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Birthplace programme overview: background, component studies and summary of findings

Birthplace in England research programme. Final report part 1

Prepared by Jennifer Hollowell on behalf of the Birthplace in England Collaborative Group

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Glossary of terms/abbreviations

AMU	Alongside Midwifery Unit
ANNP	Advanced Neonatal Nurse Practitioners
CI	Confidence Interval
CNST	Clinical Negligence Scheme for Trust
CQC	Care Quality Commission
DH	Department of Health
FMU	Freestanding Midwifery Unit
GP	General Practitioner
HCC	Healthcare Commission
HDU	High Dependency Unit
ICER	Incremental cost-effectiveness ratio
MWS	Maternity Support Workers
NCT	NCT (formerly National Childbirth Trust)
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
NPEU	National Perinatal Epidemiology Unit
OU	Obstetric Unit
PSSRU	Personal Social Services Research Unit
RCM	Royal College of Midwives
RCOG	Royal College of Obstetricians and Gynaecologists
RR	Risk Ratio
SHA	Strategic Health Authority
WTE	Whole Time Equivalent

Acknowledgements

This overview report was prepared on behalf of the Birthplace in England Collaborative Group which includes the wider group of co-investigators, advisors, researcher, project staff and coordinating midwives who contributed to the research programme, Members are listed in the Appendix to this report.

1 Introduction

The Birthplace in England research programme is an integrated programme of research, utilizing a range of methodological approaches, designed to address gaps in the evidence relating to processes, outcomes and costs associated with different settings for birth in the NHS.

1.1 The purpose of this report

The purpose of this report is to provide:

- the background to the Birthplace programme;
- an overview of the component studies; and
- a cross-study synthesis of:
 - key findings;
 - implications for policy and practice;
 - recommendations for future research.

The individual component studies are reported in detail in parts 2-6 of this report.¹⁻⁵

Two component studies are ongoing and will be completed in autumn 2011:

- Intrapartum mortality by planned place of birth (see section 2.3.6 below)
- Cost-effectiveness analysis part 2 (decision analytic model) (see section 2.3.4 below)

1.2 Background

1.2.1 Policy 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.⁶⁻⁸ 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' (p.27).⁸

This standard required that service providers and Trusts ensured that *'...options for midwife-led care will include midwife-led units in the community or on a hospital site'* and that care was to be provided in a *'...framework which enables easy and early transfer of women and babies who unexpectedly require specialist care'* (p28).⁸ *Maternity Matters* consolidated this policy direction for maternity care emphasising 'choice, access and continuity in a safe service' and setting out a 'national choice guarantee' for place of birth.⁹ In addition, the Public Service (PSA) Delivery Agreement challenged maternity service providers to ensure that services were accessible to all women, including the vulnerable and excluded, so that a risk assessment can be completed, women could make informed choices about their care, and appropriate care and services were put in place to help improve life chances for children.¹⁰

The more recently published White Paper confirmed and re-emphasised the principle of consumer choice.^{11 12}

Alongside this policy direction, a range of service specific and general NHS directed initiatives have also driven changes in the organisation and delivery of maternity care. Changes in workforce deployment such as the Changing Workforce Programme, revisions to medical training, the European Working Time Directive, maternity staffing standards and neonatal service reconfigurations have all altered professional practice boundaries, skill mix and relationships.^{13, 14} This has resulted in the introduction of support workers, of senior medical staff taking on direct care, extending the roles of nurses and midwives to include activities usually undertaken by junior doctors, and the promotion of midwifery led care.¹⁵ The implementation of these initiatives has taken place within a complex service, with care delivered in a wide range of organisational settings across the acute and primary care sectors and involving a wide range of caregivers in order to meet diverse needs ranging from promoting health and well-being in an essentially healthy population to high dependency care of sick women and babies.

In this context, 'midwife-led/midwifery units' or 'birth centres' and home birth services have become increasingly relevant to the configuration of maternity services currently under consideration in England. NHS midwifery units provide midwife-led care for women who are at 'low risk' of complications. There are two broad types of midwifery unit: 'stand-alone' or 'freestanding' units situated on a site geographically separate from a hospital obstetric or 'consultant-led' unit, and 'alongside', 'co-located' or 'integrated' midwifery units which are in the same building or on the same site as an obstetric unit. They have the potential to increase early direct access to community based maternity care, and deliver responsive and effective high quality care, that improves the quality and women's experiences of pregnancy and birth. However, the current development of

midwifery units and home birth services in England is ad-hoc and poorly evaluated, with a lack of agreed quality standards and benchmarks.¹⁶

1.2.2 Research evidence

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 midwifery units. Evidence was also lacking about the number and characteristics of women planning birth in different settings, the staffing structures within midwifery units and their position within and relationship with the wider organisation and provision of maternity care, including obstetric and home birth services.

Reviews of research have also identified a lack of accurate quantification of the risk of adverse outcomes associated with births planned in these different settings. Furthermore, interpreting available evidence has been made more difficult because actual place of birth has often been used to make inferences about planned place of birth.^{6, 17-19}

Research on outcomes for women planning birth in midwifery units has been summarised in a Cochrane systematic review comparing birth in alternative birth settings with conventional institutional settings (obstetric units).²⁰ This review included nine randomised controlled trials and 10,684 women and the alternative birth settings studied were most similar to 'alongside' or 'co-located' midwifery units. Alternative birth settings were associated with an increased likelihood of spontaneous vaginal birth, increased maternal satisfaction and fewer interventions during labour and birth. There was no association between birth setting and severe perinatal morbidity or mortality (risk ratio (RR) 1.17, 95% CI 0.51-2.67). Also, there was no association between birth setting and serious maternal morbidity or mortality (RR 1.11, 95% CI 0.23-5.36). However, it is likely that the review was underpowered to detect any differences in rare but important severe adverse perinatal and maternal outcomes. No trials of 'freestanding' midwifery units were included in this review.

