 152 trusts providing maternity care, around half do not offer MU care of any kind and there are marked geographical differences in the numbers of MUs in different areas of England. In 2007, FMUs were most common in the South West and AMUs were more common in London and South Central SHA regions. MUs varied considerably in size: FMUs tended to be smallest with a median of 192 births per year (range 8-548), AMUs had a median of 613 births (range 92-2860) and OUs had a median of 3217 births (range 914-6781). Within unit type, there was also considerable variability in the numbers of beds or bed spaces, throughput (births per bed/bed space), staffing levels and skill mix. While, overall, births planned in MUs and at home made up less than 10% of all births, there is notable geographical variation in this figure (2).

Two factors which may have limited the provision of MUs and home birth services have been (a) the lack of accurate quantification of the risk of adverse perinatal outcomes associated with births planned in these settings and (b) lack of reliable information about the comparative costs and cost-effectiveness of birth planned in these settings.

The recently completed Birthplace national cohort study has provided robust estimates of the safety and potential benefits of births planned at home, in FMUs and AMUs compared with planned obstetric unit (OU) births. The linked cost-effectiveness study has also provided estimates of the cost to the NHS of planned births in MUs and at home compared with birth in an OU. Key findings from these studies are summarised below and are published in detail elsewhere (3-6).

Birth outcomes in 'low risk' women

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.

For 'low risk' women, the incidence of adverse perinatal outcomes is low in all settings. For all settings, adverse perinatal outcome, adverse maternal outcomes and intervention during labour are 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 are no differences between birth settings in adverse perinatal outcome for multiparous women**.** For nulliparous women, there is no difference between outcomes in MUs and OUs but adverse perinatal outcomes are more likely for nulliparous women who plan birth at home.

The benefits of planned birth at home or in an MU include fewer interventions, a substantially reduced incidence of intrapartum caesarean section and a higher likelihood of 'normal birth'.

Adverse maternal outcomes - third or fourth degree perineal trauma, blood transfusion or admission to a higher level of care – tend to occur less in women planning birth at home or in an FMU and blood transfusions are less common in women planning an FMU birth compared with planned OU births. However, event rates for these outcomes are low and most of these differences are not significant at the 1% level.

Birth outcomes in 'higher risk' women

Overall 5% of women in the three planned non-OU groups were 'higher risk' at the start of labour and therefore, according to the NICE intrapartum care guideline, should have been "advised to give birth in an obstetric unit" (7). The highest proportion of 'higher risk' women was in planned home births (7%), and the lowest in planned FMU births (2.5%).

Findings are consistent with an increased incidence of an adverse perinatal outcome for 'higher risk' women planning birth at home compared with women planning OU birth. Findings for other outcomes in 'higher risk' women – 'normal birth', interventions during labour, maternal morbidities and initiation of breastfeeding – are broadly consistent with 'better' outcomes for planned non-OU births relative to the planned OU group.

However, reported findings for 'higher risk' women are less easy to interpret because the groups planning birth in each setting are 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, and nearly 7% of 'higher risk women in the OU group had multiple risk factors, compared with 1-1.3% in the non-OU groups. This both increases the risk of other interventions and, by definition, precludes a 'normal birth'.

Transfers

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.

Costs and cost-effectiveness

For 'low risk women', the cost to the NHS of intrapartum and related postnatal care, including costs associated with clinical complications, is lower for birth planned at home, in a FMU and in an AMU compared with planned birth in an OU. Planned birth at home, in a FMU or in an AMU generates cost savings per additional 'normal birth' and per adverse maternal morbidity avoided in comparison to planned birth in an OU.

The findings of the Birthplace national cohort study are supportive of a policy offering 'low risk' women a choice of birth setting. Given the current geographical variation in the provision of MUs and home birth services, in order to provide a realistic choice for women, an expansion of these non-OU settings and services may be needed.

Unanswered questions

Following the completion of the Birthplace cohort study, a number of questions remain that have the potential to inform decision making with regard to the possible reconfiguration of services; this follow-on work aims to address these questions. In particular it will explore questions relating to the configuration and organisation of services; the impact of unit characteristics, such as size and throughput, on outcomes; transfers from MUs and home; and the management of 'higher risk' women planning birth in a MU or at home. In doing so it will enhance the information available to women and their healthcare professionals in order to help them make safe, informed choices about place of birth. It will also extend the evidence base to support the commissioning of safe and equitable services for intrapartum care.

