Birthplace in England Research Programme

National Prospective Cohort Study of Planned Place of Birth

Protocol

Version 2

MREC Ref: 07/H0505/151

Contents

Background

A range of initiatives are driving changes in the organisation and delivery of maternity care. In the 1990s Changing Childbirth (1) recommended that the planning and delivery of maternity care should be responsive to individual needs, and enable women to make informed choices about their care. Subsequent NHS policies and priorities, such as Keeping the NHS Local (2), have placed greater power and control in the hands of maternity service users by aiming to provide a seamless service to facilitate service users' journeys through organisational and professional boundaries. Changes in workforce deployment such as the Changing Workforce Programme (3) revisions to medical training, the European Working Time Directive (4), maternity staffing standards (5) and neonatal service reconfigurations are altering organisational and professional practice boundaries. This has resulted in the introduction of support workers (6), extending the roles of nurses and midwives to include activities usually undertaken by medical staff, and the promotion of midwifery-led care. The implementation of these initiatives is taking place within a complex service, involving a range of caregivers in different settings across the acute and primary care sectors, to meet diverse needs which range from promoting health and well-being to high dependency care of sick women and babies.

The Maternity Standard of the National Service Framework (NSF) for Children, Young People and Maternity Services specified that "Every woman [should be] able to choose the most appropriate place and professional to attend her during childbirth based on her wishes and cultural preferences and any medical and obstetric needs she and her baby may have" (7). Maternity Matters, the implementation plan for the NSF, consolidated this policy direction for maternity care which emphasises patient choice, local service provision and easy access (8). By the end of 2009, depending on their circumstances, a woman and her partner should be able to choose where they wish to give birth: at home, in a local midwifery unit or in an obstetric unit (8).

Reviews of research used to support the development of these policies have identified major gaps in the evidence. These gaps include any accurate quantification of the risk of any adverse outcomes associated with birth in the different settings. In addition, poor and inconsistent classification of clinical settings for birth has further compromised evaluations of process, clinical outcomes and cost-effectiveness. One major problem in interpreting much of the evidence is that 'actual place of birth' has been used to make inferences about 'planned place of birth', as 'planned place of birth' is usually not recorded in routine data collection systems in the UK (9, 10, 11, 12).

A Cochrane systematic review of home versus hospital birth, which included only one trial with 11 women, showed no clear differences in safety or other outcomes between the two settings (13). A meta-analysis of observational studies comparing planned home and planned hospital birth examined perinatal outcomes for 24,092 'low risk' women and their babies (14). No difference was observed for perinatal mortality (OR = 0.87, 95% CI 0.54-1.41). However, there was evidence that women planning birth at home had a lower risk of severe perineal lacerations (OR = 0.67, 95% CI 0.54-0.83) and that their babies were less likely to have low Apgar scores (OR = 0.55, 95% CI 0.41-

0.74). Also, there was evidence that women planning birth at home had a lower frequency of induction, augmentation, episiotomy, instrumental vaginal birth, and caesarean section.

NHS midwifery units provide midwife-led care for women who are at low risk of complications at the onset of labour (15). Midwifery units can be categorised as 'freestanding' (on a site geographically separate from an obstetric unit) or 'alongside' (in the same building or on the same site as an obstetric unit). A Cochrane systematic review of randomised controlled trials of 8,677 women comparing birth in home-like settings with conventional institutional settings showed that women who gave birth in home-like settings experienced a statistically significantly greater satisfaction with care (RR = 1.14, 95% CI 1.07-1.21), were more likely to have no intrapartum analgesia (RR = 1.19, 95% CI 1.01-1.40), and were less likely to have an episiotomy (RR = 0.85, 95% CI 0.74-0.99). There was some suggestion that births in home-like settings may have been associated with higher perinatal mortality (RR = 1.83, 95% CI 0.99-3.38) (16). No trials of freestanding midwifery units were found for this review.

