FULL/LONG TITLE OF THE STUDY

Interactional practices of decision-making during childbirth in maternity units

SHORT STUDY TITLE / ACRONYM

VIP: Video Informed Practice/Voices in Partnership

- **This protocol has regard for the HRA guidance**

RESEARCH REFERENCE NUMBERS
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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.
I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor
I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

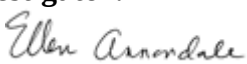
For and on behalf of the Study Sponsor:

Signature:  Date: 17/10/2018

….....

Name (please print):
Michael Barber.....
Position: Contracts & Sponsorship Manager.....

Chief Investigator:

Signature:  Date: 17/10/2018

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FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN** NIHR HS&DR, University of Southampton, Alpha House, Enterprise Rd., Southampton, SQ16 7NS Tel: 023 8059 4304
NIHR Health Services and Delivery Research Programme	£511,189.85 (excluding NHS costs)

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor (the University of York) has responsibility for the initiation and management of the study. It will have oversight of the study design and conduct during the initial set-up phase, as part of the process of applying for HRA approval. Final decisions concerning data analysis and interpretation, manuscript writing and dissemination rest with the research team, not with the sponsor.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

- Study Steering Group

The steering group will assist in the management of research ethics, in issues of research design, and the evaluation and dissemination of findings. Membership includes Professor Paul Drew (conversation analyst), Dr Emma Ferriman (Consultant Obstetrician), Dr Joyce Marshall (Senior Lecturer in Midwifery), Dr Julie Goddard (Consultant Obstetrician), Mr Patrick Tilley (Lecturer in Theatre, Film and TV), and Professor Jo Green (Professor Emeritus in Health Psychology). With the exception of Professor Jo Green (who is a vital member of the Steering Group owing to her expertise in the field and her role in the design of the original questionnaires that are being adapted for use in this study) who all Steering Group members are independent of the research team and are not based at the sponsoring organisation.

- Patient & Public Involvement Group

We very much appreciate and welcome the involvement of service users in the development, implementation and dissemination of the research. Our engagement with service users has helped us to more fully frame the relevance of our proposed study for women and their partners/families. In recognition of this, one of our co-applicants (Laura Cook) is a PPI member, and is a full member of the research team, with a specific role to provide guidance in designing, implementing and disseminating research that emphasises service-user voices and concerns.

In addition, we have set up project-specific Service User Groups (SUGs) groups (one at each of the two hospital trusts where the research is taking place: Royal Hallamshire Hospital and Calderdale Royal Hospital to advise on:

1. The research design and development of participant information resources (e.g. information sheets and consent forms);
2. Advising on matters that arise (e.g. difficult scenarios);
3. The reporting of the research by reviewing the interim and final project reports;
4. The dissemination of research findings by contributing to the project website, information for service users, and planning and running the dissemination workshops for health care practitioners.

Protocol contributors

The research team - Ellen Annandale (PI, University of York), Helen Baston (Sheffield Teaching Hospitals NHS Foundation Trust), Siân Beynon-Jones (University of York), Alison Brodrick (Sheffield Teaching Hospitals NHS Foundation Trust), Laura Cook (PPI), Clare Jackson (University of York), Victoria Land (University of York), and Sue Townend (Calderdale and Huddersfield NHS Foundation Trust) are responsible for the design of the protocol. Service users have also been involved throughout study design, and will continue to be involved in study implementation (as detailed above). A Research Associate (RA) will also be appointed to the study (and based at the University of York), and will be a member of the research team with corresponding responsibilities for study conduct, data analysis, manuscript writing and dissemination.

The sponsor (the University of York) will have oversight of the study design and conduct during the initial set-up phase, as part of the process of applying for HRA approval. Final decisions concerning data analysis and interpretation, manuscript writing and dissemination rest with the research team, not with the sponsor.

KEY WORDS: Birth, Choice, Conversation Analysis, Healthcare Interactions, Midwifery, Shared Decision-Making.

STUDY FLOW CHART

FLOWCHART FOR ANNANDALE et al. 14/70/73
Interactional practices of decision making during childbirth in maternity units

Eligible Sample Population

Women: any woman (aged 16+) attending study two sites (Sheffield and Calderdale Hospital Maternity Units) with a low risk, singleton pregnancy and who expects to have a vaginal birth at full-term in a midwife-led maternity unit (Sheffield)/birth centre (Calderdale) – hereafter referred to collectively as maternity units. Their Birth Partners. Healthcare Practitioners (HCPs): all clinical staff at study sites.

PILOT STUDY (0-4 months)

Recruitment & Consent of Women, Birth Partners and HCPs

1. Women

Initial approach

Research midwives (RM) will screen and approach eligible women to provide details of the study at the 20-week scan appointment or at antenatal appointments thereafter. Alternatively, a member of the care team will ask eligible women if they would like to talk to a member of the University of York research team (hereafter 'UoY researcher') about the study. The UoY researcher will make herself available in antenatal clinics where practical to talk to women about the study, if they are interested. She will not approach any women unless they have been referred to her by a member of the care team.

Women will be given information for themselves and birth partners and asked to indicate interest (Maybe/No) via an 'expression of interest' form which asks for contact details. The form also asks (optionally) for reasons for declining. Women (and birth partners, if present) who are interested in taking part will have the option of giving consent in one of two ways:

1) **At the 20 week scan appointment at the hospital or at antenatal appointments thereafter.** This provides women and birth partners who are certain that they wish to take part, with an option of consenting at this time point. The research midwives (or UoY researcher, following referral by the care team) will approach women for expression of interest either before their scan has taken place or after, although consent will only be taken after the scan has taken place. The research midwives (or UoY researcher) will have given women (and birth partners, if present) a full opportunity to ask any questions that they may have.

Or

2) by Follow-up phone-call/consent (for those who do not consent at the 20 week scan/other antenatal care appointment thereafter)

The RM or UoY researcher (as practicable) will follow up women who have expressed interest at the 20 week scan with a telephone call to clarify any questions and confirm whether women remain interested in taking part, as well as to screen for ongoing eligibility. If a woman still wishes to take part, the RM or UoY researcher will make an appointment to take consent in one of three ways as convenient and (depending on the participants' preferences:

1. **Face to face in the woman's home (or other location of her choosing)**
2. **In an antenatal care setting to coincide with her midwifery care**
3. **Remotely via skype /social media or telephone (with the consent form returned via s.a.e.)**
4. **If the birth partner is not present at the woman's consent meeting, the woman may take the consent form for her partner to consider and sign and post it back (S.A.E provided) to the hospital**

Consent will be re-confirmed verbally when a woman arrives at the maternity unit in labour. Women will be instructed to identify themselves as a study participant when they contact the maternity unit. Additionally, a notice that they are study participants will be placed in their hand-held notes at their consent appointment. At Calderdale, where electronic rather than hand-held notes are primarily relied upon, a notice will be placed in the woman's electronic notes following consent.