3. Need

While Birthplace studies to date have provided answers to a number of key questions relating to the safety and cost-effectiveness of different settings for birth, the data collected have the potential to

provide further evidence which can be used by commissioners and policy makers in planning the future configuration of services.

- The Birthplace mapping study revealed significant variation in the provision, organisation and configuration of intrapartum care, but the extent to which different configurations of care within a trust impact on outcomes is not clear. For example, are there benefits in terms of maternal interventions and outcomes associated with having an AMU compared with offering OU care only and what is the impact of higher or lower numbers of planned 'out of hospital' births in a trust on the outcomes of planned OU births?

- Midwifery units and home birth services vary in terms of size, throughput and staffing structures and levels, but it is not clear, for example, whether maternal interventions and outcomes also vary between MUs / trusts or whether these known characteristics of MUs and home birth services are associated with differences in interventions or outcomes.

- A substantial number of women planning birth at home or in a MU will be transferred to an OU during labour or immediately after giving birth. The overall number of women experiencing transfer will increase if more women plan birth in an MU or at home, so in order to provide evidence based information to women it is important to understand any maternal characteristics associated with transfer. It is also important for commissioners considering planning new MU services to be informed about the impact of service and organisational factors on transfer rates. Currently unpublished doctoral research funded by NIHR and carried out alongside the Birthplace programme has explored maternal characteristics associated with transfer from MUs and has indicated substantial variation between MUs in overall transfer rates (Rowe, personal communication). There is a clear need to develop and expand this work to include home births and to consider other factors associated with transfer, including MU/trust size, staffing and distance to OU.

- The Birthplace cohort study revealed that a non-negligible proportion (5%) of births planned in MUs or at home are to women at 'higher risk' of complications who, according to current guidelines, should be "advised to give birth in an obstetric unit". The doctoral research described above has given some indication of the risk characteristics of women planning birth in MUs, but more work is needed to explore the maternal demographic and clinical characteristics of 'higher risk' planning birth in all non-OU settings to support the development of policies regarding the management of 'higher risk' women who wish to opt

for a non-OU birth. The cohort study also showed that 'higher risk' women planning birth at home had a higher incidence of adverse perinatal outcome compared with 'higher risk' women planning an OU birth. It is not clear, however, whether this is attributable to the planned birth setting or to differences in clinical characteristics between the two groups. Finally, it is important to understand how 'higher risk' women, and those 'low risk' women who present with complicating conditions at the start of labour care, are managed, particularly in relation to transfer and whether this depends on other maternal characteristics / risk factors.

These proposed further analyses of the Birthplace data build on what has already been achieved and provide an excellent opportunity to further improve the evidence base for the future design and organisation of maternity services in England.

4. Methods

Data

The available datasets include:

1. The Birthplace national prospective cohort. This includes data on 79,774 eligible women from over 95% of the NHS trusts providing intrapartum care in England. Variables include maternal characteristics, risk factors in pregnancy, labour care, intrapartum transfer details, and maternal and neonatal outcomes by planned place of birth at the start of care in labour. Annex A presents details of the quality and completeness of data

2. Staffing and configuration data collected as part of the Healthcare Commission Maternity Services Review in 2007 and the Birthplace 2010 mapping survey.

3. Further staffing and organisational data collected in the form of daily staffing and workload logs alongside the Birthplace cohort study in obstetric and midwifery units

4. Birth registration statistics relating to number of births by unit and unit type (FMU, OU, OU with AMU) for 2008 and 2009

For some planned analyses, particularly those relating to staffing, service configuration and the process of transfer, the available data have not been fully cleaned and/or explored. These datasets will be further explored in order to determine the best source of data for each of the proposed analyses. .