Prospective observational studies of free-standing midwifery units also show a reduction in intervention during labour. However, it is difficult to draw clear conclusions about the effect of setting for place of birth on outcomes due to the heterogeneity of studies, poor study design and the varied outcome measures used. No randomised trials have been undertaken to evaluate freestanding midwifery units in the UK (10, 17). Current development of birth centres in England is ad-hoc and poorly evaluated, with a lack of agreed quality standards and benchmarks (18).

High quality evidence about the risks and benefits associated with planning to give birth in different settings should be available to women. The draft clinical guidance on planning place of birth, intrapartum care, published for public consultation in March 2007 by the National Institute for Health and Clinical Excellence recommended that "A prospective study should be carried out in the UK to evaluate planning to give birth at home" (19). It is in this context that the Birthplace in England Research Programme (Birthplace) (http://www.npeu.ox.ac.uk/birthplace) has been designed to compare the safety of the different settings for birth supported by the NHS in England.

The national prospective cohort study described in this document is one component of the Birthplace Research Programme. The study aims to evaluate the safety of planned birth at home, in freestanding midwifery units, in alongside midwifery units and in obstetric units. Collecting information from all births planned at home in England represents a major challenge and it is acknowledged that there is no certainty this will be possible. Therefore, the Birthplace Feasibility Study, funded by the the Department of Health (DH) Policy Research Programme, is currently being conducted to evaluate the feasibility of the inclusion of the 'planned birth at home' component in this national prospective cohort study. A decision about whether or not feasibility has been demonstrated will be made in December 2007. If it is not feasible to collect information about planned birth at home, the national cohort study will only collect information on planned birth in midwifery units and obstetric units. If feasibility is demonstrated, the

planned birth at home component will be included in the cohort study to provide a complete picture of the outcomes associated with all the settings currently supported by the NHS for birth in England.

Aim

To compare the safety of planned birth at home, in freestanding and alongside midwifery units and in obstetric units in England.

Primary Objective

To compare neonatal mortality and morbidity for planned birth at home, in a freestanding midwifery unit and in an alongside midwifery unit with planned birth in an obstetric unit, for women judged to be at 'low risk' of complications at labour onset.*

Secondary Objectives

- To compare maternal morbidity for planned birth at home, in a freestanding midwifery unit and in an alongside midwifery unit with planned birth in an obstetric unit, for women judged to be at 'low risk' of complications at labour onset.
- To compare neonatal mortality and morbidity for planned birth at home, in a freestanding midwifery unit and in an alongside midwifery unit with planned birth in an obstetric unit, for all women, irrespective of risk at labour onset.
- To compare maternal and infant birth interventions and outcomes for planned birth at home, in a freestanding midwifery unit and in an alongside midwifery unit with planned birth in an obstetric unit, for women judged to be at 'low risk' of complications at labour onset.
- To compare neonatal and maternal outcomes for women who transfer from home, freestanding midwifery units and alongside midwifery units, during or immediately after labour, with outcomes for women who are not transferred.
- To determine whether indication for transfer, time from decision making until transfer, duration of transfer or events after transfer are associated with poor outcomes for women who are transferred during or immediately after labour.

Methods

Study design

Prospective cohort study with planned place of birth as the exposure and neonatal mortality and morbidity as the primary outcome.

**Note: All comparisons between women who planned to give birth at home or in a midwifery unit and women who planned to give birth in an obstetric unit will be made using planned births in obstetric units as the reference group. This will maximise statistical efficiency and does not imply obstetric units are being considered the standard of care.*

Definitions

Planned birth at home

A birth which occurs for a woman who, at the start of care in labour, intended to give birth at home and who received care from a midwife during established labour at home, regardless of where the woman actually gives birth.

Planned birth in a midwifery unit (freestanding or alongside)

A birth which occurs for a woman who, at the start of care in labour, intended to give birth in a midwifery unit and who received care from a midwife during established labour in a midwifery unit, regardless of where the woman actually gives birth.

