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# Factors influencing the utilisation of alongside and free-standing midwifery units in England: A Mixed Methods Research Study

**FINAL Version 1**
**25th February 2016**

**Short title: Midwifery Units Study**

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## SYNOPSIS

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| Title | Factors influencing the utilisation of alongside and free-standing midwifery units in England: A Mixed Methods Research Study |
| Short title | Midwifery Units Study |
| Chief Investigator | Dr Denis Walsh |
| Objectives | To identify factors which help explain variability in the provision and utilisation of MUs across England and to identify interventions to address barriers and facilitators of MUs. |
| Study Configuration | Comparative case studies |
| Setting | Maternity Services evaluation.<br>Focus group discussions and staff interviews in six NHS Trust maternity services, to include service-users, hospital and community midwifery services, managers/directors, service-user representatives and GP locality leads. |
| Sample size estimate | This is not a randomised controlled trial; therefore there are no sample size calculations. Planned participant numbers are detailed below. |
| Number of participants | Four focus group discussions, within each Trust to include between 5 and 8 service users and midwives.<br>Interviews with approximately 9 key maternity services staff, service user representatives, commissioners and a GP locality lead, within each of the 6 participating Trusts.<br>One Stakeholder Workshop involving at least 40 participants.<br><br>Total Anticipated participants: 286 |
| Eligibility criteria | Participants aged 18 or older.<br><br>Focus Groups:<br>• Women who have given birth within one of the selected case study sites within the last 12 months.<br>• Hospital and community midwives currently employed by a case study site with any number of years experience.<br><br>Interviews:<br>• Staff currently employed by a case study site.<br>• Current maternity and neonatal networks, representatives from service-user groups.<br>• Women who have given birth within one of the selected case study sites within the last 12 months, and who could not attend a focus group discussion.<br><br>Stakeholder Workshop:<br>• Maternity services professionals including; Directors/managers, Chief Executives, maternity and neonatal networks, representatives from service-user groups. |

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| Description of interventions | Participants will be invited to participate in one of the following: focus group, individual interview, stakeholder workshop. |
| Duration of study | The study duration is 23 months. The study will end when the Stakeholder Workshop has been conducted. For individual interview/focus group participants this is no longer than 1.5 hours participation. Stakeholder Workshop participants will attend one workshop, which will be conducted over the course of one day. |
| Methods of analysis | Descriptive statistics and narrative description of configuration, organisation and operation of AMUs and FMUs.<br>Content and thematic analysis of local media coverage, focus group discussions and individual interviews.<br>Synthesis of information generated at the workshop to develop a final set of proposed interventions and recommendations. |

## ABBREVIATIONS

| | |
|---|---|
| AMU | Alongside Midwifery Unit |
| CI | Chief Investigator overall |
| FMU | Free-standing Midwifery Unit |
| GCP | Good Clinical Practice |
| HoM | Head of Midwifery |
| MU | Midwifery-led Unit |
| NHS | National Health Service |
| OU | Obstetric-led Unit |
| PALS | Patient Advice and Liaison Service |
| PI | Principal Investigator at a local centre |
| PIS | Participant Information Sheet |
| R&D | Research and Development Department |
| REC | Research Ethics Committee |
| UoN | University of Nottingham |

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## STUDY BACKGROUND INFORMATION AND RATIONALE

Since 1993, maternity care policy in England has promoted women's choice of place of birth. This became the national choice guarantee in Maternity Matters in 2007 (DoH, 2007) with three options: birth in a maternity hospital (obstetric unit or OU), birth in two types of midwifery unit (alongside [AMU] or free-standing [FMU]) or birth at home. The importance of choice was restated in the NHS 2012/13 Choices Framework document (DH, 2012) in the section, Choosing Maternity Services and identifies midwifery units (MUs) as one of the place of birth choices.

The Department of Health commissioned research into the outcomes of childbirth at home, in MUs and OUs with the subsequent Birthplace study reported in 2011. The results showed that birthing in a MU reduced labour and birth interventions significantly. Specifically, the caesarean section rate fell from 11% to 4%, the assisted vaginal birth rate (forceps and vacuum assisted) from 15% to 7% and normal birth rate rose from 73% to 90%. In addition, the epidural rate fell from 30% to 12.5%, speeding up the labour with intravenous oxytocin from 23% to 8.5% and the episiotomy rate from 19% to 10% (Brocklehurst et al, 2011).