Women may also be recruited into the study outside of this standard route. Women may not have attended their 20 week scan but may have heard of the project through a friend or seen a project poster. Or, women may have attended their 20 week scan but the RM was not able to approach them (e.g. if busy talking to another woman). **In such cases, women may be offered information about the study at subsequent antenatal appointments at any time after the 20 week scan. The study would only be discussed with women who intend to birth under midwife-led care. Once women have expressed an**

interest in the study they will follow the consenting process as detailed **above.**

2. Birth Partners

Birth Partners will receive information at 20-weeks or thereafter (via women, who will be asked to pass study information sheets to anyone who is likely to attend the birth). Every effort will be made to ensure that the birth partner is included in the woman's consent appointment in order to obtain written consent from the birth partner prior to labour**. If the birth partner is not present at the woman's consent meeting, the woman may take the consent form for her partner to consider and sign and post it back (S.A.E provided) to the hospital** However, if it is not **possible to** obtain consent from a birth partner prior to labour (for example, because a different person attends the birth than was originally planned), then, when a woman arrives in labour, maternity unit staff will verbally confirm that the birth partner is happy to be recorded. Maternity unit staff will note when a recording takes place in a research log book, using an anonymous participant code, and will indicate the need to obtain retrospective written consent from the birth partner. Consultant midwife team members or the UoY researcher (as practicable) will regularly check the log book and will follow up to obtain retrospective written consent from the birth partner for the use of footage including them for the research and/or, following digital anonymization, for presentations and workshops.

3. Healthcare Providers (HCPs)

HCPs in maternity units at both sites will be briefed in writing and invited to meetings (e.g. through maternity unit forums) and given an opportunity to provide written consent to opt into the study. Posters about the research study will also be placed around both study locations, to ensure that non-clinical staff (cleaners and administrators, for example) are aware of the study. Every effort will be made to obtain written consent from staff prior to recording. However, it is possible that staff that has not previously consented will have to enter a room to provide care during labour. Recording signs will be placed on the doors to highlight that recording is in progress and that no footage of staff will be used in the study unless written consent is given. Consultant midwife team members or the RA (as practicable) will follow up with staff post-recording to confirm whether they are happy to provide retrospective consent for the use of the footage in the research and additionally, following digital anonymization, for presentations and workshops, or if they do not want footage to be used at all.

FOUR-MONTH REVIEW POINT: we will assess the recruitment phase and proceed to purchasing main cameras if expressions of interest are received from at least 4 women (which, allowing for set up and momentum, equates to 1-2 women per week in months 3 and 4) and a viable number (to be determined) of HCPs. In the event of minimal expressions of interest (less than 4 women) but viable consent from HCPs, we will purchase cheaper alternatives to record consented women before end of month 12. Recruitment of women would continue during this time period, providing that women were expected to give birth before the end of month 12.

PILOT STUDY 5-12 Months

Antenatal Questionnaires

Consented women will fill in a self-completion questionnaire adapted from *Great(er) Expectations* studies either via post or online (according to participants' preferences as provided on the consent form) when they are around 35 weeks pregnant. These will survey demographic information (e.g. parity, age, ethnicity, and socio-economic class) and women's preferences and plans for labour. Pre-paid reply envelopes will be supplied if the postal option is chosen. Research midwives will consult women's medical notes close to this time point in order to make sure that they are still eligible (i.e low risk pregnancy) for the study. If a woman is consented into the study after 35 weeks, she will be provided with the antenatal questionnaire.

Recording of Labour

Consent of women and birth partners will be reconfirmed verbally on admission. Consenting women (and birth partners) will have their labours video or audio recorded, depending on their preference. Women and birth partners will have been informed (via the study information sheet) that the ability to record labour on the day is contingent on a number of factors including the availability of recording equipment (e.g. whether a camera is already in use) and sufficient numbers of staff who have agreed to be filmed.

Maternity unit staff or the UoY researcher (as practicable) will set up equipment and demonstrate how to turn on/off

recording (to give control to participants). To minimise intrusion, cameras will be sensitively positioned (with input from women), static, and will not require extra persons present in order to film. The SMOTS cameras used for recording will record onto an encrypted hard drive on a local remote computer positioned in a locked office, ensuring data security. Practicality and quality of recording will be evaluated and required adjustments made for the main study.*

Interviews with Healthcare Practitioners

Interviews (semi-structured) with a sample of approximately twenty practitioners (around 12 midwives and 8 doctors, selected by grade to ensure different levels of staff are represented) will be conducted across the two sites. Participants will be provided with an information sheet and written consent will be obtained prior to interviews. Interviews will ask for professional perceptions of the organizational factors that facilitate, or constrain, shared decision-making during labour. For example, the busyness of the unit, local protocols, the availability of staff, and the mix of skills they have. Interviews will also be used to explore staff experiences and views about the feasibility of recording, to inform the study design.*

Postnatal Questionnaires

Six weeks postnatally, women will be asked to self-complete a postnatal questionnaire from the *Great(er) Expectations* studies via post or online (according to participants' preferences). This will survey levels of satisfaction with both the decisions made in labour and with how they were communicated. Pre-paid reply envelopes will be supplied to women who choose the postal option. Questionnaires will also include questions about women's experiences of study participation and will ask if it they are amenable to being contacted by the research team by telephone if we would like to follow up a woman's responses to these questions in greater depth. This information will be used in order to inform practices and procedures for the main study.*

12-MONTH REVIEW POINT: Evaluation of pilot study, decision made whether to proceed to main study. Key criteria include obtaining 4-8 consented and analysable recordings of birth, 5 expressions of interest from women per week, 1-2 consents per week.

MAIN STUDY

Month 13 to 36 make refinements and roll out earlier phases of research (except for follow-up telephone calls with women/partners regarding experiences of study participation) from recruitment (ends at 27 months) through to postnatal questionnaires (data collection ends at 32-33 months).

Analyses

Analysis of recordings will focus on decisional interactions (e.g. discussions of pain relief) between staff, women and birth partners. These sections will be transcribed verbatim, anonymised, and analysed using conversation analysis (CA). We will build a collection of instances where women face decisions about their care. We will compare instances in order to identify the different ways of communicating that are used (e.g. offering/requesting options, open/closed questions). Responses will also be analysed (e.g. do some communication practices provide more/less 'shared space' for decision-making). Statistical analyses of questionnaire data will explore associations between what actually happened in the midwifery unit, women's antenatal expectations, and their subsequent levels of satisfaction with how decisions were discussed during labour and birth. Interviews with HCPs will be analysed thematically to provide contextual information about the practices of the institutions within which professionals work. See 'flowchart of data analysis' for further information about this phase of the study.