Planned birth in an obstetric unit

A birth which occurs for a woman who, at the start of care in labour, intended to give birth in an obstetric unit and who was admitted and received care during established labour in an obstetric unit.

Inclusion criteria

Data will be collected for all women planning birth at home, in freestanding midwifery units and in alongside midwifery units who are attended by a midwife during labour, for any amount of time, in their planned place of birth.

Data will be collected for all women planning birth in an obstetric unit except:

- Women who have an elective caesarean section or any caesarean section before the onset of labour
- Women who present in labour before 36 completed weeks gestation
- Women with a multiple pregnancy

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

Study sites

All NHS Trusts providing maternity care in England will be included in the study. The aim is to collect data on every woman planning a home birth in England who has an NHS midwife providing her care. All midwifery units in England, both freestanding and alongside, will be invited to participate in the study. Twenty eight randomly selected obstetric units will be included in the study, stratified by size and geographic location to be representative of obstetric units in England. Data from an ongoing national mapping survey of all NHS Trusts providing maternity care in England will provide the sampling frame for the selection of the obstetric units. These mapping data are being collected as part of the Birthplace Research Programme in collaboration with the Healthcare Commission review of maternity services and will be available in October 2007 (20).

Ethics and R&D Approvals

Relevant approvals will be sought and achieved before data collection begins.

Outcomes

Primary outcome

Composite outcome* of neonatal mortality and morbidity: stillbirth after presentation in labour, early neonatal death (within 7 days of birth), neonatal encephalopathy, meconium aspiration, brachial plexus injury, fractured humerus or clavicle.**

Secondary outcomes

Interventions during labour:

- Syntocinon augmentation
- Epidural or spinal
- General anaesthetic
- Normal birth
- Immersion in water for pain relief
- Active management of the third stage

Neonatal outcomes:

- Stillbirth after presentation in labour
- Apgar score <7 at 5 minutes
- Early neonatal death (within 7 days of birth)
- Neonatal encephalopathy
- Meconium aspiration
- Brachial plexus injury
- Fractured humerus***
- Fractured clavicle***
- Fractured skull**
- Cephalohaematoma
- Cerebral haemorrhage
- Early onset neonatal sepsis (within 48 hours of birth)
- Kernicterus
- Seizures
- Admissions to neonatal unit within 48 hours of birth for at least 48 hours with evidence of feeding difficulties or respiratory distress

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

***Note: The signs of mild encephalopathy can be subtle; hence a number of such babies are likely to have a range of non-specific signs such as respiratory difficulty and poor feeding rather than features more specifically associated with encephalopathy. Since this is a mature group of babies, any difference in the incidence of these "other" admissions is likely to result from differences in the incidence of perinatal asphyxia.*

****These outcomes refer to diagnosed fractures. Minor fractures, particularly of the clavicle, are often missed and have little or no clinical significance. These fractures will not be specifically sought by this study as the aim is to collect data routinely recorded in medical records.*

Maternal outcomes:

- Maternal death (within 42 days of giving birth)
- Mode of birth: spontaneous vaginal birth (cephalic/breech presentation), instrumental vaginal birth or caesarean section
- Episiotomy
- Third or fourth degree perineal trauma
- Blood transfusion
- Breastfeeding initiation
- Admission to Intensive Therapy Unit /High Dependency Unit

Data collection

Collection of accurate and consistent information on all women giving birth in each setting during the study period is needed to calculate a reliable estimate of the adverse outcome incidence. Routine data collection systems are not fit for this purpose because of the variety of hospital information systems in use, inconsistencies in definitions between maternity systems and poor population coverage.