Outcome measures

The main outcome measures to be used in these analyses are:

Maternal

- Straightforward vaginal birth, defined as birth without caesarean section, forceps or ventouse delivery, 3rd/4th degree perineal trauma or blood transfusion (i.e. without complications that may affect future births)
- 'Normal birth', defined as birth with none of the following[1]: induction of labour; epidural or spinal analgesia; general anaesthetic; forceps or ventouse; caesarean section; episiotomy.
- Instrumental delivery (ventouse or forceps) and/or ventouse delivery and forceps delivery separately[2]
- Intrapartum caesarean section
- Third or Fourth degree perineal trauma

Neonatal

- Apgar score less than seven at five minutes

Intrapartum transfers

- Transfer in labour
- Transfer during labour or immediately after birth

Other maternal and perinatal outcomes will be reported where relevant and appropriate, including

- 'Adverse perinatal outcome': stillbirth after the start of care in labour; neonatal encephalopathy; meconium aspiration syndrome; brachial plexus injury fractured humerus; or fractured clavicle (Birthplace primary outcome
- Other Birthplace secondary outcomes: syntocinon augmentation, epidural or spinal analgesia, general anaesthetic, active management of the third stage of labour, episiotomy

[1] Based on the NCT, RCM and RCOG Maternity Care Working party definition (ref).
[2] Ventouse and forceps deliveries will be analysed separately where sample sizes permit and combined otherwise

- Neonatal unit admission; maternal admission to higher level care (intensive therapy unit, high dependency unit or specialist unit)[3]

Explanatory variables

The following will be used as potential explanatory variables:

Maternal characteristics

Age; ethnic group; understanding of English; marital or partner status; BMI in pregnancy; Index of multiple deprivation (IMD) quintile; parity; gestation at delivery.

Unit characteristics

- Number of births per year
- Unit bed / bed space capacity
- Staffing
    - Midwifery vacancy level
    - Number of midwives (and maternity support workers) per birth and/or other more sensitive measure based on staffing logs[4])
    - Whether the unit has 24 hour midwifery staffing (FMUs)
    - Whether the unit has an on-site 24 hour epidural service
    - Whether the unit has on-site consultant cover 40 or more hours per week (OUs)
- Distance from OU and travel time to OU (for FMUs only)
- Age of the unit (years of operation as an FMU, AMU or OU)

Trust-level characteristics

- Number of home births as a proportion[5] of all births in the Trust
- Number of home births or FMU births as a proportion of all births in the Trust

3 Because of the influence of proximity on admissions, these outcomes will be used only for relevant non-OU comparisons

[4] For example, staffing levels by time of day and day of week

[5] We anticipate using a combination of the proportion and absolute number of births, in order to deal appropriately with trusts with very small numbers of non-OU births, but will seek advice to determine the most appropriate measure.

Definitions

Definition of risk status

For objectives relating to 'low risk' or 'higher risk' women, the same definitions as those used in the Birthplace cohort study will be used (4). In addition, for some analyses we will identify a subset of 'low risk' women with complicating conditions at the start of care in labour.

Planned place of birth

The same definitions of planned place of birth will be used as in the Birthplace cohort study. Four groups of women are defined 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
- women whose planned place of birth was in an alongside midwifery unit
- women whose planned place of birth was in an obstetric unit

Women will be 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. Women who made their final decision about planned place of birth during labour were included in the study.

Statistical Methods

Logistic regression[6] will be used to calculate odds ratios and confidence intervals for binary outcomes. We will report the number of events, the number of births, the weighted incidence, an unadjusted odds ratio and an adjusted odds ratio controlling for maternal characteristics as appropriate. Robust variance estimation will be used to allow for the clustered nature of the data within units/trusts. Probability weights will be 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. The stratification used in the random sampling of OUs will not be taken into account in the analysis because OUs were the only unit type sampled. Ignoring the stratified sampling will not affect point estimates and may result in slightly overestimated standard errors.

[6] Log binomial regression would give more clinically meaningful results; however this type of model potentially has convergence issues, particularly when fitting adjusted models with numerous covariates. We are currently exploring the use of binomial (and poisson) models in another project using the Birthplace dataset and will then reconsider the most appropriate model(s) to use in the present analysis.

For specified objectives, multilevel modelling will be used to model the clustering within units and trusts explicitly as a random variable, fitting women as level one and units/trusts as level two in the hierarchy. The intracluster correlation coefficient will be calculated and between-unit variability estimated. Funnel plots will also be used to assess the variability for each outcome and to identify units which are outliers (8).