Dissemination

STUDY PROTOCOL
Interactional practices of decision-making during childbirth in maternity units

1 BACKGROUND

Numerous studies show the nature of the interaction between a labouring woman and her caregivers is key to a woman's experience (Attanasio & Kozhimannil, 2015; Attanasio, McPherson, & Kozhimannil, 2014; Baas et al., 2015; Hodnett, 2002; Kozhimannil et al., 2015) with a systematic review (Hodnett, 2002 p.171) concluding that 'influences of pain, pain relief, and intrapartum medical interventions on subsequent satisfaction are neither as obvious, as direct, nor as powerful as the influences of the attitudes and behaviours of the caregivers'. However, we know from women's retrospective accounts that there is much variation in women's feelings of inclusion in decision-making (Boyle, Thomas, & Brooks, 2016; Bylund, 2005; RCM, 2013). A survey conducted by Thompson & Miller (2014) emphasises variability of practice and reports low involvement in decisions about vaginal examinations, foetal monitoring, episiotomies, and blood tests. A Care Quality Commission (2013, p.2) states almost 1 in 5 'felt that their concerns during labour were not taken seriously', with some feeling demeaned by dismissive/disrespectful conduct of staff during labour. So, we know communication in labour matters. What we do not know is what exactly it is that practitioners say and do in practice that leads to these appraisals and outcomes.

Most studies have relied on retrospective reports, rather than analysis of *in situ* practices that occur during labour, where decision-making is ultimately accomplished. Ethnographic observations (e.g. Annandale, 1987, 1988; Hunt & Symonds, 1995; Machin & Scamell, 1997; Scamell, 2011; Walsh, 2006) have provided valuable insights but these often gloss the features of interaction. As a consequence of retrospective data and the lack of focus on the details of actual instances of interaction, only general recommendations for effective practice are offered. For example, the Standards for Maternity Care (Royal College of Obstetricians and Gynaecologists, Royal College of Midwives, Royal College of Anaesthetists, 2009) require that 'professionals should work in partnership with women and their families, respecting their views and striving to ensure safe and positive outcomes for women and babies at all times' (Standard 22.3). However, there is little guidance on exactly how to facilitate women's involvement in decision-making. This study aims to address the gap in knowledge about what actually happens in labour.

To do this, we will:

- Video (or audio record if women prefer) the labours of 20-30 low-risk, full-term women and write down in full what was said and how it was said (e.g. laughing, sighing). Recording will be initiated only when all parties (women, partners and staff) agree to it. Women will have the explicit right to change their mind at any point during the recording, and request that the recording is stopped and/or not used for the project.
- Analyse how decisions are discussed using Conversation Analysis (CA), which is the leading research method for understanding how talk works.
- Use questionnaires before birth to ask women about their expectations and after birth to ask about their satisfaction.
- Look at patterns between how satisfied women were with their experience and the decision-making interactions that actually happened during birth.

- Conduct one-to-one interviews with selected midwives and doctors to ask about what they think is helpful and unhelpful in giving women choice.

2 RATIONALE

Why the research questions/aims are important in terms of improving the health of the public and/or to patients and the NHS:
Health Need: There are health-related benefits for women in labour when they can participate in decisions that impact their care and treatment.

Expressed need: Examination of decision-relevant discussion in clinical settings is of significant concern to the NHS, health care practitioners (HCPs) and service-users because it is in these discussions that the distributed rights and obligations of all parties can be realised or inhibited. The DH and NHS recognise that skilled communication is a key to ensuring that service-users can participate in health decisions. The translation of 'choice' policies into practice, however, has proven challenging in many healthcare contexts (Elwyn et al., 2010). There is a need for training materials, based on the details of what really happens to more effectively translate policy into practice. Our key research questions have arisen out of the three consultant midwife co-applicant's experience and aim to address uncertainty expressed by their colleagues about how to achieve a shared approach without either, imposing, or abandoning, the authority necessary for patient safety.

Sustained interest and intent: A shared approach to decision-making for women giving birth has been a key tenet of NHS policy for the last twenty-years. The Chair of the influential Health Select Committee review of maternity services (Department of Health, 1993) has commented *(*RCM, 2013), that, 'Changing Childbirth is as relevant today as it was then [in 1993]. But we should be making further progress. It is unfinished business.'

Capacity to generate new knowledge; building on existing work: Most research on decision-making has not focused on what happens during real interactions and hence is unable to provide specific, evidence-based guidance on what works best. To our knowledge, no research has focused specifically on the communication strategies HCPs use to include women in decision-making during labour. We will be building on: research on shared decision-making; women's experiences of, and satisfaction with the birth experience, and; the CA literature on examining interactions in medical settings.

Generalisable findings and prospects for change: We will produce findings of practical value to HCPs working in a range of settings; particularly in acute settings.

Organisational focus consistent with HS&DR remit: Our research addresses 'an issue of major strategic importance to the NHS' through a direct focus on choice and shared decision-making. The focus on providing an evidence base for how to implement a shared approach in maternity care

(labour) has the potential to lead to 'changes in practice that will have a significant impact on a large number of patients across the UK'. There is no current research that systematically examines the details of interactions between HCPs, women and partners and so aims to, 'fill a clear 'evidence gap', ... likely to generate new knowledge of direct relevance to the NHS'. The findings will be relevant for all medical contexts where HCPs and service users interact with each other, and so has 'the potential for findings to be applied to other conditions or situations outside the immediate area of research'. Our core research team comprises of 4 academic staff with different yet complimentary expertise, 3 consultant midwives (based in 2 different hospital settings) and a member of the public, and hence bring[s] together a team with strong expertise and track record across the full range of relevant disciplines and will be carried out across more than 1 research site.

3 THEORETICAL FRAMEWORK

Shared decision-making is a relational process (Légaré & Witteman, 2013) and the DH and NHS recognise that skilled communication is key to ensuring that service-users can participate in health decisions. The translation of 'choice' policies into practice, however, has proven challenging in many healthcare contexts (Elwyn et al., 2010; Elwyn et al., 2013) and has led to considerable research on conceptualising and fostering shared decision-making. One major output has been the development of models that capture the elements of a shared approach. For example, (Elwyn et al., 2012) identify choice talk, option talk and decision talk and offer hypothetical phrases to elicit these. However, as (Pilnick, 2008, p. 512) argues, '…what the offering and exercising of choice actually looks like in practice… remains unclear. The potential implications of these interactional processes, though, are immense, since… 'good' practice is ultimately achieved through interaction rather than through policy or regulation' (something not yet done in maternity unit interactions).