Prospective observational studies have shown a lower rate of intervention during labour for births planned in 'freestanding' midwifery units.^{19, 21}

Looking at home birth, a Cochrane systematic review of home versus hospital birth identified only one randomised controlled trial which included 11 women and was unable to detect any differences in safety or other outcomes between the two settings.²² A meta-analysis of six observational studies examined perinatal outcomes for 24,092 'low risk' women and their babies.²³ No difference was observed for perinatal mortality. There was

evidence that women planning birth at home had a lower risk of induction, augmentation, instrumental vaginal birth, caesarean section, episiotomy, severe perineal lacerations and that their babies were less likely to have low Apgar scores.

The results of several large observational studies comparing home births with birth in an obstetric unit have been published since the Birthplace Research Programme began in 2007. A retrospective cohort study from the Netherlands using routine data from over 500,000 women found no evidence of a difference in perinatal mortality or morbidity between 'low risk' women who planned to give birth at home and 'low risk' women who planned to give birth in hospital.²⁴ Canadian and Swedish studies of planned home births compared to planned hospital births for 'low risk' women also showed no difference in perinatal mortality.^{25, 26} Lower rates of obstetric interventions were observed in the planned home birth group for both studies. However, both studies included fewer than 20,000 births and lacked statistical power to demonstrate differences in rare but important adverse outcomes. A study using data from England and Wales attempted to quantify the intrapartum-related perinatal mortality rates for booked home births from 1994 to 2003 using routine statistics.²⁷ However, the data available were inadequate for this comparison and highlighted the need for a more rigorous quantification of the risks associated with each planned place of birth. A recent meta-analysis found planned home births, compared to planned hospital births, were associated with less medical intervention, had a similar perinatal mortality rate and an increased neonatal mortality rate.²⁸ This study has been criticised for failing to report the assessment of the quality of the studies included and for other methodological weaknesses.^{29 30}

It is difficult to draw clear conclusions about the effect of planned place of birth on outcomes due to differences in the health care systems in which studies were undertaken, the heterogeneity of studies, poor study design and the use of varied outcome measures. The National Institute for Health and Clinical Excellence's (NICE) clinical guidance on Intrapartum Care included guidance on planning place of birth and stated that "Of particular concern is the lack of reliable data, relating to relatively rare but serious outcomes such as perinatal mortality that is directly related to intrapartum events or serious maternal morbidity in all places of birth".³¹

Finally, given the complexity of maternity care provision, there is also a need for evidence about the features of maternity care organisations that are associated with high quality and safe care. High quality maternity care that crosses professional, institutional, geographical and temporal boundaries is predicated on developing effective pathways of care for a range of women. Research has highlighted communication barriers and a lack of collaborative working between health professionals as contributory factors to reduced safety.³² Successive confidential enquiries into maternal

deaths have also shown the contribution of poor interprofessional or interagency communication or teamwork to sub-standard care affecting outcomes.³³ There is a need to investigate how good communication and teamworking are pursued and achieved in different configurations of care.³⁴ It is also unclear to what extent midwifery unit care and home birth services can help meet the needs of individuals and communities that have been traditionally under-served, or where consultant obstetric services are no longer available locally. There is a need to investigate what kind of features work in practice to ensure equity of access and a high quality and safe service.

The Birthplace in England research programme was designed to fill these identified gaps in the research evidence and provide high quality evidence for use by policy makers, commissioners of services, health care professionals, women and their families to inform discussions and decisions about place of birth.

2 Overview of the Birthplace in England research programme

The main questions addressed by Birthplace are:

- How is intrapartum care organised?
- Are there differences in maternal and child outcomes between the various birth settings and, in particular, are there differences in safety for the babies of women at 'low risk' of complications according to current clinical guidelines?
- What is the comparative cost-effectiveness of the planned settings for birth?
- What are the features of maternity care systems that affect the quality and safety of care?

2.1 Aim

To provide high quality evidence about processes, outcomes and costs associated with different settings for birth in the NHS in England.

2.2 Objectives

Although conducted as an integrated research programme, the Birthplace in England research programme encompasses two separate programmes:

- Evaluation of Maternity Units in England, funded by the NIHR SDO Programme;
- Birth at Home in England study, funded by the Department of Health Policy research Programme.

Objectives of the Evaluation of Maternity units in England programme:

1. Determine the existing service configuration, system of care/network, process and outcomes of midwife-led units in England and to map changes over the three years of the project and describe the key drivers for change.
2. Describe women's choices, information needs, experiences and wellbeing associated with each type of clinical location for birth.
3. Evaluate the management and impact of transfer during labour from women's intended locations for birth at the time of onset of labour in relation to outcomes for mothers and babies.

4. Evaluate clinical outcomes, associated with location of birth, including safety, for woman and their babies at low risk of complications during labour and birth.
5. Evaluate the cost effectiveness of midwifery-led units and standard consultant-led units.
6. Identify valid and reliable woman-centred indicators and outcome measures for future benchmarking

Objectives of the Birth at Home in England study:

7. Determine the proportion of women in the England who plan to give birth at home.
8. Determine the proportion of women who transfer from home to another birth setting during labour.
9. Determine the clinical outcomes associated with planned birth at home in relation to maternal and neonatal morbidity, and to compare this with planned birth in freestanding midwifery units, alongside midwifery units and consultant-led units.
10. Determine the cost-effectiveness of planned birth at home compared with planned birth in freestanding midwifery units, alongside midwifery units and obstetric units.
11. Compare birth outcomes for women who plan birth at home and deliver at home with those who plan birth at home and who deliver in another birth setting

2.3 Overview of the component studies

The Birthplace in England research programme was planned as a series of six component studies, as outlined below.