95% confidence intervals will be used throughout. We acknowledge that the analysis will be exploratory in nature and will involve multiple testing; we will take this into consideration when interpreting the results. The statistical analysis of each objective is described separately below, and refers to data from the Birthplace cohort unless otherwise specified:

Objective 1: The impact of service configuration on maternal interventions and outcomes

To compare planned births in OUs with an attached AMU and those in OUs not attached to an AMU, unadjusted and adjusted odds ratios will be presented for each outcome. To determine whether outcomes in planned OU births are affected by the proportion of non-OU births in the trust, each trust will be categorised as having a high or low annual proportion/volume of non-OU births(home/FMU/AMU combined) and home/FMU births combined. These data will be obtained from The Healthcare Commission Maternity Services Review 2007, the Birthplace 2010 Mapping Survey and other sources as appropriate. Unadjusted and adjusted odds ratios comparing women in OUs based in trusts with a low versus high volume of planned non-OU births will be presented for each outcome. A similar approach will be used to examine the effect of volume on outcomes in planned home births. To examine whether outcomes in planned AMU or FMU births are affected by characteristics of the unit, the relationship between each outcome and unit characteristic will be examined in a bivariate analysis, followed by a multivariate logistic analysis to identify the factors most strongly associated with each outcome (AMUs and FMUs separately).

Objective 2: Factors affecting variability in maternal interventions and outcomes

All analyses described in this section will be performed for each intervention and outcome, separately by planned place of birth. Funnel plots will be used to assess the variability between units/trusts in operative and instrumental deliveries and third/fourth degree perineal trauma, and multilevel modelling will be used to calculate between-unit variability. We will explore factors that explain any variability between units/trusts by including individual women level characteristics, and unit level characteristics in the model. To examine the effect of planned place of birth on maternal interventions/outcomes in specific sub-groups of women, we will summarise the number of events

within each sub-group category. We will fit a logistic regression model and test for differences in the effect of planned place of birth across sub-group categories using the statistical test of interaction.

To investigate the impact of time and day we will use logistic regression, fitting time and day as explanatory variables. We will report the staffing levels at each unit (e.g. births per midwife and births per maternity support worker) using data from the Healthcare Commission Maternity Services Review 2007 and the Birthplace 2010 Mapping Survey. Funnel plots will be used to assess the variability in staffing levels and to identify units which are outliers separately for each planned place of birth. Logistic regression will be used to assess the association between staffing levels and maternal interventions and outcomes. For a subset of units, in which daily staffing and workload logs were completed, we will describe and compare staffing levels and characteristics for different shifts in greater detail.

Objective 3: Factors affecting intrapartum transfers of women and the transfer process

We will summarise the maternal characteristics of women who are and are not transferred separately for planned FMU, AMU and home births. We will examine the associations of each maternal characteristic with transfer status (yes/no) in a bivariate analysis, followed by a multivariate analysis to identify the strongest predictors. We will also do a subgroup analysis by parity, to investigate whether associations between transfer and maternal characteristics differ for nulliparous and multiparous women. We will perform an additional analysis restricted to transfers that occur prior to delivery, as the reasons for these are very different to those that occur after delivery. The variability in transfer rates between units/trusts will be examined separately for each planned place of birth using funnel plots and multilevel modelling will be used to calculate between-unit variability. We will explore factors that explain any variability in transfer rates between units by adding individual women level characteristics, and unit level characteristic to the model. To examine the impact of time and day on transfer rates, we will use logistic regression, fitting time and day as explanatory variables. For the analysis exploring the association between the timing and urgency of transfer in planned home and FMU births, transferred women in these setting will be categorised as 'urgent' transfers (e.g. fetal distress in 2nd stage) and 'non-urgent' transfers (eg epidural request, failure to progress in 1st stage). We will report the median time from decision to transfer to start of transfer, and decision to transfer to OU assessment for each group. The Wilcoxon Rank Sum test will be used to test for differences.