A focus on the detail of communication (using conversation analysis) matters for several reasons. First, patient satisfaction with practitioners' communication strategies more broadly is found to be associated with patients being: 'more likely to have an increased level of physical functioning, more likely to adhere to medical recommendations, less likely to request post-operative narcotics, [and] less likely to change physicians' (Robinson & Heritage, 2006, p. 280). Second, the precise wording that practitioners use can make a significant difference to the interaction in ways that might not be open to speakers' intuitions. For example, a small change in question format from, ''is there anything else you want to address today' to 'is there something else you want to address today' elicits significantly more reported concerns from patients (Heritage et al., 2007). Third, what might on the surface appear to be providing choice through, for example, describing a menu of options from which a patient can select, can be achieved in practice in ways that can open up or close down, a space for patients to participate in decisions. For example, a HSR funded project (see Toerien, et al., 2011; Toerien, Shaw, & Reuber, 2013) shows that the precise interactional features of the ways alternative options are offered can effectively produce one or other of them as favoured by the HCP, hence constraining rather than encouraging patient participation.

Policy level conceptualisations of choices available to women tend to emphasise 'big' decisions about, for example, place of birth, choice of birth partner and preferences for the presence or absence of partners if particular events should occur (e.g. 'assisted delivery). These are, of course, important decisions for women, and can in large part be taken outside of the context of birth itself. However, once in labour, a woman may be faced with numerous decisional moments that may or may not have been foreseen and which have to be acted upon in the moment, when she might be in pain and/or focusing inwardly to manage the birth (Nieuwenhuijze & Low, 2013). The decisions made before birth may have to be revisited again and again in the unfolding moments of events. As far as we know, no study has systematically examined situated decision-making in this kind of fast-moving, time-limited context.

This study aims to directly address this gap in knowledge about what actually happens in situated clinically relevant talk during labour to demonstrate shared decision-making may be nurtured (Gee & Corry, 2012) in a context (not unique in healthcare) where there are special time-limited contingencies.

Addressing these questions requires close analysis of authentic real-time (video or audio-recorded) discussions in the midwifery unit. The interactional data will be considered alongside antenatal and postnatal surveys to assess whether women expect to be involved in decision-making and the extent to which the communication strategies actually used are associated with satisfaction with the birth experience. Together, the findings will provide an understanding of situated interactional practices for managing and sharing decision-making in clinical practice.

Our primary focus is on communication between women, their birth partners and HCPs (rather than on clinical practice). However, communication takes place within particular social contexts, and our study aims to foreground this. As numerous studies within the sociology of technology attest, provision of healthcare inevitably involves interactions between patients, health providers and technologies. Studies highlight, for example, how record-keeping devices shape clinical practice (Berg & Bowker, 1997), and how technologies used to measure blood sugar levels become part of the interactions which take place between diabetic patients and care providers (Mol, 2009). In the context of birth, ethnographic research suggests that the centrality of the electronic fetal monitor impacts on the dynamics of obstetric care (Cartwright, 1998). Accordingly, our research will include examination of how technologies (such as patient records, fetal monitors, and devices used to deliver pain relief) feature in interactions between women and HCPs.

We also aim to capture HCPs' views about interaction and decision-making and experiences of possible tensions that arise for them in their institutional practice. Enacting a woman- centred approach, including the continuity of care commitment, is resource-rich in terms of staff-time and skill (NICE, 2015). There is a lack of research on the relationship between how maternity care workforces are organised, timeliness and quality of care (Sandall, 2012) of which good communication and shared decision-making are a part. Thus, we seek to explore HCPs' view of the

possible impacts of organisational factors such as staffing levels, skills mix, case mix, transfers and (planned and unplanned) fluctuations in demand upon interactional strategies and how decision-making is implemented.

4 RESEARCH QUESTION/AIM(S)

The main study aim is to identify the key interactional strategies used in practice by healthcare professionals, labouring women and their birth partners to initiate and manage decision-making during normal childbirth. Its primary research questions are:

> What communication strategies are used to initiate decision-making? For example, are decisional moments posed as open questions, through option-listing, asking yes/no interrogatives, making requests? How do participants use non-verbal cues such as facial expressions, body language of distress/pleasure, to evoke responses from others?
>
> What responses are made relevant by these strategies? For example, do the initiating turns at talk provide space for a narrative response, informed selection of an option, or a yes/no answer? How are these responses conveyed non-verbally (e.g. nods, closing of eyes to withdraw from the interaction)?

4.1 Objectives

1. To create a rich dataset based on 20-30 women's experiences of giving birth in midwifery-led units in hospitals. We will collect data from women at three points: antenatal questionnaires surveying women's expectations and preferences for birth; intra-partum video/audio recording of labour and births; postnatal questionnaires about their experiences of, and satisfaction with, decision-making during labour.

2. To contribute to the evidence base for shared decision-making through our fine-grained analysis of the verbal and non-verbal detail of interactions that take place in real-time during birth, specifically: how decisions are initiated; who initiates them, and; how different ways of initiating decisions are responded to. The focus will be on how talk is used (by all parties) to encourage or discourage shared-decision making over the course and events of a birth. The primary analytic method will be Conversation Analysis.

3. To assess whether women's actual experiences reflect their antenatal expectations and whether there is an association between interactional strategies used (by all parties) during labour (particularly the extent to which decisions are shared) and women's later reported level of satisfaction. In this way, we can assess whether satisfaction is related to definable aspects of practice in the maternity unit.

4. To disseminate findings to healthcare providers and service-users to contribute to translating existing Department of Health and NHS policy directives on sharing decision-making into clinical practice.

4.2 Outcome

As this is an explorative qualitative study it is not appropriate to predict potential outcomes at this stage. However, as noted above, we anticipate that the conversation analysis of video-recorded interactions will provide insights into how decision-making actually takes place during birth. This will enable us to contribute to attempts to translate Department of Health and NHS policy directives on sharing decision-making into clinical practice.

5 STUDY DESIGN AND METHODS OF DATA COLLECTION AND DATA ANALYIS

To identify how decisions are initiated, managed, and responded to moment-by-moment in real-time we will video or audio record (as consented to) and analyse 20-30 births across two midwife-led maternity units (at Sheffield Royal Hallamshire and Calderdale Royal Hospitals). We adopt an 'action-based' approach to understanding communication in medical care, derived from the micro-analytic tradition of conversation analysis (CA). We start from the understanding that talk is used to perform social actions; to 'do' things (like offering choice of pain relief). We know that the same action may be accomplished in very different ways, so a woman can be offered choice about pain relief in a way that invites her active participation in the decision, or in a way that more or less closes down a range of options. The key question, then, is not necessarily whether something occurred during the birth but how it was accomplished (Drew, Chatwin, & Collins, 2001). Our approach is thus empirical, focusing on the verbal and non-verbal detail of what happens between practitioners, labouring women and their birth partners; and applied, seeking to produce findings that are demonstrably relevant for practice.

In recognition of the ambitious and ethically challenging nature of the research this is a staged project that includes a 12-month pilot study to ensure its feasibility (with opt out at 4 and 12 months). The following information is based on implementing the full study (months 12-36) but will also show how our review criteria (RC) concerning key uncertain parameters are embedded into our staged study design.