2.3.1 Terms and definitions consensus process

This consensus study was undertaken to build on the existing literature review undertaken by the NPEU.³⁵ Current definitions and terminology associated with the settings in which birth takes place were synthesised and a consensus development process was undertaken to develop and agree terms and definitions to be used in the Birthplace programme.

Further details can be found in part 2 of the final report.¹

2.3.2 Mapping maternity care: the configuration of maternity care in England

The mapping study addressed the following key questions: How and where is intrapartum care organised? What role do midwifery-led units play in the current provision? How will changes in staffing influence the development of different settings of delivery. What are the future plans for midwifery-led unit development? How will changes in staffing in response to the European Working Time Directive (EWTD) influence the development of different settings for delivery?

The components study involved two questionnaire surveys of trusts and units providing maternity healthcare in England in 2007 and 2010. The first of the two surveys was a mandatory survey conducted by the Healthcare Commission in collaboration with Birthplace. The data used in the Birthplace analysis included details of midwifery and medical staffing, numbers of births/women delivered, planned and unplanned home births, eligibility criteria for planned AMU and FMU births, rooms and beds available, location and provision of specialist services, planned changes in capacity and staffing. The 2010 survey documented changes in configuration.

Further details can be found in part 3 of the final report.²

2.3.3 National prospective study of planned place of birth

This prospective cohort study of women using different models of intrapartum care addresses a number of questions: What are the maternal and child outcomes for the different types of care? What proportion of mothers and babies require transfer during labour or after birth from home, or a freestanding or alongside midwifery led setting to an obstetric led setting? How long do transfers take and is this acceptable in terms of safety? How can safe and effective transfer be ensured?

The cohort study was designed to compare outcomes by planned place of birth at the start of care in labour (Obstetric unit (OU), home, Freestanding Midwifery Unit (FMU), Alongside Midwifery Unit (AMU)). The primary objective was to compare intrapartum and early neonatal mortality and morbidity¹ by planned place of birth at the start of care in labour in women judged to be at 'low risk' of complications according to current national clinical guidelines. The study also compared a range of secondary outcomes (neonatal morbidities, 'normal birth', maternal interventions and maternal morbidities) by planned place of birth.

¹ Neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle.

The cohort study aimed to collect data from the vast majority of midwifery units and NHS trusts providing home birth services across England and a stratified, random sample of OUs.

Further details can be found in part 4 of the final report.³

2.3.4 Cost-effectiveness analysis

The aim of this component study was to determine the cost-effectiveness of the four planned settings for birth (OU, home FMU, AMU) in women at 'low risk' of complications prior to the onset of labour. This component study is being undertaken in two parts:

- An initial cost-effectiveness analysis using individual level data on resource use/costs and outcomes (effectiveness) collected in the Birthplace prospective cohort study. Findings of this study are presented in this report.
- A decision analytic modelling study addresses the cost-effectiveness of each type of care. This study will use a decision-analytic modelling approach to synthesise data from Birthplace with published, clinical, epidemiological and economic evidence within a cost-effectiveness modelling framework. This work is ongoing: results will be available in autumn 2011.

In the individual patient analyses presented here:

- The analysis of costs takes account of costs attributable to the episode of intrapartum care and the additional costs of any higher level health care associated with complications arising during labour or immediately after birth.
- Three measures of the effectiveness of planned place of birth were examined: adverse perinatal outcomes averted (the cohort study primary outcome), maternal morbidity avoided (a composite of secondary outcomes from the cohort study), and 'normal birth'.

The study provides estimates of:

- the relative costs of planned births in each setting; and
- the cost-effectiveness of planned birth in each non-OU setting compared with a planned OU birth; cost-effectiveness is assessed separately for each of three effectiveness measures outlined above

Further details can be found in part 5 of the final report.⁴

2.3.5 Qualitative organisational case studies

The primary aim of the organisational case studies was to describe and explore features of maternity care systems that may affect the provision of

high quality and safe care in different birth settings. A secondary aim was to describe and explore professional and consumer perceptions regarding access to choice of place of birth, and experiences of escalation of care when complications occur during labour and birth in different birth settings.

The case studies used qualitative methods to explore issues that may affect risks and safety in different settings with a particular focus on systems of care. Data were collected in four 'best' or 'better performing' NHS Trusts as identified by the Health Care Commission Review of Maternity Services in England in 2007. Data collection focused on Trust policies and practice, and the experiences of women and birth partners in their journey through the system of care from March through to December 2010. Interviews were conducted with service providers, managers and other key stakeholders including user-group representatives (n=86), service users and their birth partners (n=72). Other data included document analysis (approximately 200 documents) and observation of key 'nodes' in the service (n=50 transcripts).

Further details can be found in part 6 of the final report.⁵

2.3.6 National study of intrapartum related mortality

Because intrapartum related mortality is rare in 'low risk' women, the prospective cohort study evaluated the effect of planned place of birth on a composite outcome designed to capture both intrapartum mortality and intrapartum related neonatal morbidity. This component study will use a modelling approach, incorporating data from the Birthplace prospective cohort study, routine birth statistics and data from the Confidential Enquiry into Stillbirths and Deaths in Infancy (CEMACH) to evaluate intrapartum related mortality by planned place of birth.