Operative births and labour interventions put the mother at greater risk both physically and psychologically. The major complications of caesarean sections are severe haemorrhage, thromboembolism, infection and risks for subsequent pregnancies (Goer et al, 2012). Emergency caesarean sections are also linked to post-traumatic stress (Olde et al, 2006). Assisted vaginal birth is associated with perineal trauma, anal sphincter tear and urinary stress incontinence (Walsh, 2012). Epidurals increase the risk of assisted vaginal birth (Anim-Somuah et al, 2009) and intravenous oxytocin is more likely to be associated with fetal compromise (Oscarrson et al, 2006). Higher rates of episiotomy are linked with additional perineal trauma (Carroli et al, 2009).

The reduction in all of these labour interventions and operative birth outcomes should be achieved if low risk women birth in MUs. Critically, outcomes for babies when women birth in MUs is no different to OUs. The Birthplace study also found that having a baby in a MU was cheaper. The unadjusted mean costs were £1435, £1461, and £1631 for births in FMUs, in AMUs, and in OUs, respectively (Schroeder et al, 2012). If 20% of birth occurred in MUs rather than the current 11%, based on these costs, savings to the NHS maternity budget could be around 85 million pounds. This represents a 3% saving on the current budget of 2.6 billion pounds for maternity care.

MUs also improve continuity of care, one-to-one care in labour (Walsh & Devane, 2012) and increase women's sense of control and their satisfaction with care (Hodnett et al, 2013), areas where the Care Quality Commission say current maternity services need to improve (CQC, 2013).

In 2014, McCourt et al (2014) reported follow-up research to Birthplace on AMUs' organisation, staffing and provision. They called for further research into the facilitators and barriers to expansion of MU capacity. This need is even more urgent, given the results from the Office of National Statistics mapping exercise of the availability and utilisation of MUs in England (NAO, 2013). It found that only 11% of women gave birth there while the vast majority continue to give birth in OUs. This is probably due to a number of factors. The availability of MUs is unequally distributed across the country. A third of services have no MUs, while others achieve 20% or more of all birth in these facilities (usually have an AMU and FMU) and the remainder have MUs but they are frequently under-utilised i.e. 10% or less (usually have either an AMU or FMU).

Prior research on broader organisational change in the NHS described multifaceted barriers and drivers to change (Iles and Sutherland, 2001; Greenhalgh et al, 2004). Considering this work, a wide range of factors may facilitate or create barriers to the establishment and utilisation of MUs, including issues of staffing, service leadership, attitudes and preferences of childbearing women and staff, the influence of local media's reporting of changes in local maternity services, perceptions of clinical risk e.g. safety of FMUs regarding the absence of medical backup on site and need for ambulance transfer if labour complications develop (McCourt et al, 2012; Bourke, 2013) and finally, the relationship between professional groups. Currently, the prevalence and impact of such potential barriers remain unclear. This is important to know so potential interventions and service guidance can be developed to address barriers and facilitators of MUs and then utilised for future maternity services commissioning and provision.

Our study will explore the reasons for the variable provision of MUs in England by undertaking comparative case studies in the high achieving (those birthing 20% of more of low risk women in MUs) and low achieving services (those birthing 10% or less in MUs) and will then identify interventions to address barriers and facilitators of MUs. This work will inform a national maternity care stakeholder workshop near the end of the project which aims to identify potential interventions to address barriers and facilitators of MUs for maternity care commissioners and providers.

In summary, there are substantial benefits to be realised for childbearing women and for the NHS if low risk women across England deliver in MUs. We want to investigate why some services have 20% or more of their population of pregnant women birthing in these facilities while others, either have no MUs or 10% or less of their women using them. With the results, we will identify interventions to address barriers and facilitators of MUs and develop service guidance to inform future maternity service commissioning and provision.

## STUDY OBJECTIVES AND PURPOSE

## PURPOSE

The purpose of the research is to investigate the barriers and facilitators to provision of MUs across England, to identify interventions to increase MU provision and uptake and to develop service guidance based on these for commissioners and providers.

## OBJECTIVES

Phase 1 Objectives:
To describe the configuration, organisation and operation of MUs, both AMUs and FMUs in England, and to build an understanding of key issues and barriers to uptake facing MUs (including why some maternity services have closed MUs).

Phase 2 Objectives:
To explore why some maternity services in England have no MUs.
To identify why some maternity services in England have 20% or more of all birth in MUs.
To identify why some maternity services in England have MUs but are running substantially under capacity (10% or less of all births).