Participants:

20-30 women[1] (aged 16+) with a healthy singleton pregnancy expected to labour spontaneously and give birth vaginally at term at the alongside midwifery led unit (Sheffield) or birth centre (Calderdale), their birth partners (where relevant) and HCPs (midwife-led unit clinical staff at each site). Given the ethnic diversity of our research sites, we anticipate that a minority of women may not be able to converse in English. We do not wish to exclude these women and so have included costs for translation of study materials.

Sampling, Recruitment and Consent:

Posters highlighting the study will be placed in clinic waiting rooms to raise awareness among staff, women and their birth partners. Research midwives (RM) will approach eligible women at the 20-week scan appointment, or at antenatal appointments thereafter. **Alternatively, members of the care team will ask eligible women if they would like to talk to the UoY researcher about the research at the 20 week scan appointment, or at antenatal appointments thereafter. The UoY researcher will make herself available in clinics to talk to women (and their**

[1] A sample size of 20-30 women has been selected to allow for a diverse range of participants to participate whilst producing data that are manageable for the conversation analytic work.

birth partners) about the study, if they are interested. She will not approach any women unless they have been referred to her by a member of the care team.

Women will be given information for themselves and birth partners (where relevant) and asked to indicate their interest (Maybe/No) via a form, which also asks (optionally) for reasons for declining.

Women (and birth partners, if present) who are interested in taking part will have the option of giving consent in one of two ways:
1) At the 20 week scan appointment at the hospital, or at antenatal appointments thereafter. This enables women and birth partners who are sure at this time point that they wish to take part, with the option of consenting at this point. The research midwives (or UoY researcher, following referral) will approach women for expressions of interest either before their scan has taken place or after, although consent will only be taken after the scan has taken place. The research midwives (or UoY researcher) will have given women (and birth partners if present) a full opportunity to ask any questions that they may have.
Or
2) by Follow-up phone-call/consent (for those who do not consent at the 20 week scan/other antenatal appointment thereafter)
The RM or UoY researcher (as practicable) will follow up women who have expressed interest with a phone call and will consent women who want to take part (See section 7.3.2 for full details of consent process). Birth Partners will receive information at 20-weeks or thereafter (via women) and will be consented by the UoY researcher or RM at the woman's consent appointment, where possible (see section 7.3.2 for full details of birth partner consent process).

/Following the pilot phase of the research we now know that approximately 10% of women approached consent to recording. We also know that the conversion rate of consents to recordings is approximately 20%. On this basis we will approach approximately 1500 women across both sites over the recruitment period in order to obtain 150 consents, which we anticipate will convert to 30 recordings. In the event of over-recruitment we will develop selection criteria for purposive sampling based on parity and socio-demographic characteristics.

HCPs will be briefed in writing and invited to meetings (e.g. through maternity unit forums) to discuss the project and will be given the opportunity to opt into the study (see section 7.3.2 for full details of HCP consent process). We do not yet know what percentage of HCPs will need to give consent in order to make the study viable. We will use months 0-4 of the project to determine a specific figure to use as a criterion for feasibility. Video/Audio recording will be initiated only in cases where all parties - women, birth partners (where relevant) and HCPs - agree.
All of these procedures will be piloted and adapted as necessary in the first four months of the project.

*Review Criteria at 4 months Pilot Study***:** In order to recruit 50[2] women we need to achieve expressions of interest from approximately 5 women per week over 12 months (from month 5-18). Allowing for initially slow momentum in the early stages of our research, our criterion for the first two months of recruitment (months 3-4) is to achieve expressions of interest from 4-8 women which equates to 1-2 per week, their birth partners and viable consent from HCPs. In the event that we do not meet these criteria but have secured expressions of interest from any women and have viable consent from HCPs, we will purchase cheaper cameras and record the births of consented women before the end of month 12. Real-time recordings of any births will provide invaluable information to inform practice.

Data collection:

We will collect three forms of data:

1) Video/audio recordings (as consented) from a convenient point for the woman following admission to the midwifery unit until after birth (or as consented). The study aims to examine routine care, so HCPs will be advised by the consultant midwife team members not to diverge from their usual practice. To minimise intrusion, recording will not require extra persons to be present. Instead, women and their birth partners will have key input into positioning recording devices and will have the capacity to switch on/off (or to request that others do so).* In switching the camera/audio off we have prioritised the woman's consent in making this decision. Thus HCPs cannot switch the camera off without the woman's consent (unless there is a medical emergency) and we have encouraged the birth partner to switch the camera off only with the woman's consent wherever possible. Practicality and quality of recording will be evaluated in the first 12 months of the project (pilot stage) and any required adjustments will be made for the main study. Consultant midwife team members or research associate (RA) (as practicable) will take responsibility for collecting and storing recordings.* Data will be encrypted and raw footage viewed only by the research team (additional consent will be sought to use anonymised clips for conferences, training purposes). Postnatal questionnaires (see below) will include questions concerning women's experiences of study participation to inform our procedures as we progress to the main study. Additionally, a sample of women will be re-contacted by phone (permission for this will be sought via questionnaires) to explore their responses concerning study participation in greater depth.

Review Criteria at 12 months: Data will be collected on the number of women approached, the number expressing an interest, the number finally consenting, and the reasons why women opt out at expression of interest stage and full consent stage. By month 12, we need to be achieving expressions of interest from at least 5 women per week and consent from 1-2 women per week. Additional criteria are completion of 4-8 consented recordings; evidence (from questionnaires and debrief telephone calls with women) that filming is practical and ethical, and that it produces good quality audio and/or visual data for CA purposes (i.e. that data is properly hearable and visible).

[2] This was the original target figure during the successfully completed pilot phase. However, as noted elsewhere in the protocol our revised target following the pilot phase is 20-30 recordings.

2) Questionnaires

Postal or online (as preferred by participants) self-completion questionnaires adapted, from *Great(er) Expectations* studies (Green, 1993; Green & Baston, 2003, 2004; Green, Coupland, & Kitzinger, 1990) (ANQ2, PNQ questionnaires) with permission of the researchers and relevant institutions will be completed by consented and eligible women at two points:
Antenatal at 35 weeks pregnancy.* Based on ANQ2, these will capture demographic information (e.g. parity, age, ethnicity and socio-economic class), and women's expectations and plans for giving birth.
Postnatal at 6 weeks.* Based on PNQ, these will capture women's views of how decisions were made and levels of satisfaction with both the decisions made in labour and with how they were communicated between parties.
The questionnaires will help us to determine any associations between women's antenatal expectations and satisfaction expressed postnatally with decisions made during labour. These data will also be triangulated with data from the recordings which will show how decisions were actually communicated in interaction between HCPs, women and their birth partners.