This work is ongoing: results will be available in autumn 2011.

3 Overview of results

The main findings of the component studies are summarised below.

3.1 Terms and definitions

The terms obstetric unit, alongside midwifery unit and freestanding midwifery unit and associated definitions were agreed for use in the Birthplace programme.

3.2 Mapping maternity care

3.2.1 Units and configuration

In 2007 data were returned from all 152 trusts providing maternity care in England (100%). Fewer trusts responded to the 2010 survey (63%) though these were representative in terms of configuration. Basic data were available for all trusts in 2010 (100%) on numbers and types of unit and trust configuration.

The configuration of maternity care within trusts changed over the course of the study: in 2007, two thirds of trusts (66%) contained only one or more obstetric units and by 2010 the proportion had decreased to half (49%); in 2007, less than a fifth of trusts contained at least one AMU and by 2010 the proportion had increased to 35%; in 2007, 18% of trusts contained an FMU and by 2010 the proportion was 24%.

By 2010 the overall number of maternity units had increased by 11%, with twice as many AMUs as in 2007 (53 compared with 26)

Based on 2007 data the geographical distribution of maternity units, particularly OUs and delivery beds reflects the centres of population.

There were marked differences in the numbers of midwife-led units in different areas of England in 2007: FMUs were most common in the South West and AMUs were more likely in London and South Central SHAs.

3.2.2 Workload

Intrapartum care in an OU was the most common form of provision, with staff in OUs caring for more than 95% of women giving birth in hospital in the year ending 31 March 2007 (1% in FMUs and 3% in AMUs).

Each type of unit provided intrapartum care for radically different numbers of women: a median of 192 in FMUs, 613 in AMUs and 3217 in OUs in 2007.

All types of unit varied in the numbers of women giving birth: over a quarter of OUs (29%) reported having fewer than 2500 women giving birth and a similar proportion (26%) delivered more than 4000 women

Based on the 2007 trust data the median proportion of births that took place at home was 2.5%, including both planned and unplanned home births.

3.2.3 Capacity, occupancy and eligibility

Data were returned from 262 units in 2007 with 2193 delivery beds or bed spaces, 6.2% in FMUs, 6% in AMUs and most (88%) in OUs.

There was considerable variation in capacity for care during labour and birth between and within the types of unit: the medium number of delivery beds ranged from 2 in FMUs, 5 in AMUs to 10 in OUs.

There was substantial variability in 'occupancy' (women delivered per bed) across all unit types and between geographical regions. Eligibility criteria for admission to FMUs and to AMUs were not consistent for either type of unit.

3.2.4 Staffing

A total of 19,415 whole time equivalent (WTE) midwifery posts were reported in March 2007 and 5263 WTE maternity support worker posts.

A total of 3864 WTE medical staff working in obstetrics were reported in March 2007, almost entirely in OUs: similar proportions were senior house officers (31%), registrars (30%) and consultants (30%) and 9% were staff grades or associate specialists.

General practitioner (GP) involvement in intrapartum care was widely distributed, but at low density with only 11% of maternity units reporting GP engagement with maternity care (2 FMUs, 1 AMU and 30 OUs).

Paediatric or neonatal staff were on-call for the delivery suites or theatres associated with all AMUs and FMUs and in 44% of OUs Advanced Neonatal Nurse Practitioners (ANNPs) took on this role.

Overall the largest components of the midwifery maternity workforce were midwives employed at Bands 6 (52%) and 7 (21%), followed by maternity support workers at Band 2 (14%); less than 3% of the workforce were employed above this level.

Midwifery staffing levels (midwives per 1000 births) were higher in FMUs (median of 35 midwives per 1000 women giving birth compared with 31 per 1000 in AMUs and OUs); the number of maternity support staff per 1000 births was also higher in FMUs (23 per thousand women delivered vs. 7 and 8 per 1000 in AMUs and OUs respectively).

Some units did not employ MSWs in 2007: 15% of FMUs, 35% of AMUs and 2% of OUs did not do so. Of those that did, OUs were most likely to use them in delivery suite (99%, compared with 79% of AMUs and 46% of FMUs).

There was considerable variation between OUs in the ratio of obstetric medical staff per 1000 women delivered per year (median 6.8 per 1000), obstetric consultants (median 2 per 1000) and obstetric anaesthetist staff (2.5 per 1000).

3.2.5 Intrapartum related services

Almost all units provided a telephone triage system for early labour assessment and half reported providing early labour assessment by a midwife at home, a service most commonly provided by FMUs (65%) and AMUs (58%) compared with 47% of OUs.

A large proportion of maternity units of all types had fixed birthing pools (79%).

Specialist medical services on site that included a 24 hour epidural service, dedicated obstetric theatres, adult intensive care units and neonatal units and obstetric high dependency beds were more likely to be associated with OUs.

Where adult intensive care and neonatal care were not available on-site, the distance to such a facility varied considerably (median distance 17 miles).

3.2.6 Gaps in provision

Gaps in provision occur as a consequence of staffing, capacity and other issues: 4% of midwifery posts and 11% of maternity support worker posts were reported to be vacant on March 31 2007.

Midwifery vacancy rates varied with geographical area and were highest in London and lowest in the Yorkshire and Humberside region.

A total of 39% of maternity units reported closing to admissions on one or more occasions in the year to 31 March 2007 (32% of FMUs, 35% of AMUs and 39% of OUs); while OUs were more likely to have closed at all, AMUs and FMUs were more likely to have closed more often or for longer.