Phase 3 Objectives:
To identify potential interventions to address barriers and facilitators of MUs and to develop service guidance to improve the availability and utilisation of MUs. To convene a national maternity care stakeholders workshop to develop appropriate interventions and service

guidance to inform future maternity service commissioning and provision regarding improving the availability and utilisation of MUs.

## STUDY DESIGN

## STUDY CONFIGURATION

***Design***
This is a multi-centre, mixed methods comparative case study combining interviews, focus groups and one workshop.

***Setting***
The study combines 3 phases:
**Phase 1**: Service Evaluation (service evaluation element not included in this protocol)
Mapping of the configuration, organisation and operation of MUs in England.
**Phase 2**: An in depth multiple case study of six sites (NHS Trusts) in England.
**Phase 3:** To hold a collaborative stakeholder workshop, to identify interventions to address the barriers and facilitators of MUs.

## STUDY MANAGEMENT

Core members of the research and administrative support team are co-located on the campus of the University of Nottingham; this will facilitate project management and team cohesion. Monthly minuted project management meetings will be held, led by the CI.
All co-applicants will be invited to join these in person or by teleconference every 6 months up to 18 months and then every 4 months until the end of the project. A multi-disciplinary Advisory Group will oversee the project and provide specialist advice. We anticipate a maximum of five Advisory Group meetings during the course of the research, attended by all investigators, and Advisory Group members. Advisory Group members have agreed to provide additional advice between meetings by email and teleconference.

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

The data custodian will be the Chief Investigator.

## DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration:
Research participant enrolment will commence during Phase 2 of the study (during months 7-16) and once Ethics Committee and relevant NHS Trusts' R&I approvals have been obtained. Data collection will continue until 4 focus groups and at least 9 interviews have been completed at each of the six participating case study sites. Phase 3 of the study begins during month 21 of the study and will continue until the stakeholder workshop is completed during month 23.

Total study duration: 23 months

Participant Duration:

- Interview participants will be consenting to one single interview, with a maximum duration of 90mins.
- Focus group participants will be asked to attend one focus group, with a maximum duration of 90 minutes.

- Stakeholder Workshop participants will be invited to attend one workshop, lasting a full day.

## End of the Study

The end of the study will be upon completion of the Stakeholder Workshop.

## SELECTION AND WITHDRAWAL OF PARTICIPANTS

### Recruitment

***Service-user participants.***

Service-user participants (women who have given birth within the last 12 months), will be recruited from alongside midwifery units, freestanding midwifery units, obstetric units, with support from the CLRN and maternity unit staff, or by a member of the maternity services research network, or they may self-refer directly to a member of the research team upon viewing a poster, social media or study website.

Women who are of low medical and obstetric risk at first contact with a midwife, will be initially approached by a member of the woman's usual care team or a CLRN employed midwife, who has a contract with the study site NHS Trust and has access to patients. Women interested in taking part in the study will be offered information about the study (Service User – Focus group information sheet and consent form) and an 'expression of interest' form.

Posters will be displayed in relevant clinical areas, in community centres where maternity network meetings are held, in general practices, and in areas where postnatal/new baby clinics are held. Expression of interest forms, study leaflets and FREEPOST address labels will be displayed alongside study posters. Social media accounts (Facebook, Twitter) and a webpage will also be developed to disseminate study information and facilitate recruitment.

Completed expression of interest forms can be returned to the research co-ordinating centre through use of a freepost address label, or completed forms can be handed back to the approaching member of staff, who will collect completed forms for postage to the study coordinating centre. FREEPOST envelopes will be provided to recruiting centres for use by staff.

Upon receipt of completed expression of interest forms, the research fellow will post or email the appropriate information sheet and corresponding consent form (if they have only received the brief study leaflet) to the potential participant. The potential participant will be given a sufficient period of time to read the information sheet, before being contacted again by telephone.

During initial telephone contact with a potential participant, the researcher will inform the participant of all aspects pertaining to participation in the study, ensuring they understand their involvement and fit the inclusion criteria.

Once the researcher is satisfied the participant understands their involvement and if the potential participant is still keen to take part in the study, the researcher will inform the potential participant that they will be asked to complete a consent form when they arrive at the focus group.