3) Interviews

We will conduct in-depth qualitative interviews (and audio record with consent) a purposive sample of around 20 HCPs (approximately 6 midwives, and 4 obstetricians at each site) on the basis of grade to provide insights into professional perceptions of the factors that facilitate, or constrain, shared decision-making during labour, as well as to provide contextual information about the organisational arrangements in which they work, and HCPs experiences of the study implementation (i.e. how recording is working in practice). These interviews are to be conducted relatively early in the study to inform our procedures, but can be used independently of progression to the main study in order to produce findings on organizational factors that promote and inhibit shared decision-making in the context of midwife-led maternity units.

*These processes will be piloted and adapted over the first year of the study. Any substantial amendments made as a result of the pilot will be submitted for review by the NHS REC.

Data analysis
The research will generate a substantial amount of varied and diverse data and it will be important to fully integrate findings in order to tell a 'whole' and coherent story about the object of study (Britten, 2011). Our primary data will be the interactional data (i.e. recordings of labour).
Prior to analyses, all recordings will be viewed to identify times when HCPs, women and birth partners are interacting together. A professional transcriber (with the help of a translator where needed) will transcribe (from audio) these selected moments verbatim (for up to three hours per birth).[3] These basic transcripts will provide a foundation from which members of the research team can develop the more detailed conversation analytic transcription.
The video interactions between women, their birth partners and HCPs will be analysed using a two-stage process. First, conversation analysis will be used to identify and qualitatively analyse the

[3] Based on clinical experience, we have estimated that there will be, on average, three hours of decision-related talk between HCPs, women and birth partners in each birth.

'decisional moments' that take place during labour. CA is a systematic qualitative method for studying real-life interaction. It is widely recognised as the leading methodology for investigating how communication operates in clinical practice (Heritage & Maynard, 2006). It uses audio- and video-recordings of authentic interactions to enable direct observation and fine-grained analysis, focusing not only on what is said but how it is said. This includes, for example, an analysis of the exact words used, evidence of hesitation, use of laughter and non-verbal aspects such as gaze alignment or use of touch. CA has two key advantages: 1) It does not rely on recall – which can often be incomplete or inaccurate, and; 2) It investigates how people behave implicitly, at a level of detail that they could not be expected to articulate (e.g. in a research interview). Given the likely long length of each recording, it will not be feasible to analyse every moment of interaction. For the purpose of this study, we will specifically focus on interactions between practitioners, labouring women and their partners and will identify key 'decisional moments'. Members of the team with expertise in CA will then produce detailed transcripts of these sections, using Jeffersonian notation – a system for conveying features of speech (e.g. loudness, emphasis, overlapping talk) using typographical symbols (e.g. capital letters, underlining, brackets). The full collection of 'decisional moments' will be examined to identify different strategies used by HCPs, women and birth partners to facilitate decision-making (and, importantly, will include examination of how technologies feature in these decisions). Close attention will be paid to patterns of similarity and difference (e.g. in words or phrases used). Participant's responses to the initiating strategies will be compared to identify any patterns (e.g. some strategies may typically be met with minimal responses, while others might typically elicit narratives). Focusing on details of the talk, our aim will be to see whether some strategies are more effective at implementing shared decision-making than others.

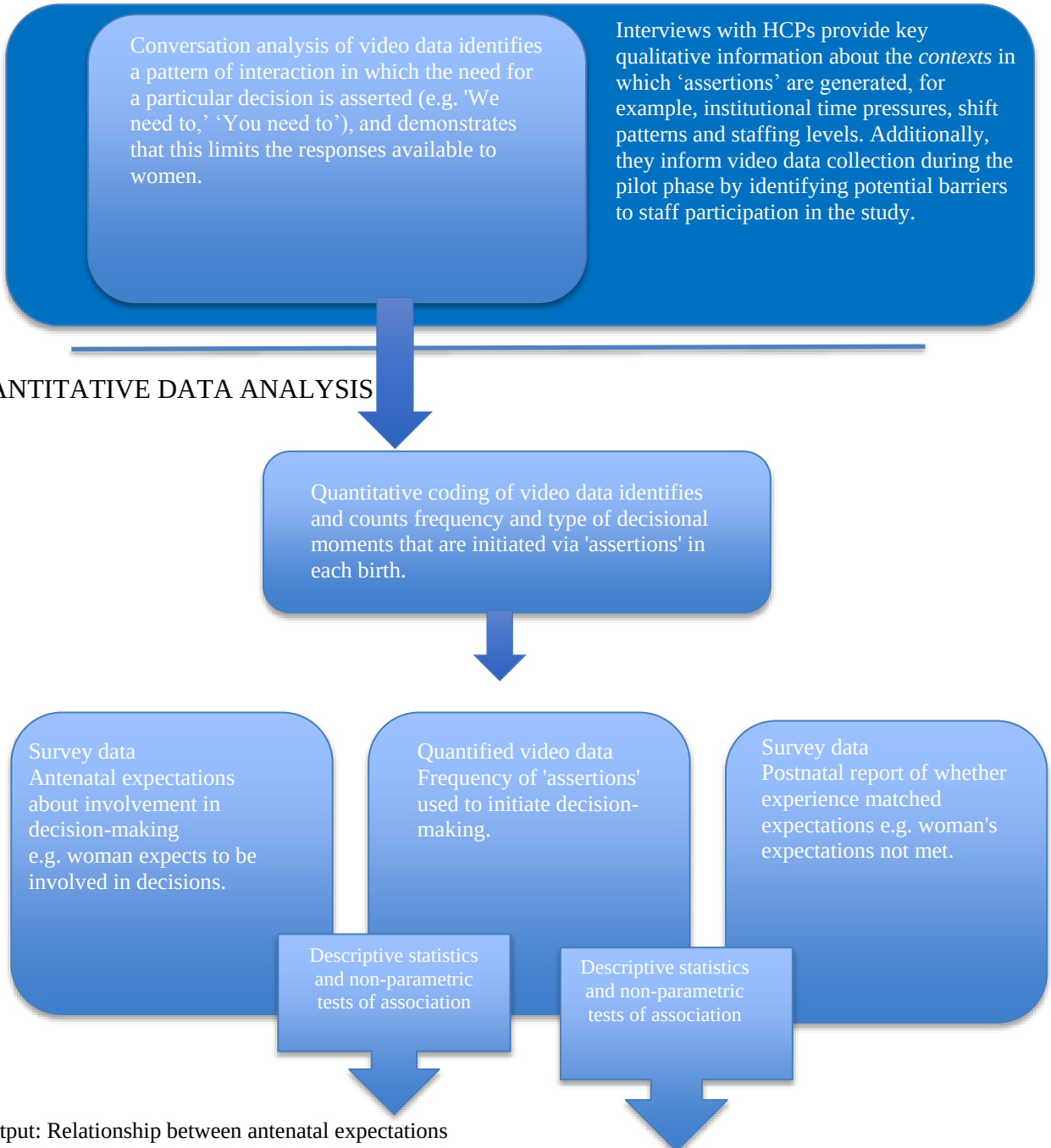
We will use the knowledge gained from the conversation analysis to categorise the different strategies that are used to initiate decisions (for example, as 'assertions', 'recommendations,' or 'open questions') and respond to them (for example, 'agreement,' or 'resistance'). In the second phase of our analysis we will use these categories to 'code' the video transcripts and generate quantitative data that will enable us to bring the video and questionnaire data together. Coding means that we will identify and count the types of interactional strategies (e.g. 'assertions', 'recommendations', etc.) used during decisional moments. Using this quantitative data, we will explore statistical relationships between the types of interaction that take place and women's antenatal expectations and postnatal assessments. For example, we will compare women's antenatal expectations about involvement in decision-making, with the forms of interaction which actually take place during labour. We will also explore whether particular types of interaction during labour are associated with women feeling postnatally that their expectations have not been met.