The overall turnover rate of midwifery staff due to resignations and retirements in the year to 31 March 2007 differed little across the different types of unit (7% FMUs, 8% AMUs and 7% OUs); individual unit turnover which varied from 0-40% was not related to size of OU or FMU unit as reflected in the numbers of women delivered, though an association was indicated for AMUs.

In 2007 the proportion of midwives aged 50 years or more was 21% (26% in FMUs, 22% in OUs and 19% in AMUs).

3.2.7 Recent and future changes in service provision

In comparison with 2007 by 2010 over three quarters of trusts had increased their midwifery establishments (77%), increased the numbers of consultant obstetricians (80%) and obstetric cover (77%).

By 2010 a third or more of trusts had increased the overall number of delivery units (36%), delivery bed capacity (44%) and paediatric cover (32%).

In 2010 substantial proportions of trusts were planning yet further increases in the number of delivery units (54%), delivery bed capacity (57%), the midwifery establishments set (66%), the numbers of consultant obstetricians (64%) and obstetric cover (58%).

3.3 National prospective study of planned place of birth

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

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

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

3.3.1 Births to 'low risk' women

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

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

Instrumental and operative deliveries and other interventions were less frequent in planned home, FMU and AMU births. Women in these groups

were significantly more likely to have a 'normal birth', defined as a spontaneous vaginal birth without induction of labour, an epidural or spinal anaesthetic or episiotomy, compared with women in the planned OU group. Higher rates of 'normal birth' were seen in the non-OU groups for both nulliparous and multiparous women.

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

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

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

3.3.2 Births to 'higher risk' women

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

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

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

3.4 Cost effectiveness analysis

3.4.1 Socio-demographic characteristics

A total of 62,036 women at 'low risk' of complications prior to the onset of labour were included in this analysis. Of these, 18,847 planned to give birth in an OU, 16,187 planned to give birth at home, 10,971 planned to give birth in a freestanding midwifery unit and 16,031 planned to give birth in an alongside midwifery unit.

The socio-demographic characteristics of women planning a birth at home were more similar to those planning birth in an FMU. The characteristics of women planning birth in an AMU were generally more similar to that of the planned OU group. The most marked contrast between the planned home birth group and the three other planned groups was in the distribution of parity: 27% of women planning a birth at home were nulliparous compared to 46%, 50% and 54%, respectively, in the planned FMU, AMU and OU groups.

3.4.2 Costs

Total costs captured all the resource use and the unit costs associated with intrapartum care and the immediate postnatal period after birth, including any higher level care for the mother or baby. The total unadjusted mean costs per 'low risk' woman at 'low risk' of complications prior to the onset of labour planning a birth in each setting were as follows: OU £1,631.2, AMU £1,461.2, FMU £1,434.9 and home £1,066.5. The total unadjusted mean costs per 'low risk' woman without complicating conditions at the start of care in labour were: OU £1,510.6, AMU £1,426.4, FMU £1,405.0 and home £1,026.9.

Adjusted cost differences were calculated for planned place of birth with birth in an OU as the reference group. The estimates were cost saving for all births planned in non-OU settings and this was statistically significant. The adjusted cost savings averaged £310 (home), £130.1 (FMU) and £134 (AMU). Adjusting for parity in a regression analysis on total cost resulted in sizable and significant cost differences, which overshadowed all other adjustments for confounding. The mean costs of care were substantially reduced for women who were parous compared to nulliparous. This cost-saving was accentuated for each previous pregnancy. The costs of care increased for a baby born above forty weeks gestation, representing a cost increment per additional week of gestation. A maternal age of thirty years and above was associated with an increase in the costs of care, and this was more apparent in women aged over forty years.

Mean differences in costs per woman for planned OU and non-OU births were weighted, adjusted and bootstrapped in an additional analysis. All

means costs of births in planned non-OU settings were cost-saving when compared with the mean cost of births planned in OUs, and the cost savings were as follows: £366.8 (home), £182.1 (FMU), £129.3 (AMU).

Additional subgroup analyses by parity were conducted. These identified that the total bootstrapped weighted mean costs per 'low risk' nulliparous woman was OU £2075.2, AMU £1,983.1, FMU £1,912.5 and home £1,793.7. In contrast, the total bootstrapped weighted mean costs per 'low risk' multiparous woman was: OU £1,142.4, AMU £991.3, FMU £968.9 and home £780.4.

3.4.3 Cost-effectiveness

Three sets of cost-effectiveness analyses were conducted; for the baby, the mother and for the outcome of 'normal birth'.

The incidence of adverse perinatal outcomes was low in all settings. The ICERs showed that, on average, births planned in non-OU settings would be cost saving when compared with births planned in an OU, and would lead to improved perinatal outcomes on average for births planned in the midwifery units, although considerable uncertainty surrounded the latter. Although the cohort study found no significant differences in the primary outcome by planned place of birth for 'low risk' women, analyses stratified by parity identified a significantly increased odds of an adverse perinatal outcome for 'low risk' nulliparous women in the planned home birth group. An additional cost-effectiveness analysis performed on nulliparous women who planned a birth at home resulted in a less-costly intrapartum maternity option but with increased adverse perinatal outcomes. This finding was repeated for nulliparous women of 'low risk' without complicating conditions at the start of care in labour where the economic evaluation showed planned home birth to be less costly but with statistically significantly worse perinatal outcomes. For multiparous women, there were no statistically significant differences between births planned in the different settings in rates of adverse perinatal outcome. For all bootstrapped replicates, the scatterplots of mean ICERs fell across the south east and south west quadrants of the cost-effectiveness plane, reflecting lower costs in planned non-OU settings accompanied by uncertainty surrounding changes to perinatal outcomes when compared to planned births in an OU.