Objective 4: The characteristics and management of 'higher risk' women in non-OU settings

The characteristics of 'higher risk' women will be described to identify the most common risk factors and explore the relative contribution of medical and obstetric factors. We will focus primarily on home births in this section as there are very few high risk women in the FMUs and AMUs due to 'stricter' eligibility criteria. We will compare the clinical characteristics of 'higher risk' women in the midwifery units with home to see if they differ. To examine the reasons for the increased risk of adverse outcome observed in 'higher risk' women in planned home births relative to planned OU births, we will present odds ratios for each outcome and fit the clinical characteristics of each group as explanatory variables in a logistic regression model (including previous caesarian section and medical/obstetric risk factors). In order to create groups that are more homogeneous with regard to risk, the analysis will be restricted to women who did not have induction of labour (since these are only present in the OU group). To investigate the management with respect to transfer of 'higher risk' women in non-OU settings, we will describe the relationship between the timing of transfer and; (i) type of medical/ obstetric risk factors present (ii) complicating conditions at the start of care in labour (iii) reason for transfer and (iv) maternal characteristics, by planned place of birth in the non-OU settings. A logistic regression model will then be fitted with timing of transfer (immediate/not immediate) as the independent variable to identify the strongest predictors of immediate transfer, for 'higher risk' and 'low risk' women with complications separately. This analysis will be performed both for 'higher risk' women (NICE criteria) and women who are 'low risk' prior to the onset of labour but have complicating conditions at the start of care in labour.

Statistical power and precision

The original sample size calculation for the Birthplace cohort study was based on an uncommon primary outcome with an event rate of 3.6 per 1000 births. Many of the outcomes in this follow on application have a much higher event rate; hence there is potentially adequate power to detect differences between smaller subgroups. Annex B presents power calculations for a selection of the pre-specified subgroup comparisons to give some indication of the range of precision for key outcomes (straightforward vaginal birth, intrapartum caesarean section and intrapartum transfer).

Some of the analyses are explicitly exploratory and descriptive in nature. For example, in analyses relating to 'higher risk' women, we will have limited power to detect differences in perinatal outcome between settings because of the low event rate and the small number of 'higher risk' women planning birth outside an obstetric unit. Thus although we will estimate and report the incidence of adverse perinatal outcomes in this group of women, the primary focus of objective 4 is

on describing the characteristics and management of 'higher risk' women who plan birth outside an obstetric unit.

5. Contribution to collective research effort and research utilization

Birthplace has involved a wide range of researchers and stakeholders and, through its Advisory Group, a wide range of additional stakeholders, including commissioners. The dissemination and application of Birthplace findings has been actively discussed and considered by this group.

The evidence arising from this follow-on research will be of particular use to policy makers, professionals and local communities involved in commissioning and developing their maternity services. It will also be available to practicing health care professionals and women to inform discussions and decisions about place of birth. The results of this project will be disseminated in a number of ways, including published reports, summaries to Strategic Health Authorities (or equivalent), publications in peer-reviewed and other journals, conference presentations and seminars targeting different audiences including policy makers, professional bodies, user groups, health professionals and academics. Results relating to each objective will be written up and available for dissemination as the programme or research progresses. We anticipate a minimum of six journal publications over the course of the project (1-2 articles for each of the four objectives), with at least two of these prepared and submitted during the initial 13 months of the project (as shown in the project timeline contained in the project description). In order to make the findings accessible to policy makers, service providers and clinicians, we will additionally prepare non technical summaries of our findings which we will make available on our website and publicize/disseminate through the Birthplace team's network of contacts with key DH policy leads, professional and NHS bodies and others. We will also further develop our use of newer technologies (for example Twitter @BirthplaceStudy) to reach broader audiences. Following the well-received format of the initial Birthplace report part 1, (3) our final report will include a separate overview report. This will include a non-technical description of the project and methods, together with a succinct summary of key findings, implications for policy and practice and research recommendations.

We are conscious however that this proposal has been prepared at a time when the future shape of commissioning within the NHS is uncertain. In order to ensure that the outputs from this research reflect and meet the needs of health service managers and commissioners, we will consult and work

closely with DH policy leads, key members of the Birthplace Advisory Group and other relevant stakeholders throughout the project.