The data gathered from interviews with HCPs will be transcribed verbatim (by a professional transcriber) and interrogated thematically to situate our understanding of the interactions, most notably the extent to which decision-making is shared, within the organisational and professional context in which birth takes place. The interviews with staff are not designed to be used in the statistical analyses. Instead, they will be used in the qualitative phase of analysis to help us to make sense of the institutional contexts in which women are more or less included in decisions about their care and treatment. For example, we will explore how organisational factors, such as staffing levels, skills mix, case mix, transfers and (planned and unplanned) fluctuations in demand are felt to facilitate or constrain HPCs' capacity to engage in shared decision-making. Data analysis of the interviews and the verbatim transcripts will be facilitated by the use of NVivo10 data analytic software.

A flowchart illustrating the integration of interview, survey and video data, based on an illustrative example, is included below:

Flowchart of data analysis, based on a hypothetical example of a particular interactional strategy identified using conversation analysis:

QUALITATIVE DATA ANALYSIS



Potential output: Relationship between antenatal expectations about involvement in decision-making and the extent of shared decision-making in practice (for example, an expectation of involvement in decision-making about vaginal examinations is associated with a high frequency of 'assertions' in practice).

Potential output: Relationship between extent of shared decision-making in practice and postnatal reports of the extent to which expectations have been met (for example, a high frequency of 'assertions' during vaginal examinations in practice is associated with unmet expectations).

6 STUDY SETTING

Two research sites - Sheffield and Calderdale hospitals – that contrast in size and population (making it likely that patients from different backgrounds will participate) will be included:

Sheffield Royal Hallamshire Hospital houses a purpose built midwifery led maternity unit where approximately 1400 babies are born each year. On a standard pathway Sheffield sees 260 women per month at the 20-week scan (our first contact with women for recruitment to the study). The city of Sheffield is the primary catchment area. Sheffield is a socially polarised city with populations that are amongst the most and least deprived in the UK (Sheffield City Council, 2015). It is also an ethnically diverse city with just under 20% of its population from black and minority ethnic (BME) groups.

The Royal Calderdale Hospital (which as part of Calderdale and Huddersfield NHS Foundation Trust performed 'better than expected' for giving women choice in positions for labour in a recent CQC survey (Care Quality Commission, 2016) contains a midwifery led birth centre, where approximately 776 babies are born each year. Calderdale & Huddersfield NHS Trust sees 500 women per month across all pathways at the 20-week scan. The main catchment areas are Calderdale (comprising Brighouse, Elland, Halifax, Hebden Bridge, Sowerby Bridge and Todmorden) and Huddersfield, but could include out-of-area women from Bradford, Dewsbury, Barnsley, and Rochdale. The size of catchment area makes it difficult to provide precise diversity figures. However, figures for the Borough of Calderdale suggest there is less deprivation than in other West Yorkshire districts (but still higher than the national average) (Calderdale Council, 2010), and that 12.5% of its population are from BME groups. Kirklees Borough Council, which includes Huddersfield, reports less than national average deprivation and that 21% of its population are from BME groups (Kirklees Council, 2015).

Access to these sites has been facilitated through the Consultant midwife team members who have extensive clinical experience in these units and can directly enable management of recruitment. Each site employs a diverse team of maternity HCPs, with different specialisms, ensuring a broad range of HCP-service-user interactions. Sampling at these sites offers a cost-effective, closely managed approach to capturing the communication strategies used by a range of HCPs with a diverse group of women. The same sampling, recruitment and data collection approaches will be employed at both sites.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

Women (aged 16+) with a healthy singleton pregnancy expected to labour spontaneously and give birth vaginally at term in a midwifery-led unit, their birth partners (where relevant) and HCPs (clinical healthcare practitioners at each site).

7.1.2 Exclusion criteria

Women under the age of 16
Multiple pregnancy
High risk pregnancy
Any woman or birth partner who lacks capacity to consent for themselves

7.2 Sampling

7.2.1 Size of sample

Full details of the sample size are provided in section 5 of the protocol. The figure of 20-30 recorded labours has been selected to allow for a diverse range of participants to participate whilst producing data that are manageable for the detailed conversation analytic work required.

7.2.2 Sampling technique

HCPs to be interviewed: Information about the study will be provided to staff at both clinic sites (for example, via maternity unit forums) and staff will be told (verbally and via written information sheets) about the opportunity to take part in an interview. Interview participants will be self-selecting. As the study aims to include a mix of staff roles and grades at each site, this recruitment process may be supplemented by direct invitations being made to staff at each site (by the consultant midwife team members) in order to ensure an appropriate range of staff are included in the study.

Women and birth partners: Eligible women attending their 20 week scan appointment (or antenatal appointments thereafter) will be approached and invited to indicate their interest in the study. Women may also approach the RM outside of this standard route as outlined in the flow chart. Ultimately, however, the sample of women who choose to participate in the study will be self-selecting. This raises important questions about sample diversity. This is a key research goal and will be addressed in multiple ways. In designing recruitment materials (for example, study information sheets), we have drawn on the expertise of the PPI groups to explore the best ways of presenting the study so that it is accessible to diverse groups of women. PPI groups will also help us to anticipate particular questions or concerns that women may have about the study, so that we are able to provide RMs and the UoY researchers with ways of addressing these during recruitment. The demographics of the two research sites afford a good opportunity to recruit an ethnically and SES diverse sample.