It is not possible to convene a focus group or 'mini' focus groups (due to lack of available participants, low focus group attendance, or logistical issues), one-to-one interviews will be

offered as an alternative option for participants who have already consented into the study. Participants who would like their voice to be heard, but do not wish to participate in a focus group due to language barriers or other reasons, may also be offered an interview as an alternative to the focus group. A maximum number of 4 - 6 service-user interviews, will be conducted per site. The interviews will be conducted in a location chosen by the participant (which may be in the participant's own home, on Trust premises, or by telephone). Participants who are offered a one-to-one interview with a researcher will be provided with an information sheet (Service User- Interviews information sheet) and corresponding consent form.

Participants who are being interviewed over the telephone, will be asked to complete the consent form and post it to the researcher (using the FREEPOST address), before the telephone interview commences. Participants who are interviewed face-to-face will be asked to complete their consent form upon arrival for their interview.

All potential participants (focus group or interview participants) will also be asked to provide a list of days/times they are most likely to be available to attend a focus group/interview, to assist in organising a mutually convenient time. Once the date/time of the focus group/interview has been arranged, the participant will receive a further phone call to confirm their attendance. A confirmation of the date/time may also be sent to the participant by email or in the post to their home address, if required.

*Consideration of participants whose first language is not English.*

When appropriate, the focus group or one-to-one interview will be facilitated in the language of the participant(s) within the focus group, by an experienced translator. Funding is available to cover the costs of a translating service.

### *NHS staff and service-user representatives as participants*

The structure of maternity services within each individual Trust will determine who makes the initial approach. In most Trusts, the initial approach will be made by Heads of Midwifery (HoMs). The CI will email or telephone HoMs, informing them the research team are seeking to interview staff within their Trust and would like to undertake focus groups with midwives.

HoMs will be asked to cascade one of two emails using appropriate distribution lists, to aid researchers identify potential participants. Both emails will include; an invitation to take part in the study, the appropriate study information sheet, consent form and contact details of the research fellows. If the HoM does not have all the required distribution lists, he/she may suggest another member of Trust staff to distribute email on our behalf.

The HoMs will be asked to cascade the email containing the focus group invitation, to their unit midwives and local community midwives and to cascade the email containing an invitation to interview, to maternity services managers and directors, business managers, obstetric leads and GP commissioners, and any other appropriate senior members of staff by snowballing the invitation.

The HoM will also be asked to provide details of their local Chair of MSLC (Maternity Services Liaison Committee), who may be able to cascade the invitation to local service-user representatives. If response rates to the initial invitation are low, HoMs/MSLC Chairs will be asked to send the email(s) again, as a reminder.

Upon receipt of an invitation email, potential staff/service-user representative participants can express an interest in taking part in the study by emailing/telephoning/posting their preferred contact details to the research fellows. The research fellow will then contact the potential

participant to ensure they have read and understood the information sheet, answer questions and provide further details about their involvement in the study. If the staff member/service user representative is still happy to take part, a mutually convenient time to conduct the interview/focus group will be arranged. Consent will be sought prior to commencement of the interview/focus group.

Interviews will be conducted face-to-face whilst the research fellow is on Trust premises, or over the telephone. Focus groups with midwives will be conducted on Trust premises, at a time most convenient for participating staff.

***Stakeholder Workshop Participants***

Stakeholders will be invited to the stakeholder workshop by email or telephone communication from the CI. The initial communication will provide information about the purpose of the Stakeholder Workshop, proposed date/time of the meeting, an invitation to attend, a participant information sheet and a consent form. Participants will be advised the workshop will be held in Nottingham. Interested participants will be asked to reply to the email or telephone the CI, to obtain further information about the workshop, should they require it. If the potential participant is happy to take part, they will be asked to complete the consent form and to bring it along with them to the Stakeholder Workshop, or post it back to the study co-ordinating centre. Spare consent forms will be taken along to the Stakeholder Workshop.

All Participants:

It will be explained to all participant that entry into the study is entirely voluntary and that their treatment and care/employment will not be affected by their decision. It will also be explained that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

## Eligibility criteria

## Inclusion criteria

***Midwife Focus Group discussions:***

Individuals aged 18 or over and currently employed in a case study site:

> The age limit for midwives is likely to reflect working age (respectively 21-65 for midwives and 18-65 for the other groups).

Hospital and community midwives employed by their local Trust with any number of years' experience.

Able to participate in a focus group.

***Service-user Focus group discussions or interview:***

Participants aged 18-40years

Women who used a maternity service to give birth within the last 12 months, within a local case study site.

Women who were eligible for birthing in a MU (low medical and obstetric risk).