Detailed information will be collected for every eligible woman giving birth during the study period using specially designed data collection forms. The following core data items to be collected will be the same for each planned place of birth:

Demographic data

- Mother's full name
- Mother's date of birth
- Mother's NHS number
- Mother's address including postcode
- Mother's age
- Mother's ethnicity
- Mother's understanding of English language
- Mother's marital status
- Mother's BMI
- Baby's NHS number

Obstetric details

- Mother's medical history
- Mother's obstetric history
- Gestation at delivery

Process data

- Date of delivery
- Transfer data

Maternal and infant outcomes

- Mode of onset of labour

- Mode of birth
- Perineal trauma (Episiotomy, 3rd and 4th degree trauma)
- Outcome of pregnancy (live/stillbirth)
- Sex of baby
- Birthweight of baby
- Apgar score at 5 minutes
- Postnatal maternal transfer
- Maternal blood transfusion
- Initiation of breastfeeding
- Neonatal transfer
- Neonatal morbidity
- Early neonatal death (within 7 days of birth)

Organisational data

A number of organisational and staffing factors are known to impact on the quality of care women receive. Checks will be made on changes to overall midwifery and medical staffing since the mapping data were collected. Within each trust, detailed data will be collected prospectively on throughput, staffing and outcomes at discharge. This will allow us to look at case-mix and outcomes directly linked with staffing and organisation on a day-to-day basis using methods similar to those successfully employed in the National Sentinel Caesarean Section Audit (NSCSA) (21) and the UK Neonatal Staffing Study (22). This will involve completing labour ward logs twice a day in all freestanding midwifery units, alongside midwifery units and the stratified sample of obstetric units, selected on the basis of the size and geographic location data provided by the mapping study. Staff will be asked to complete data sheets daily at specified times logging staffing levels and availability, admissions, transfers, and discharges.

Local co-ordinating midwives (LCMs)

Designated local co-ordinating midwives (LCMs) will act as the link between the midwives providing intrapartum care to women throughout England and the co-ordinating centre at the National Perinatal Epidemiology Unit (NPEU). Through consultation with Heads of Midwifery, at least one LCM will be identified in each Trust, depending on the size and service configuration within the Trust. LCMs are likely to be clinical midwives involved in intrapartum care. Supported by the Birthplace Research Programme staff at the NPEU, the LCMs will organise and manage the data collection forms which will be completed by the midwives who provide intrapartum care for women in their Trust.

The Birthplace Research Programme staff at the NPEU will organise study days for the LCMs, to provide information about the study background and methodology. These study days will also offer opportunities for wider consultation on the study procedures and consideration of potential problems that could arise at Trust level during data collection. A number of resources will also be made available to support the LCMs to publicise the study locally including teaching materials, posters and pens.

Tools and systems for data collection

The systems that will be used for data collection have been adapted from those used successfully in the National Sentinel Caesarean Section Audit (19) and have been tested in the Birthplace Feasibility Study. In order to make accurate and reliable comparisons between women planning birth in different settings it will be necessary to collect data for large numbers of women and their babies.

Data collection for the Birthplace Feasibility Study only included planned home births. The organisation of intrapartum care and postnatal care services are similar for home births and for freestanding midwifery units. The midwife who provides intrapartum care in these settings is likely to continue caring for the woman during the postnatal period. In alongside midwifery units and obstetric units the organisation of maternity services is more separate. The midwife who provides intrapartum care is unlikely to continue providing care during the postnatal period. As a result, it will be necessary to test the data collection systems that were developed in the Birthplace Feasibility Study in alongside midwifery units and obstetric units. The data collection systems will be tested for two weeks in the three Trusts that participated in the Birthplace Feasibility Study. This will ensure that the current data collection systems are adequate for births that are planned in alongside midwifery units and obstetric units.

Individual women will not be asked to give consent to participate in the study as the care they receive will not change in any way as a result of the study. Also, all of the data that will be collected are routinely recorded in the maternity, postnatal or neonatal notes. In addition the process of seeking and obtaining consent would be likely to introduce substantial bias in the composition of the comparison groups.

A unique participant number will be on the front page and the second page of each data collection form. The data collection form will have a detachable front page, on which the woman's identifying information will be recorded. The rest of the data collection form will not contain any identifiers, except for the woman's postcode. The information collected on the section of the form that will be returned to the NPEU will include demographic information, details of maternal obstetric history, pregnancy, labour, birth and neonatal and maternal outcomes. The attending midwife will complete the data collection form using information available in the woman's maternity notes and from the outcome of the birth.