6. Plan of investigation and timetable

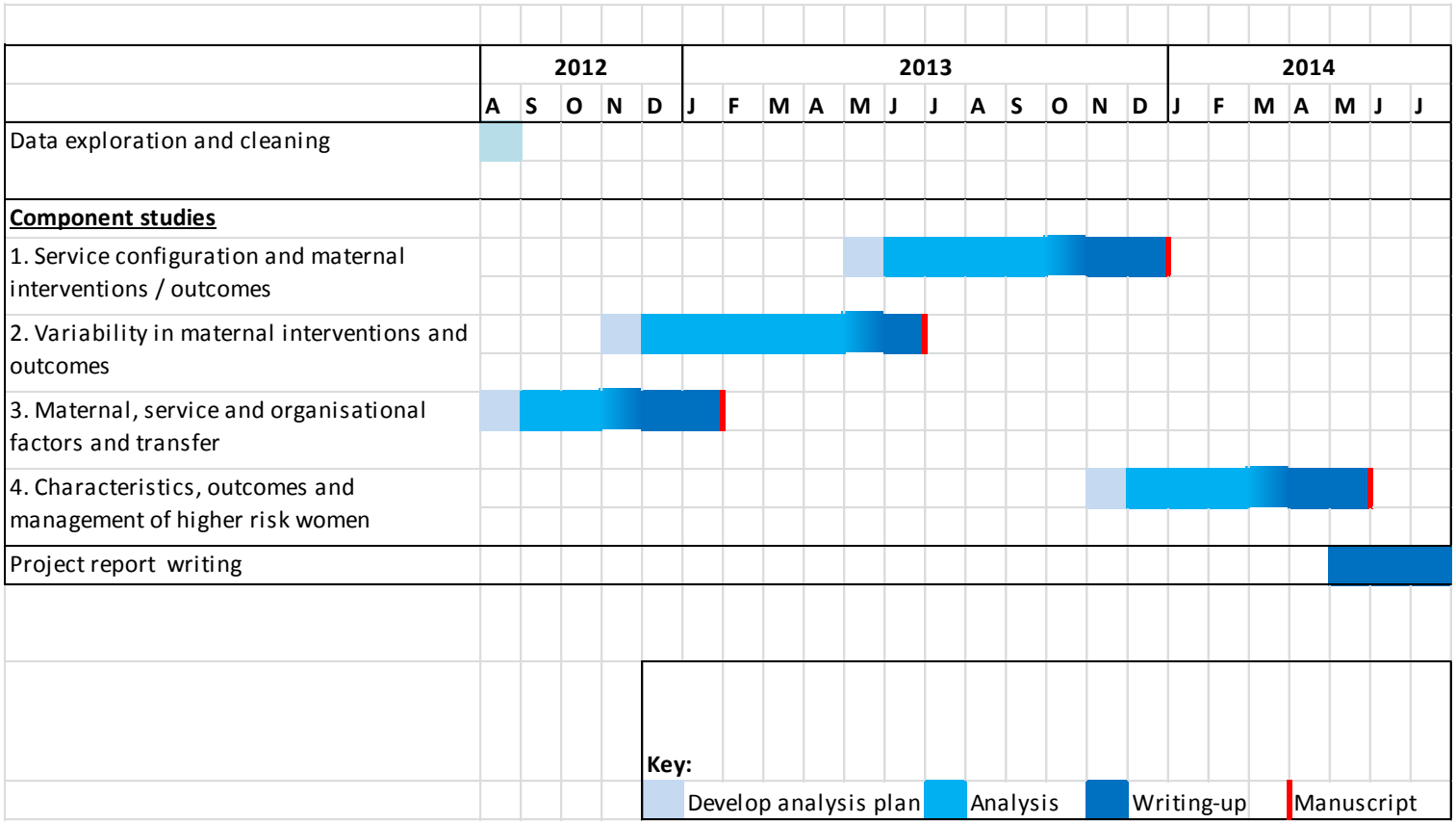
Each objective, and group of research questions, will be addressed sequentially as shown in Figure 1. An analysis plan will be developed and agreed at the outset of each sub-study, and, to ensure rapid dissemination of results, each study will be written-up in manuscript form for publication as each sub-study is completed.

Time has additionally been scheduled at the start of the project for exploration and cleaning of datasets that have not previously been analysed (staffing logs) and further cleaning of date/time and text variables that were not analysed in the Birthplace primary analysis (eg transfer times and clinical risk factors)

7. Approval by ethics committee

The chair of the Berkshire Research Ethics Committee will be informed of the project but, since the project does not involve new data collection and involves the analysis of data already collected within the current Birthplace research programme, no further ethics committee approval is required.