Able to give informed consent.

Able to participate in a focus group setting.

***NHS Staff/service-user representative Interviews and Stakeholder Workshop:***

Currently employed within a case study site.

Participants aged 18 or over:

The age limit is likely to reflect working age (respectively 21-65 for midwives and 18-65 for the other groups); however, any participants over retirement age will also be eligible to participate.

Participants to include:
Maternity unit NHS staff and Managers/Directors.
Maternity Services Business Manager
Head of Midwifery.
Consultant Neonatologist.
Lead Obstetrician.
Chief Executive of Hospital Trust.
Community NHS midwives.
GP Locality Lead.
Current maternity and neonatal networks, service-user group representatives, proximal to case study sites.
Representative from local maternity support/liaison/ campaigning groups.

## Exclusion criteria

Potential participants will exclude themselves by choosing not to take part in focus group discussions or interviews.

Participants aged <18 years

***Service-user participants:***
Women who have given birth > 12 months prior to study invitation.
Pregnant women.
Women not considered 'low medical and obstetric risk' for birthplace decision making.

## Expected duration of participant participation

Focus group participants will be participating for a maximum of one and a half hours.
Staff and service-user interviews will have duration of no longer than 1 and a half hours.
The Stakeholder Workshop will have a duration of one day.

## Participant Withdrawal

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future care. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

## Informed consent

All participants will provide written informed consent. The Consent Form will be signed and dated by the participant before they enter the study. The Investigator will explain the details of the study and provide a Participant Information Sheet, ensuring that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation.

Informed consent will be collected from each participant before they undergo any interviews or focus group discussions related to the study. One copy of this will be kept by the participant, one will be kept by the Investigator.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the study, continuing consent will be obtained using an amended Consent Form which will be signed by the participant.

## STUDY REGIMEN

### *Phase 1 – Service Evaluation*

Mapping of the configuration, organisation and operation of MUs in England. Service evaluation element not included in this protocol.

### *Phase 2 - Selection of case study sites:*

Using the data from Phase one, six case study sites will be purposively sampled:

- 2 higher performing services with both an AMU and a FMU achieving 20% or more of total births
- 2 lower performing services with one or more MUs (AMU and/or FMU) achieving 10% or less of total births
- 2 services with no MUs

Within each of the three categories, study sites will be chosen to represent both rural and urban settings to enhance representativeness, if possible. One case study site is planned to be in London.

### *Data collection at each case study site:*

Research Fellows will undertake data collection at each of the six sites, including;

*Semi-structured Interviews:*
Chief Executive of Hospital Trust, Head of Midwifery, senior obstetrician, midwifery management lead for community, business manager of maternity service, neonatologist, MSLC service user or service-user group representative, local maternity support/campaigning groups. In addition, snowball sampling will be used to identify other key individuals that have shaped the local development of maternity services.

Questions will be focused on discussing the evolution of services in each of the sites. Interview schedules will be developed by the research team, drawing on the findings from the first stage of the study, existing literature regarding the organisation of maternity services, literature on implementation and organisational change, as well as the expertise of the project's service user reference group and project advisory group and piloted prior to use.

Participants will be invited to one audio recorded semi-structured interview. Interviews will be undertaken within one of the six NHS Trusts, or over the telephone. The interview will be conducted by one Research Fellow. A topic guide/interview questionnaire will be developed, informed by literature and the service evaluation stage of the study. Questions will be focussed on the evolution of services in the host site.

Interviews will be audio recorded and then professionally transcribed verbatim. Pseudonyms will be applied to all interviewees and any site identifying data will be anonymised. The

identity of participants in the interviews will not be disclosed to their employers or any professional body.

*Focus groups:*

- Two Focus groups of between 5 to 8 women who have had a baby in the previous 12 months exploring their perception of local service options around place of birth. Within each site, we will try to ensure that participants include low risk women of a range of parities chosen from geographical areas of deprivation and ethnic diversity.

  Reimbursement of travel and childcare expenses which may be incurred due to focus group attendance will be offered to all service-user participants. Additionally, a £10 high-street shopping vouchers will be presented to participants upon completion of a focus group. Refreshments will be provided.

- Two Focus groups with 5 to 8 midwives (one with hospital midwives and one with community midwives) exploring how choice of place of birth is presented and their views on the barriers and facilitators for MUs in their service.