The only personally identifying information that will be returned to the NPEU will be the woman's postcode. The post code will be used to generate an index of multiple deprivation score for each woman. A measure of deprivation is important because if it is related to planned place of birth and having an adverse outcome it could be an important confounding factor that should be controlled for in the analysis. An application will be submitted to the Patient Information and Advisory Group (PIAG) in order to gain permission to collect women's postcode without asking for their consent to participate in the study (23). If approval is not granted by PIAG women's postcode will not be collected.

The outcomes for women and their babies who are transferred from their planned place of birth during or after labour will also be collected. This is important as these births are more likely to be associated with adverse outcomes. When a woman is transferred, the attending midwife will ensure the data form goes with the woman and that remaining data items are completed. The process of collecting these data will rely on the participation of midwives and occasionally neonatologists. Working with LCMs and, for example, the supervisors of midwives and heads of midwifery, a system to validate maternal and neonatal outcomes collected in the Birthplace forms will be developed, implemented and assured in each Trust. This will build on existing risk management reporting systems.

Completed data collection forms will be sent by midwives collecting data to their LCM. In order to ensure data quality, LCMs will validate data content and completeness, checking the maternity case notes if necessary. Also, to ensure all planned home births are included, the LCM will compare the number of forms received with appropriate local records, including records of planned home births, delivery suite and theatre registers and records of transfers to obstetric care. The LCM will detach and retain the front page and send the rest of the data collection form to the data management company for double data entry. The front page of the data collection forms will be retained by the LCMs and will be stored in a locked filing cabinet for at least 5 years or, if longer, the duration of time specified by local NHS Trust R&D procedures. LCMs will liaise with the relevant R&D departments in their Trust to ensure secure storage of these data.

Completed data collection forms will be sent from the LCM to the data management company on a regular basis, at least once every two weeks. On receiving data collection forms the data management company will scan the forms to record that they have been received. The data management company will coordinate the double data entry. Two different operators will enter the data for each data collection form. Checks will be run for inconsistencies and incomplete data. An electronic copy of the most up to date data set along with a report of all of the validation checks that have been run will be provided to the NPEU by the data management company on a weekly basis using a secure online system. The research team at the NPEU will refer any data queries that need to be followed up to the appropriate LCM. The unique identifier on each form will allow the NPEU to tell the LCM which participants have inconsistent, ambiguous, or missing data that needs to be checked.

During the period of data collection, regular contact will be maintained between the LCMs and the research staff at the NPEU in order to address any problems or queries with data collection.

After each batch of forms has been double data entered, the data management company will send the data collection forms to the NPEU. Data forms will be stored at the NPEU in a secure space, with access restricted to specified staff. It is the policy of the NPEU that data are held in perpetuity.

A data management company will be used for the double data entry due to the large amount of data entry that will be required for the study. During peak periods it is anticipated that over 3000 data collection forms will need to be double data entered each week. Outsourcing the data entry will be much more efficient and cost effective than entering the data in house at the NPEU. The company that is contracted to manage the data entry will provide evidence that they comply with the Data Protection Act 1998 and will be registered with the Information Commissioner.

Sample size considerations

The primary outcome for the national study is a composite outcome of neonatal mortality and morbidity likely to be related to the quality of intrapartum care: stillbirth after presentation in labour, early neonatal death (within 7 days of birth), neonatal encephalopathy, meconium aspiration, brachial plexus injury, fractured humerus or clavicle. The incidence of this composite outcome in women judged to be at "low risk" when presenting in labour has been used to determine the sample size needed for the national study to have adequate power to detect clinically important differences in outcome by planned place of birth. Fortunately, major neonatal and maternal morbidity in women judged to be at "low risk" at term are rare. The incidence of neonatal encephalopathy at term is approximately 1.8 per 1,000 live births (24). However, the incidence of intrapartum stillbirth after labour onset, early neonatal death and other related neonatal morbidity at term is much less certain. A reasonable estimate of the incidence of the composite measure of any neonatal morbidity, the primary outcome for the study, is 3.6 per 1,000 births. As the vast majority of data on neonatal morbidity are from obstetric units, this estimate is assumed to be the incidence of the composite outcome in obstetric units.