Figure 1: Project timeline



10. Co-investigator Group

Dr Jennifer Hollowell, (Chief investigator) Epidemiologist, NPEU

Dr Maggie Redshaw, Social Scientist, NPEU

Professor Marian Knight, NIHR Research Professor, NPEU

Dr Rachel Rowe, Senior Health Services Researcher, NPEU

Ms Louise Linsell, Senior medical statistician, NPEU

Professor Peter Brocklehurst, Professor of Women's Health, UCL

Professor Chris McCourt, Professor of Maternal and Child Health, City University London

Professor Jane Sandall, NIHR King's Patient Safety and Service Quality Research Centre

Professor Alison Macfarlane, Professor of Perinatal Health, City University London

Ms Louise Silverton, Deputy General Secretary, Royal College of Midwives

Ms Mary Newburn, Head of Policy Research, NCT

Professor Neil Marlow, Professor of Neonatal Medicine, University College London

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Annex A: Completeness and quality of data

The level of missing data in the Birthplace dataset is extremely low. The completeness of key variables is summarized below.

Risk status

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.

Data relating to 'low risk' women

- **Outcome data**: Overall, 1.1% of records (711 births 1.1%) had missing data for the primary outcome; individual maternal and neonatal outcome variables were missing for less than 1% of records (for example, the composite variable 'normal birth' was missing in 0.7% of records).
- **Confounder variables:** 2.9% of records (1903 births) had missing data for any of the confounder variables listed in Table 1.
- **Outcome and confounder variables:** Taking both the missing primary outcome data and missing confounder data into account, 3.9% of records (2502 births) contained missing data for either the primary outcome or any of the confounder variables (Table 2). The completeness of data (primary outcome and confounder variables combined) by planned birth setting was good with all settings achieving more than 95% completeness.

Table 1. 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

Table 2: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.

Data relating to 'higher risk' women

The pattern of missing confounder data was similar for 'higher risk' women:

- Individual outcomes were coded as missing in less than 0.7% of records
- For all individual confounder variables, the proportion of records with missing data was less than 1% with the exception of marital status, which was missing in 1.25% of records.

A more detailed description of the pattern of missing data can be found in appendix 4 of the final study report (part 4)[7].

[7] Hollowell J, Puddicombe D, Rowe R, Linsell L, Hardy P, Stewart M, et al. The Birthplace national prospective cohort study: perinatal and maternal outcomes by planned place of birth. Birthplace in England research programme. Final report part 4: NIHR Service Delivery and Organisation programme; 2011.

Annex B: Statistical power and precision

The original sample size calculation for the Birthplace cohort study was based on an uncommon primary outcome with an event rate of 3.6 per 1000 births. Many of the outcomes in this follow on application have a much higher event rate; hence there is potentially adequate power to detect differences between smaller subgroups.

The following sections present power calculations for a selection of the pre-specified subgroup comparisons to give some indication of the range of precision for key outcomes (straightforward vaginal birth, intrapartum caesarean section and intrapartum transfer). We have not included any allowance for clustering; the intracluster correlation coefficient (ICC) varies for different outcomes and the design effect varies for different comparison groups (depending on the mean size (SD) of the maternity units/trusts involved in the comparison). The ICC for the outcomes used in the power calculations ranged from 0.0004 for adverse perinatal outcome to 0.01 for straightforward vaginal birth.

(a) Comparison of maternal outcomes between planned births in OUs with an attached AMU and planned births in OUs not attached to an AMU

In the Birthplace cohort study, 9 of the 36 participating OUs were attached to an AMU, representing approximately 26% of the population of 32,000 women in the study who planned a birth in an OU. This gives a sample size of ~8,300 women in the group of OUs with an attached AMU and ~23,700 women in the group of OUs with no attached AMU.

- **Straightforward vaginal birth**
  The event rate for straightforward vaginal birth for all women (high and low risk combined) who planned an OU birth was 17,464/31,198 = 56%. With a sample size of 8,300 in one group and 23,700 in the other, we would have 80% power to detect an absolute difference of 1.8% between groups.
- **Intrapartum caesarean section**
  The event rate for caesarean section for all women (high and low risk combined) who planned an OU birth was 4,505/32,052 = 14%. With a sample size of 8,300 in one group and 23,700 in the other, we would have 80% power to detect an absolute difference of 1.2% between groups.