The midwives' Focus groups will be co-facilitated by two research fellows. Service user focus group will be facilitated by two research fellows or a research fellow and a member of the service-user (PPI) representative group. Letters of Access will be obtained for PPI representatives, who wish to co-facilitate a service-user focus group.

Two 'mini' focus groups (3-4 participants) will be conducted, if difficulties arise in convening 6-8 participants together into one focus group.

If it is not possible to convene a focus group or 'mini' focus groups (due to lack of available participants, or logistical issues), a small number of participants will be invited to attended a one-to-one interview with a researcher. Participants who do not wish to participate in a focus group due to language barriers or other issues, may also be offered an interview as an alternative to the focus group. A maximum number of 4 - 6 interviews will be conducted per site. The interviews will be conducted in a location chosen by the participant (which may be in the participant's own home, on Trust premises, or by telephone).

A topic guide will be developed, informed by literature and the service evaluation stage of the study. Questions will be posed to explore such issues as choice of birth place and barriers and facilitators for MU use.

Focus groups will be audio recorded and professionally transcribed verbatim. Pseudonyms will be applied to all interviewees and any site identifying data will be anonymised.

*GP Locality Lead telephone interviews:*
At least one commissioning GP Locality Lead proximal to each case study site, will be invited to a telephone interview. Each Locality lead GP will be asked questions about the barriers and facilitators for the utilisation of MUs.

*Documentary analysis:*
Review of policies, protocols, guidelines and minutes of strategic meetings related to birth place choices/provision in each of the sites.

*Local media analysis (radio, TV, newspapers) of stories about local maternity services:*
In case study sites where researchers are notified of relevant media outputs (local newspapers, TV, radio), debates and discussions within these outputs will be explored and the presentation of local maternity provision will be examined. This will enable the team to

further understand the local context and potential influences on local demand and service provision.

***Phase 3 -***

After barriers and facilitators have been reviewed by the entire team, we will then develop potential interventions and service guidance that will subsequently be discussed with the service user reference group, members of the advisory and stakeholder groups. The exact nature of the interventions that we will develop cannot be specified prior to data collection. They are likely to be multifaceted or complex interventions of behavioural, organizational and/or policy change, rather than discrete technical or clinical interventions (Craig et al 2008).

Findings from phase 1 and 2 will allow us to identify potential interventions, and draw out the theory of change (the cause and effect model) by which these interventions are understood to work (Weiss, 1998). In developing potential interventions, existing evidence from other studies will also be reviewed to identify the forms of interventions that have previously been used to address the type of barriers we identify. In addition to this, a stakeholder workshop (details provided below) will be held to allow detailed discussion of the potential interventions.

*Stakeholder Workshop:*
The Workshop will be structured to perform a dialogue to enhance the ontological, educative and catalytic authenticity of the research (Guba & Lincoln 1994). The team will present their findings from Stage 1 & 2 and the potential interventions to improve services in line with existing evidence.

Participants will be invited to attend a one-day workshop, in Nottingham. The workshop will be facilitated by members of the research team. Participants will collaborate in mixed interdisciplinary small groups, led by a facilitator from the project team, in examining, developing and refining the proposed interventions. This will be done in two ways. First by asking participants to scrutinize the theory of change associated with each of the potential interventions developed. For example if it is found in the study that the staff mix in midwifery provision has led to an uptake in AMU services, workshop participants will be asked to consider the process by which changing staffing mix could improve service provision, or if there are other issues that would need to be considered for this to work in practice. This will contribute to a more detailed understanding of potential interventions and improve their transferability to varied contexts of practice.

Second, by asking the participants to consider the feasibility and utility of each of the proposed interventions in relation to their own organisations or areas of work. This would lead to a clearer understanding of priorities when disseminating project findings and which interventions should be promoted for pilot implementation.

In addition, the groups will be asked to decide and detail key elements of service guidance that can assist both commissioners and providers. The workshop will thus link research knowledge with decision-making processes and potential interventions (Smith 2007).

Proceedings of workshop will be audio recorded and notes may be taken during small group discussions. The research team will synthesise information generated at the workshop to develop a final set of proposed interventions and recommendations and content for commissioning guidance for inclusion in the final report.

Workshop participants will be consulted for their recommendations for priority approaches for dissemination of the research findings to their constituencies.

Reimbursement of travel expenses for workshop attendance will be offered to all participants.

## Compliance

This is not a treatment study, therefore issues of compliance are not applicable.

## Criteria for terminating the study

We do not envisage circumstances that would require early termination of the study. The study as a whole will end after the Stakeholder Workshop and completion of data synthesis.