The cost-effectiveness analyses conducted for maternal outcomes showed that planned births in non-OU unit settings led to improvements in maternal outcomes and reductions in costs to the NHS when compared to planned birth in an OU. All bootstrapped ICERs fell within the south east quadrant of the cost-effectiveness plane, confirming that births in planned non-OU settings would generate positive maternal health effects and less costly care.

All planned births in non-OU settings led to significant increases in 'normal birth' and significant reductions in costs to the NHS when compared to planned birth in an OU.

3.4.4 Sensitivity analyses

Uncertainty surrounded the modelled overhead costs and the midwifery costs, which included CNST charges. These were also seen to be generic cost drivers relevant to all settings of birth. We compared the effects of variations in these costs on all three incremental cost effectiveness measures. Results from the sensitivity analyses showed that the study findings were robust and the ICERs responded to changes in the cost variables in a manner consistent with expectations.

3.5 Qualitative organisational case studies

3.5.1 Choice of birthplace, information and access

There were variations in the number of women who had practical access to the full range of birth settings within their locality, as most women did not see travelling over a long distance in labour as a realistic choice. Choice was influenced by geographical, organisational, service culture and provider factors. Some women were not aware that choice of birthplace was possible, and lacked sources of evidence-based information on which to base choices. Women's views of safe care were influenced by what was locally on offer, their previous experience and that of other women that they knew. The prospect of intrapartum transfer was a major consideration when women made a decision around place of birth, and women often cited concerns about transfer distance as reasons for planning labour in hospital. Women who did exercise more agency had greater access to information, skills and confidence in asking for the choices they wanted, and had the support of family friends and health professionals in doing so.

There was considerable variation in service provision between and within sites due to geography, and the variation in the organisation of community midwifery services. In all sites, there were examples of service and information provision designed to reduce inequalities in access and choice for women with complex social needs, those from poorer socio-economic localities and women who needed English language support.

3.5.2 Delivery of safe and high quality of care

The design of the environment was tailored in the case study sites to positively support midwife-led and active birth care for low-risk women, but proximity of the AMUs created specific issues around blurring of spatial and professional boundaries in all sites. Competition over birth rooms and

staffing often overlapped with philosophical differences, which could undermine effective team working and safety. In contrast, FMUs although they appeared to have clear boundaries, were not viewed as financially viable. The cultivation of relatively positive and respectful relationships between and within professional groups, was the rule rather than the more 'embattled' relationships described in some studies.

Deployment of community midwifery staffing across distributed settings was a key challenge for managers in all sites. For example, coverage for women living in more rural areas, staffing free-standing units, and reducing variation in models and coverage of community midwifery services. Additional challenges at some time points were an increase in complexity of case mix resulting in some women finding difficulty accessing overcrowded units. These led to women and birth partners feeling psychologically unsafe, as well as posing potential clinical safety problems.

All sites demonstrated a commitment to multi-disciplinary training and included attention to emergency skills and escalation of care. However, more attention was given to the needs of FMU midwives and less attention to the needs of midwives working in AMUs or community midwives providing home births, some of whom attended very few births each year. Community midwives appeared to be less integrated in such processes, and some reported a sense of isolation and exposure when attending births at home.

In all sites this was mitigated in models of care where midwives worked across the continuum of care, and both in the community and hospital settings. For example within team/caseload models or where midwives rotated between community and the different units in order to maintain a range of skills as in the 'hub and spoke' model where an obstetric unit served a number of freestanding midwife units. Midwives working in FMUs indicated the value of their working relationships in the unit, including the role of maternity support workers.

Guidelines were generally used as support to knowledge and decision-making, rather than as substitutes for these, and were used to drive service improvement and appropriate levels of care. Positive organisational culture factors included a learning climate, which incorporated commitment to audit and review as sources of learning and improvement. When problems arose between professionals, these were tackled openly, rather than ignored.

The management of complications, escalation and transfer emerged as a key issue. These include the management of physical, geographical, professional and inter-personal boundaries, not only when transfers of women or staff were needed, but also in terms of information, knowledge and resources. Effective and safe transfer was contingent on good communication systems, clear guidelines that were used appropriately to support decision-making, trusting and respectful relationships between staff

groups, management of conflict over resources, and the confidence and competence of professionals.

3.5.3 Women's experiences of escalation and transfer

Although some women's experience of transfer and escalation was characterised by feelings of worry, disempowerment or disappointment, most women were prepared for the unpredictability of events in childbirth. Clear and careful explanation of events by professionals was a common theme that ran through women's *positive* narratives about escalation. Trust in professionals was an important aspect of feeling safe, physically and psychologically.

Some women described difficulty in being listened to when they raised concerns about complications they had noticed themselves, while concerns about medicalisation or previous negative birth experiences led women to avoid intervention in some cases, or request it in others. A few professionals viewed service users as both 'risky' and 'demanding' and consequently were less open to listening to their views, which were often not seen as relevant to safety.

Sometimes speaking up was effective, and women's wishes were heard and acted upon, but the experience of speaking up and *not* being heard was also manifested as a safety issue. When women felt *unable* to ask about their options or challenge professional views they could experience feelings of frustration, self-blame or anger and felt this resulted in delay in the management of complications.