(b) Comparison of maternal outcomes between planned births in OUs with a high volume of non OU births and planned births in OUs with a low volume of non OU births.

Data on the volume of non OU births in each trust will be obtained during the study, but we anticipate that trusts with a high volume will be in the minority. Assuming that 10% of planned OU births are in a high volume trust gives a sample size of 3,200 women (10% of 32,000) in this group and 28,800 in the low volume trust group. If the proportion of births in a high volume trust is higher than 10% then the power to detect the differences below will increase.

- **Straightforward vaginal birth**
  With a sample size of 3,200 in the high volume trusts and 28,800 in the low volume trusts, we would have 80% power to detect an absolute difference of 2.6% between groups (an increase from 56% to 58.6% or decrease to 53.4%).
- **Intrapartum caesarean section**
  With a sample size of 3,200 in the high volume trusts and 28,800 in the low volume trusts, we would have 80% power to detect an absolute difference of 1.2% between groups (an increase from 14% to 15.2% or decrease to 12.8%).

(c) Comparison of maternal outcomes and transfer rates between time and day

This will be performed separately for each planned place of birth; FMUs were the smallest group with 11,666 women. If we assume that deliveries are distributed evenly during the week, then around 4,166 of these women would have given birth on a weekday, 4,166 on a weekday night, 1,667 on a weekend day and 1,667 on a weekend night.

- **Straightforward vaginal birth**
  The event rate for straightforward vaginal birth for all women (high and low risk combined) who planned a birth in an FMU in the Birthplace Cohort study was 9,875/11,537 = 86%. Comparing the 2 largest groups of size 4,166, we would have 80% power to detect an absolute difference of 2.1%. Comparing the 2 smallest groups of size 1,667, we would have 80% power to detect an absolute difference of 3.2%.
- **Intrapartum caesarean section**
  The event rate for caesarean section for all women (high and low risk combined) who planned a birth in an FMU was 418/11,569 = 3.6%. Comparing the 2 largest groups of size 4,166, we would have 80% power to detect an absolute decrease of 1.1% from to 2.5% or an absolute increase of 1.4% to 4.8%. Comparing the 2 smallest groups of size 1,667, we would have 80% power to detect an absolute decrease of 1.6% to 2% or an absolute increase of 2% to 5.6%.
- **Transfers during labour or immediately after birth** The event rate for transfer during labour or immediately after birth for all women (high and low risk combined) who planned a birth in an FMU in the Birthplace Cohort study was 2,553/11,571 = 22%. Comparing the 2 largest groups of size 4,166, we would have 80% power to detect an absolute difference of 2.6%. Comparing the 2 smallest groups of size 1,667, we would have 80% power to detect an absolute difference of 3.9%.

(d) Perinatal outcomes among "higher risk" women with planned OU births (excluding women who had induction of labour) compared to women with planned home births

In the Birthplace cohort study, there were 12,374 "higher risk" women who planned an OU birth, and 5,811 of these had induction of labour, leaving 6,563 for this analysis. There were 1,346 "higher risk" women who planned a home birth (1,325 with non missing data).

- **'Adverse perinatal outcome'**
  The event rate for 'adverse perinatal outcome' for "higher risk" women (including those who had induction of labour) was 57/12308 = 4.7 per 1000 among those who planned an OU birth and 12/1,325 = 7.7 per 1000 among those that planned a home birth. With a sample size of 6,563 in the OU group and 1,325 in the home group, we would have 80% power to detect an absolute decrease from 7.7 per 1000 in the home group to 1.6 per 1000 in the OU group.
- **Apgar score <7 at 5 minutes**
  The event rate for Apgar <7 at 5 minutes for "higher risk" women (including those who had induction of labour) was 166/12,352 = 13.8 per 1000 among those who planned an OU birth and 19/1,342 = 13.9 per 1000 among those that planned a home birth. With a sample size of 6,563 in the OU group and 1,342 in the home group, we would have 80% power to detect an absolute decrease from 13.9 per 1000 in the home group to 5.3 per 1000 in the OU group.