## ANALYSES

## Methods

***Phase 1 – Service Evaluation element***
*Not included in this protocol*

***Phase 2 - Focus group discussions, interview data and Local media analysis.***
Focus group discussions and interview data will be fully transcribed, and thematic analysis will be undertaken, with transcripts being read and re-read to identify relevant themes (Braun & Clarke, 2006). Analysis will begin as data is collected and will be utilised to inform later focus groups. NVivo software will be used to assist with the thematic analysis of interviews/focus groups.

Local media output will be analysed thematically using insights from critical discourse analysis, to ascertain both extent of local debate and the ways in which key issues have been framed (Machin & Meyer 2010). This will add to an understanding of the broader context of service provision and this analysis will be integrated into the case comparison in phase three of the project.

***Phase 3 - Stakeholder Workshop***
The research team will synthesise information generated at the workshop to develop a final set of proposed interventions and recommendations and content for commissioning guidance for inclusion in the final report.

All analysis will be undertaken on University of Nottingham computers and backed-up to the University of Nottingham secure servers.

## Sample size and justification

This is an exploratory study; therefore no formal estimates of sample size have been undertaken. However 4 focus groups will be conducted in each of the 6 participating NHS Trusts, in order to represent a range of local contexts and birth place options. We plan to include up to 8 participants per group, providing a maximum of 192 participants. In addition to the focus groups, staff and service-user representative interviews will be conducted at each of the six NHS Trusts. Approximately nine staff/service-user representative interviews will be conducted at each trust, totalling 54 interviews. The sample size of each focus group and number of interviews conducted, may vary in accordance with participant availability and withdrawals.

We aim to invite a minimum of 40 participants to the Stakeholder Workshop.

Total anticipated number of participants 286.

## ADVERSE EVENTS

The occurrence of an adverse event as a result of participation within this study is not expected and no adverse event data will be collected.

## ETHICAL AND REGULATORY ASPECTS

Participation will be voluntary and participants will choose what they wish to disclose. We do not anticipate that participation in the focus groups, interviews or workshop will cause distress to participants; however should that occur, participating NHS Staff will be advised to seek support from their supervisor and service users will be advised to contact the Patient Advice and Liaison Service or a member of their clinical care team. We will minimise inconvenience and demands on participants and offer flexibility to support participation; for example focus groups and interviews will be conducted within participants local area.

It is highly unlikely participants will disclose any information that is deemed to be a criminal offence or require further action. If information is disclosed that could pose a risk of harm to the participant or others, the research team will discuss it and report accordingly where appropriate. If information is disclosed during focus groups or interviews that relates to poor practice, the research fellows will discuss it with the Chief Investigator and, where appropriate, report accordingly to the Manager of the relevant Trust.

Where research staff may undertake interviews and site visits alone, the University of Nottingham Lone Working Policy will be adhered to.

## ETHICS COMMITTEE AND REGULATORY APPROVALS

Phase 1 of the study is a service evaluation and therefore does not require ethical review.

Phase 2 and 3 of the study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), and the respective National Health Service (NHS) Research & Development (R&D) department. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki (1996); the principles of Good Clinical Practice, and the Department of Health Research Governance Framework for Health and Social care (2005).

## INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator or their nominee and the participant shall both sign and date the Consent Form before the person can participate in the study. The participant will receive a copy of the signed and dated forms.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled. No study-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Consent Form by the REC and use of the amended form (including for ongoing participants).

## RECORDS

All participants will be made aware that all data will be anonymised with pseudonyms applied.

Each participant will be assigned a study identity code number, for use on transcripts, other study documents and the electronic database. The documents and database will also use their initials (of first and last names separated by a hyphen, or a middle name initial when available).

Transcripts and other study documents and databases, will be treated as confidential documents and held securely in accordance with regulations. Transcripts and other study documents and database shall be restricted to those personnel approved by the Chief or local Investigator and recorded as such in the study records.

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated.
The Chief or local Investigator shall sign a declaration ensuring accuracy of data recorded in the transcriptions or other study data.

### Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, study records, field notes, interview transcriptions and audio records. Only study staff shall have access to study documentation other than the regulatory requirements listed below.

### Direct access to source data / documents

All source documents shall made be available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities.

## DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 1998. The researchers will only collect the minimum required information for the purposes of the study and this information will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the study staff and investigators and any relevant

regulatory authorities (see above). Computer held data including the study database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method).