4 Key findings

4.1 The configuration of maternity care in England

- Options for place of birth have improved since 2007 but a substantial proportion of women are unlikely to have a full range of choices available locally.
- While midwifery units have increased in number, there are regional differences in availability and capacity is limited, such that most women will give birth in an obstetric unit.
- Future planned changes by NHS trusts include provision of more AMUs, more beds, more midwifery posts and more consultant cover.
- Marked variation is evident in almost all aspects of provision, yet the needs of mothers and babies during labour and birth are unlikely to vary in any fundamental respects.
- Staffing levels vary between units and regions of the country: an easily applied and validated method of matching staffing numbers to care requirements is needed that could assist in reducing this variation and planning appropriate staffing for maternity care.

4.2 The national prospective study of planned place of birth

- For 'low risk women', the incidence of adverse perinatal outcomes is low in all birth settings (4.3 primary outcome events per 1000 births).
- The benefits of planned birth at home or in a midwifery unit include fewer interventions, a substantially reduced incidence of intrapartum caesarean section and a higher likelihood of a 'normal birth'.
- For multiparous 'low' risk women there are no differences in adverse perinatal outcomes between settings but the risk of an adverse perinatal outcome appears to be higher for nulliparous women who plan to give birth at home (9.3 primary outcome events per 1000 births vs. 5.3 per 1000 births in an OU).
- For nulliparous 'low risk' women the intrapartum transfer rate is high in settings other than an OU (home 45%; FMU 36%, AMU 40%).
- A non negligible proportion (5%) of planned home and midwifery unit births are to women at 'higher risk' of complications who, according

to current clinical guidelines, should be advised to give birth in an obstetric unit.

4.3 Cost effectiveness analysis

- 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.
- Cost differences between settings are partly attributable to differences in the characteristics of women planning birth in each setting; the three non-OU settings remain cost saving after accounting for these differences. Compared to a planned OU birth, home births cost £367 less, planned FMU births £182 less and planned AMU birth £129 less on average.
- The main cost drivers are unit overheads and staffing; there is substantial variability in costs between units.
- 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. 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. Analysis of the incremental cost per adverse perinatal outcome for the three non-OU settings was inconclusive for the reasons explained in the main report.
- When analysed by parity:
 - For nulliparous 'low risk' women, planned birth at home generated incremental cost savings compared to planned birth in an OU, but increased adverse perinatal outcomes.
 - For multiparous 'low risk' women, planned birth at home generated incremental cost savings compared to planned birth in an OU, but uncertainty surrounded adverse perinatal outcomes avoided.

4.4 Organisational case studies

- Access to good quality information often differed across social groups. Variations existed in how services and professionals provided such information in order to deliver equity of access and choice.
- Concerns around transfer distance meant that many women did not feel they had any realistic choice of place of birth. Travel distance to OUs was a concern for women living in more rural areas.

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- Out-of hospital birthplaces functioned best when they were embedded into the system of maternity services, supported by all staff, and not just seen as a midwifery concern.
- Variations existed at Trust level in support given to out-of-hospital births, including training for safety and teamwork across the maternity workforce. The deployment and resourcing of community midwifery was especially variable across Trusts, and those providing such support took a systematic approach to staff deployment to underpin women's choice of birth setting.
- Strong midwifery and obstetric leadership and a culture of mutually supportive professional teamwork appeared to be central features of Trusts where midwifery led and obstetric services functioned well.
- Audit and review were sources of organisational learning and improvement. These were promoted by leadership and staff involvement, and a 'learning and accountability' rather than a 'blame' culture, with attention to system processes and structures as well as individual professional practices.
- In some Trusts, community and birth centre midwives who had a low volume of births, and only attended 'low risk' births appeared to benefit from periodic rotation into settings in which they could gain experience of higher risk births. In well-integrated services, midwives working on obstetric units were also periodically rotated into low risk settings.
- The presence of an AMU sometimes highlighted contrasts in birth philosophies across units. There were also some cases of strong leadership for promotion of normal birth across the maternity system.
- The presence of an AMU appeared to intensify the workload in the adjoining obstetric unit where service providers struggled to support normal birth.
- Women's concerns about their safety and that of their baby (or babies) were expressed but not always listened to by staff. Being heard and receiving timely support was aided by continuity of carer and/or presence of a birth partner or relative.
- Early labour assessment at home appeared to provide an opportunity for accurate clinical assessment and women's informed decision-making about the safest place to give birth.

5 Implications for policy and practice

- Guidance given to women on planning place of birth should be updated to reflect the new evidence provided by this study. As a result of the cohort study, women can now be provided with more reliable information on outcomes in the available birth settings, and can also be given a more accurate estimate of the overall likelihood of intrapartum transfer.
- The evidence provided by the cohort study supports the policy of offering 'low risk' women a choice of birth setting:
 - Freestanding and alongside midwifery units appear to be safe for babies and offer benefits to both the mother (fewer interventions) and baby (more frequent initiation of breastfeeding). Nulliparous women should be informed of the relatively high probability of intrapartum transfer in these settings when choosing their planned place of birth.
 - For multiparous women, home births appear to be safe for babies and offer benefits to both the mother (fewer interventions) and baby (more frequent initiation of breastfeeding).
 - The substantially lower incidence of major interventions, including intrapartum caesarean section, in all three non-OU settings has potential future benefits to both the woman and the NHS in terms of avoiding surgical complications and reducing the need for repeat caesarean sections in future births. There is a need to address the higher frequency of major interventions and the relatively low proportion of 'normal births' in 'low risk' women in obstetric units
 - The continued provision of a home birth service is important so that multiparous women, and some nulliparous women who are aware of the additional risks to the baby and the high likelihood of transfer, can plan to have their baby at home.
 - Expansion of the provision of FMUs and AMUs would provide a choice of birth setting for 'low risk' nulliparous women who do not wish to opt for an OU birth
- A non negligible proportion of planned home and midwifery unit births are to women who, according to current clinical guidelines, should be advised to give birth in an obstetric unit. The reasons for this are not clear but some consideration needs to be given to the information and options offered to 'higher risk' women.