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

Obstetric Units

Since most births in England occur in obstetric units, the national study will collect data from more women planning to deliver in this setting than any of the other settings in order to increase the statistical power of the study. We will aim to collect data on at least 20,000 women planning to give birth in an obstetric unit, who are considered to be at 'low risk' of complications at labour onset. As not all women who plan to give birth in an obstetric unit are considered to be 'low risk', we will collect data on approximately 30,000 women planning birth in obstetric units, in order to achieve the sample size of at least 20,000 'low risk' women. Data will be collected from a stratified random sample of 28 obstetric units for approximately 3 months in each unit.

Birth at Home

Although the number of women planning birth at home in England is not known, we do know the number of women who give birth at home, and the most recent published

statistics demonstrate that approximately 15,000 women gave birth at home in England in 2005 (25). Using this and other available data we can estimate the number of women who plan to give birth at home in England. The proportion of women who plan to give birth at home but transfer in labour from home to hospital may be as high as 43% of those who begin a planned home birth and the proportion of women who have unplanned home births may be as high as 50% of those who give birth at home (26, 27). Excluding women who plan birth at home but transfer from home to hospital during labour would underestimate the number of planned home births. Inclusion of unplanned home births would overestimate the number of planned home births. Taking these parameters into account we have estimated the number of women planning birth at home in England to be approximately 15,000 per year. The study aims to collect data on at least 85% of all women planning birth at home over 16 months, that is, from at least 17,000 women.

With data from 17,000 births which were planned to be at home, it will be possible to detect an increase in the incidence of the composite outcome, from 3.6 per 1,000 births in obstetric units to 5.7 per 1,000 for planned home births, at a 5% significance level with 82% power. Alternatively, the study will be able to detect a reduction in the incidence of the composite outcome, from 3.6 per 1,000 births in obstetric units to 2.0 per 1,000 births for home births, at a 5% significance level with 80% power.

Midwifery Units

In 2004 there were estimated to be 57 freestanding and 32 alongside midwifery units in England (25). This number is likely to have increased, given the policy direction of the NSF Maternity Standard. The median number of births in freestanding midwifery units in 2004 was 175, ranging from 18 to 1,891 (25). Based on these numbers, we estimate that there are approximately 10,000 births in freestanding midwifery units per year. No data are available for the number of births in alongside midwifery units but we believe it may be similar to the number of births in freestanding midwifery units. Data collection is planned for 6 months in each type of midwifery unit, which will allow approximately 5,000 women from each type of unit to be included in the study. Freestanding and alongside midwifery units will be analysed separately when being compared to obstetric units.

The study will be able to detect an increase in the incidence of the composite outcome, from 3.6 per 1,000 births in obstetric units to 6.8 per 1,000 in midwifery units, at a 5% significance level with 80% power. Alternatively, the study will be able to detect a reduction in the incidence of the composite outcome, from 3.6 per 1,000 births in obstetric units to 1.2 per 1,000 births in midwifery units, at a 5% significance level with 80% power.

If freestanding and alongside midwifery units are analysed as one group, there will be data from at least 10,000 planned births in these units for the analysis. The study will be able to detect an increase in the incidence of the composite outcome, from 3.6 per 1,000 births in obstetric units to 6.0 per 1,000 in midwifery units, at a 5% significance level with 80% power. Alternatively, the study will be able to detect a reduction in the

incidence of the composite outcome, from 3.6 per 1,000 births in obstetric units to 1.7 per 1,000 births in midwifery units, at a 5% significance level with 81% power. The study will also be able to detect much more modest differences in relatively common serious outcomes of maternal morbidity amongst women at low risk of complications, such as blood transfusion which affects approximately 0.5% of women (28), and 3rd and 4th degree perineal trauma which is experienced by 1.2% of women (29).