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

## QUALITY ASSURANCE & AUDIT

## INSURANCE AND INDEMNITY

Insurance and indemnity for clinical study participants and study staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

## STUDY CONDUCT

Study conduct may be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria); accountability of study materials.

## STUDY DATA .

Monitoring of study data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The Study Coordinator, or where required, a nominated designee of the Sponsor, shall carry out monitoring of study data as an ongoing activity.

Study data and evidence of monitoring and systems audits will be made available for inspection by the REC as required.

## RECORD RETENTION AND ARCHIVING

In compliance with the University of Nottingham Code of Research Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all anonymised audio recordings, study databases and associated meta-data encryption codes.

## DISCONTINUATION OF THE STUDY BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

## STATEMENT OF CONFIDENTIALITY

Individual participant medical (for service users) or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Participant confidentiality will be further ensured by utilising pseudonyms.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

## PUBLICATION AND DISSEMINATION POLICY

Following approval of workshop outcomes by the funder, the interventions and service guidance that have been developed from the workshop will be made available to commissioners and providers of maternity services in England. The guidance will address both services currently without MUs to facilitate the establishment of MUs and services that need to maximise utilisation of existing MUs. The guidance will be disseminated via email and post to commissioner and provider groups across England, through the existing maternity and neonatal networks, whose representatives have participated in the stakeholder workshop. In addition, they will also be sent to the NICE Intrapartum Guideline Group, the Royal College of Midwives Heads of Midwifery network in England, the Department of Health, the all-party parliamentary group on Maternity and all other organisations and professional bodies represented by the workshop stakeholders.

A final and full research report detailing all the work undertaken, an abstract and an executive summary will be made available on the HSDR programme website. PowerPoint slides (up to 10 maximum) which present the main findings will be made available on the HDSR programme website.

All participants in the research will be sent an Executive Summary of the findings (a plain English summary in accessible language will be produced for service-users). The plain English summary will be reviewed by the study PPI representatives, before distribution.

In addition to the research being published in the NIHR HS&DR Journal, key themes within the findings and interventions/service guidance will be published in high impact journals targeting midwifery, obstetric, sociology of organisations and sociology of health/reproductive studies, particularly those with Open Access. In addition, papers will be submitted to non-academic professional journals like MIDIRS. As the user organisations (NCT, AIMS, National Federation of Women's Institutes, Mumsnet, BirthChoiceUK) are either on our Advisory Group or involved in the stakeholder workshop, we will offer summaries for their respective journals and web sites.

The key findings, implications, proposed interventions and service guidance will be presented by the CI and members of the research team at a range of international and

national conferences: NHS Confederation Conference, NICE Annual Conference, International Confederation of Midwives' Congress, British Perinatal Medicine Society. All impact activities will be supported by a project webpage, a regular project newsletter and Twitter account.
BirthChoiceUK will release a press statement on the primary findings.

Participants will not be identified in any publications.

## USER AND PUBLIC INVOLVEMENT

Service users (from both local and national groups) have been involved at all stages of the development of the study and are represented in its advisory, and management groups. An experienced service user representative is a co-applicant on the bid.

Members of the Nottingham Maternity Research Network will review our draft posters, information leaflets, consent forms and data collection tools. In addition, they will provide advice from the patient perspective, throughout the life time of the project, comment on design of information materials for women, focus group and interview schedules and review the interpretation of findings, the proposed interventions and service guidance.

Service users will be reimbursed for all out of pocket expenditure, and receive acknowledgement for their contribution, according to INVOLVE guidelines. Members of the Nottingham Maternity Research Network will also be invited to take part contribute in the stakeholder workshop.

We are asking a member(s) of the Nottingham Maternity Research Network to co-facilitate the user focus groups in the 6 case study sites. Training will be provided and all appropriate clearances will be obtained appropriate to the co-researcher role.

## STUDY FINANCES

### Funding source

This study is funded by NIHR Health Services and Delivery Research Programme

### Participant stipends and payments

Participants will not be paid to participate in the study. Reimbursement of travel and childcare expenses will be offered to service-users for expenses incurred during focus group/interview attendance. Additionally, a high-street voucher of £10 will be provided to service-users upon completion of a focus group. Travel expenses will be reimbursed to stakeholders who attend a workshop.

## SIGNATURE PAGES

Signatories to Protocol:

**Chief Investigator:** (name)_____

Signature:_____

Date: _____

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