- Increased provision of home birth services and midwifery units is potentially cost saving but the evidence provided by the Birthplace studies indicates that the following issues may require consideration:
 - The higher midwife to birth ratio in non-OU settings – which women value – means that although such an expansion is potentially cost saving, it would be likely to require an overall increase in midwifery staffing numbers.
 - There is considerable variation between midwifery units in size, staffing levels, skill mix and throughput. These all affect costs, and may affect safety and other aspects of care, including women's experiences. Further work is required to determine whether particular 'models' are more cost-effective for the NHS and valued by women.
 - Strong midwifery and obstetric leadership and a culture of mutual professional respect appears to be a central feature of trusts where midwifery led and obstetric services function well alongside each other.
 - Attention needs to be given to the skills and training of midwives working in different settings. For example, community midwives who may assist at a low volume of births and only attend 'low risk' births may benefit from periodic rotation into settings in which they can gain experience of births, including higher risk births.
 - Attention needs to be given to staffing models in units with an AMU and OU.
- Intrapartum transfers from home and midwifery units into obstetric units occur relatively frequently and are potentially distressing for women. Further research into intrapartum transfers is recommended but maternity services could potentially use audit and review processes to identify actions that could already be taken to improve the experience and safety of women requiring intrapartum transfer.
- Discussion between maternity services and ambulance trusts may be needed to identify the most appropriate and effective protocols for intrapartum transfers.
- There is an urgent need for routine data collection systems to collect data on planned place of birth at start of care in labour so that outcomes can be monitored by planned place of birth.

6 Recommendations for future research

Key areas for further research arising from the Birthplace programme are outlined below. Additional details and further recommendations for research are given in the individual reports

- **Avoidable or remediable factors in adverse intrapartum outcomes which are specific to particular birth settings**
 - What are the aspects of clinical care and service delivery associated with adverse intrapartum related outcomes by planned place of birth?
 - What potentially modifiable aspects of current services are associated with poorer outcomes in particular birth settings.
- **'Out of hospital' births in women at 'higher risk'**
 - What factors influence 'higher risk' women to give birth outside an obstetric unit?
 - How should services be provided for women who wish to give birth outside hospital against professional advice?
- **Obstetric units**
 - How can the frequency of unnecessary interventions be reduced for 'low risk' women giving birth in obstetric units?
 - What is the impact of AMUs on intrapartum care in their adjoining obstetric units?
- **Choice and equity**
 - To what extent do less socially advantaged women have reduced access to choice of birth setting and what strategies might improve equity?
- **Intrapartum transfers**
 - How can the experience of intrapartum transfer be improved for women and their partners?
- **Broader economic evaluation encompassing both health impacts on the mother and infant and non-health effects**
 - Commonly used outcome measures in economic evaluations do not enable the value women attach to 'positive birth experiences' to be compared against values attached to different health outcomes. Methodological research is required to enable such

preferences to be incorporated in a broader economic evaluation framework.

- **Models of care**

- Do midwife-led models of care (team and caseload midwifery) that provide continuity of care across settings improve quality and safety of care?

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Appendix: Membership of the Birthplace in England Collaborative Group

The Birthplace in England Collaborative Group includes the wider group of co-investigators, researchers, project staff and coordinating midwives who contributed to the research programme:

Co-investigators

Professor Peter Brocklehurst, Professor of Perinatal Epidemiology, NPEU, University of Oxford

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

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

Professor Rona McCandlish, Midwifery Professional Advisor, Chief Nursing Officer's Professional Leadership Team, Department of Health (on secondment from NPEU);

Professor Christine McCourt, Professor of Maternal and Child Health, City University London;

Mrs Alison Miller, Programme Director and Midwifery Lead, CMACE

Mary Newburn, Head of Research and Information, NCT;

Professor Stavros Petrou, Professor of Health Economics, University of Warwick

Dr Maggie Redshaw, Social Scientist, NPEU, University of Oxford

Professor Jane Sandall, Professor of Women's Health and Programme Director (Innovations), NIHR King's Patient Safety and Service Quality Research Centre, King's College, London

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

Birthplace Advisory group

Professor Cathy Warwick (Chair), King's College Hospital Foundation Trust, replaced by Kate Sallah, Tashie Consulting

Jill Demilew (Deputy Chair), Consultant Midwife, Kings College Hospital Foundation Trust

Professor Maggie Blott, replaced by Professor David Richmond, Vice President, Royal College of Obstetricians and Gynaecologists.

Sue Eardley, Children and Maternity Strategy and Safeguarding Care Quality Commission

Professor Naomi Fulop, School of Social Science and Public Policy, King's College, London

Dr Gary Hartnoll, Consultant Neonatologist, Chelsea and Westminster Hospital

Dr Sara Kenyon, Senior Lecturer, School of Health and Population Studies, University of Birmingham

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Addendum

The Birthplace in England Research Programme combines the Evaluation of Maternity Units in England (EMU) study funded in 2006 by the National Institute for Health Research Service Delivery and Organisation (NIHR SDO) programme, and the Birth at Home study in England, funded in 2007 by the Department of Health Policy Research Programme (DH PRP). This document is part of a suite of reports representing the combined output from this jointly funded research. Should you have any queries please contact Sdoedit@southampton.ac.uk