Analysis

The detailed analysis plan will be formally agreed by the Co-investigator Group, with input from the Advisory Group, before data collection starts. Initially, the outcomes and characteristics of the women who planned birth in each setting will be described. Odds ratios will be calculated to compare outcomes by planned place of birth using the obstetric unit women as the comparison group. All women will be analysed by the setting in which they first received care from a health professional during labour, if that was their planned place of birth. Appropriate referral and transfer is an important element of the quality of care received by women. It is therefore important to count women in the group where they planned to give birth, regardless of where the birth actually took place.

The primary outcome of neonatal mortality and morbidity, for women considered to be at 'low risk' of complications at labour onset, will be compared by planned place of birth. The criteria set out in the NICE Intrapartum Care Guidelines, which are due for publication in September 2007, will be used to assess whether a woman would be defined as "low risk" at the onset of labour (30). Crude odds ratios will be calculated, each with a 95% confidence interval. Outcomes for each group (home, freestanding midwifery unit and alongside midwifery unit) will be compared with outcomes for women planning birth in an obstetric unit. These crude odds ratios will be adjusted in a regression model, to take account of potential confounders such as parity, age, deprivation score and other factors which may be associated with planned place of birth and adverse outcomes in pregnancy.

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

Crude odds ratios will be calculated comparing outcomes for women who transferred from each setting to the women who did not transfer from that setting, with 99% confidence intervals. These crude odds ratios will be adjusted in a regression model, to take account of potential confounders such as parity, age, deprivation score and other factors which may be associated with planned place of birth and adverse outcomes in pregnancy.

Women who transferred from their planned place of birth and had an adverse outcome will be compared to women who transferred and did not have an adverse outcome. Indication for transfer, time from decision to transfer to start of transfer, duration of transfer, and events after the transfer will be investigated as factors that may be associated with adverse outcomes.

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

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

Timetable

In December 2007, a decision will be made about whether or not it is feasible to include planned birth at home in the national cohort study. If it is feasible, data collection on planned birth at home will continue on a national level for 16 months, from January 2008 to April 2009. If it is not feasible, the planned birth at home component will not be included in the national study.

Each midwifery unit will collect data for at least 6 months and each obstetric unit will collect data for at least 3 months. However, not all midwifery units or obstetric units will start and finish collecting data at the same time and data in these units will be collected over approximately 7 months, from May to November 2008.

Data analysis will take place over 4 months, from April to July 2009. The results of the study will be disseminated in July and August of 2009.

A detailed timetable is given in Appendix A.

Funding

Birthplace combines the Evaluation of Maternity Units in England (EMU) research programme funded by the NIHR Service Delivery and Organisation (SDO) Programme, and the Birth at Home study, funded by the Department of Health's Policy Research Programme.

Organisation & Governance

Co-investigator Group (CiG)

CiG members will be responsible for assisting the Chief Investigator to achieve governance of the whole programme. The CiG will be accountable to the Department of Health and the NIHR Service Delivery and Organisation (SDO) Programme. Members are drawn from a wide range of maternity care stakeholder groups: clinical, service

management, planning, policy, research and consumer representation. This group will normally meet face-to-face twice a year, with teleconference meetings at least every three months. The CiG members are listed below:

Professor Peter Brocklehurst Director, NPEU	Chief investigator, expert obstetric epidemiologist
Ms Rona McCandlish Epidemiologist, NPEU	Co-investigator, expert in co-ordination of epidemiological research and analysis of clinical data
Dr Stavros Petrou Health Economist, NPEU	Co-investigator, expert health economist
Dr Maggie Redshaw Social Scientist, NPEU	Co-investigator, expert in social science and in organisation and systems of care
Professor Alison Macfarlane City University	Expert in maternity service organisation and statistical analysis of routine data
Professor Chris McCourt Thames Valley University	Expert in social science and in systems and organisation of care, access and women's choices
Professor Jane Sandall King's College London	Expert in use of mixed-methods in social science and in organisation of care and woman's choices
Professor Rona Campbell University of Bristol	Expert in maternity service organisation and statistical analysis of routine data
Ms Alison Miller CEMACH	Expert in collection, organisation and statistical analysis of routine data
Professor Neil Marlow University of Nottingham	Expert in neonatal care, service organisation and clinical research
Ms Louise Silverton Royal College of Midwives	Expert in maternity service management, organisation and policy
Ms Mary Newburn National Childbirth Trust	Expert in maternity service policy, organisation and consumers' experiences of services
Professor Deirdre Murphy University of Dublin	Expert in obstetric care, service provision and clinical research

Project management group (PMG)

The PMG will be accountable to the Co-investigator group. Core membership will be co-investigators and study staff, all of whom are based at the NPEU. This group will normally meet at least every 2 weeks for the duration of the study. The PMG members are listed below:

Professor Peter Brocklehurst	Director
Ms Rona McCandlish	Epidemiologist
Dr Stavros Petrou	Health Economist
Dr Maggie Redshaw	Social Scientist
Ms Liz Schroeder	Health Economist
Ms Rachel Rowe	Co-ordinating Researcher
Mr David Puddicombe	Research Assistant
Ms Laura Murray-White	Administrator
Ms Mary Stewart	Research Midwife
Dr Bob Gatten	Computer Programmer

Advisory Group (AG)

The advisory group will provide advice to the CiG on the overall conduct of the study. Membership is drawn from stakeholders with knowledge and experience of contemporary maternity services in England, including experienced maternity care researchers. The Advisory group members are listed below:

Professor Allan Templeton RCOG	President of the Royal College of Obstetricians and Gynaecologists
Mr Jim Dornan RCOG	Vice-President of the Royal College of Obstetricians and Gynaecologists
Professor Cathy Warwick King's College Hospital	General Manager Women's and Children's Services
Ms Jill Demilew King's College Hospital	Consultant Midwife
Ms Sara Kenyon University of Leicester	MRC ORACLE Children's Study
Ms Jane Walker Homerton University Hospital	Consultant Midwife, Supervisor of Midwives
Ms Kate Sallah Tashie Consulting Ltd	Independent midwifery management consultant

Ms Christina McKenzie Nursing and Midwifery Council	Head of Midwifery
Ms Gail McConnell Barnet, Enfield & Haringey	Chair, Maternity Services Liaison Committee
Ms Maddie McMahon Rosie Hospital Cambridge	Birth & Postnatal Doula & Chair, Maternity Services Liaison Committee
Ms Sue Eardley Healthcare Commission	Project Lead - JARS and Maternity Services Children's Strategy Team
Professor Naomi Fulop King's College London	Department of Management School of Social Science and Public Policy
Dr Gary Hartnoll Chelsea & Westminster Hospital	Consultant Neonatologist
Dr Gwyneth Lewis Partnerships for Children, Families and Maternity Health and Care Partnerships Directorate	National Clinical Lead for Maternal Health and Maternity Services Director of the Maternal Deaths Enquiry for CEMACH

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Appendix A: Timetable

Birthplace: National prospective cohort study

	2007										2008												2009							
	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug
Develop protocol																														
Ethics / R&D approval																														
Develop and test tools/systems																														
Contact & engage heads of midwifery																														
Contact & engage clinical staff																														
Distribute data collection tools																														
Feasibility study																														
Data collection (Birth at Home)																														
Data collection (MUs & OUs)																														
Analysis																														
Advisors meetings					X					X										X										
Co-investigator group meetings								X				X				X				X				X				X		
Component working group leads meetings								X				X		X		X				X				X				X		
Reporting to SDO/DH										X																				X
Dissemination																														

Note: the hashed boxes indicate that the decision about whether birth at home is considered feasible will be made in December 2007