Nonetheless, we are aware that a major impediment to recruiting diverse samples in health research occurs at the initial stages of approach, where there is a tendency to, target ‘familiar’ populations and concerns with, ‘real or perceived barriers to communication and extra costs’ (Bhopal, 2008: 17). We are grateful to HS&DR for supporting the recruitment of a diverse sample via clear commitment and funding of translators. With this in place, the next step will be to ensure that eligible women of all backgrounds are invited to take part. To monitor the sample characteristics we will keep a running record of the (anonymised) demographic characteristics of women consented into the study. We will review this regularly and, in the event that the sample is more homogeneous than anticipated, we will feed this back to the recruitment teams in order to, firstly, re-emphasise the importance of approaching

all eligible women and, secondly, explore whether resolvable barriers (for example, the timing of approaches to women in relation to other aspects of clinic schedules, or the framing of the study) are making it more difficult to approach and/or discuss the study with particular groups of women. In addition to taking these steps to ensure that all eligible women are invited to take part, we aim to over-sample by approaching at least 1500 women over the recruitment period . Of the women approached, we conservatively expect that 20-30 women will be recorded. In the event of over-recruitment (i.e. once the target of 20-30 recordingshas been achieved), if concerns remain about the demographic homogeneity of the sample then we will develop selection criteria for purposive sampling based on demographic (specifically, BME and SES) characteristics. Following initial screening for eligibility (women 16 years plus who have a healthy, singleton pregnancy, and are expected to deliver normally in a midwifery-led unit), RMs will screen the list of eligible women attending antenatal clinic each morning, and will only approach those who meet the purposive sampling criteria. Through these combined strategies, we aim to achieve a diverse sample.

7.3 Recruitment

HCPs to be interviewed: Information about the study will be provided to staff at meetings, or via invitations forwarded by the Consultant midwife team members.
Women and birth partners: As described in section 5, research midwives at participating trusts will screen and identify eligible women and will approach them with information about the study at their 20 week scan appointment (or at antenatal appointments thereafter), inviting them to complete an 'expression of interest' form. **Alternatively, a member of the care team will ask eligible women if they would like to talk to the UoY researcher about the research at the 20 week scan appointment (or at antenatal appointments thereafter). The UoY researcher will make herself available in clinics to talk to women about the study, and will invite them to complete an 'expression of interest' form. She will not approach any women unless they have been referred to her by a member of the care team.**
Women (and birth partners, if present) who are interested in taking part will have the option of giving consent in one of two ways:
1) At the 20 week scan appointment at the hospital/other antenatal appointment thereafter. This enables women and birth partners who are sure at this time point that they wish to take part, with the option of consenting at this point. The research midwives (or UoY researcher, following referral) will approach women for expressions of interest either before their scan has taken place or after, although consent will only be taken after the scan has taken place. The research midwives (or UoY researcher) will have given women (and birth partners, if present) a full opportunity to ask any questions that they may have.
Or
2) by Follow-up phone-call/consent (for those who do not consent at the 20 week scan)
In this phone call, the RM or UoY researcher will re-confirm eligibility and ongoing interest, and will make arrangements for an appointment to consent women into the study (and, if possible, their birth partners).
HCPs to be recorded: Information about the study will be provided to staff at meetings and posters displaying information about the study will also be used to raise awareness.

7.3.1 Sample identification

RMs will identify participants by reviewing patient records to screen for eligible women attending clinics. Women's contact details will not be shared outside the patient care team without their explicit consent. RMs will ask women to complete an 'expression of interest' form if they are interested in involvement in the study, on which they have the option to leave contact details to be passed to the research team. Alternatively, **clinical staff will ask eligible women if they would like to talk to the UoY researcher about the research at the 20 week scan appointment, or at antenatal appointments thereafter. The UoY researcher will make herself available in clinics to talk to women about the study, and will invite them to complete an 'expression of interest' form. She will not approach any patients unless they have been first been referred to her by a member of clinical staff.**

7.3.2 Consent

Women: We recognize that a decision to take part in research that will be conducted at one of the most personally significant moments in a woman's life requires time and consideration. We will provide women with information sheets (developed in consultation with Laura Cook (PPI) and our service-user groups) when they are about halfway through their pregnancy (at 20 weeks). As noted in the flowchart, women can also enter the study outside the standard route. These women will be screened for the study by the RM and if admitted will be consented in the usual way. Women may recruit to the study via this route from, for example, a project poster or a friend's participation. This allows women enough time to have discussions with their family, friends and their own HCPs before making a decision.

Women (and birth partners, if present at the scan) who are interested in taking part will have the option of giving consent in one of two ways:

1) At the time of the 20 week scan. This enables women and birth partners who, at this time point, are sure that they wish to take part with the option of consenting straight away. The research midwives (or UoY researcher) will have given women (and birth partners, if present) a full opportunity to ask any questions that they may have.

Or

2) by Follow-up phone-call/consent (for those who do not consent at the 20 week scan/other antenatal appointment thereafter)

The RM or UoY researcher (as practicable) will follow up women who expressed interest with a telephone call to clarify any questions and confirm whether women remain interested in taking part, as well as to screen for ongoing eligibility. If a woman still wishes to take part, the RM or UoY researcher will make arrangements to take consent in one of three ways as convenient and depending on the participants' preferences:

1. Preferably, consent will be taken face to face in the woman's home
2. In an antenatal care setting to coincide with her midwifery care
3. Remotely via skype or telephone (with the form returned via s.a.e.).
4. If the birth partner is not present at the woman's consent meeting, the woman may take the consent form for her partner to consider and sign and post it back (S.A.E provided) to the hospital

We would prefer that all recordings are video because of the importance of non-verbal aspects of the communication and the use of technologies in birth. The research team's experience with related studies has demonstrated that audio-only data often provides incomplete and partial information about interactions (e.g. it can be hard to work out who is talking, and how others are – often nonverbally - responding to them). However, in recognition of the sensitivity of videoing, we will also offer women the choice of audio recording the birth. The consent materials will make it clear to women that whether recording ultimately takes place is dependent on a number of contingent circumstances (e.g. availability of equipment, staff agreement).
Consent would be re-confirmed verbally when a woman arrives at the maternity unit in labour. Women will be instructed to identify themselves as a study participant when they ring the maternity unit. Additionally, a notice that they are study participants will be placed in their hand-held notes at the consent appointment. At Calderdale, where electronic rather than hand-held notes are primarily relied upon, a notice will also be placed in the woman's electronic notes following the consent appointment.
Birth Partners: Birth partners will receive information at 20-weeks or thereafter (via women, who will be asked to pass study information sheets to anyone who is likely to attend the birth). Every effort will be made to ensure that the birth partner is included in the woman's consent appointment in order to obtain written consent from the birth partner prior to labour. However, if it is not possible to obtain consent from a birth partner prior to labour (for example, because a different person attends the birth than was originally planned), then, when a woman arrives in labour, midwifery staff will verbally confirm that the birth partner is happy to be recorded. Midwifery staff will note when a recording takes place in a research log book, using an anonymous participant code, and will highlight whether follow-up to obtain retrospective written consent from the birth partner is required. Consultant midwife team members or the UoY researcher (as practicable) would regularly check the log book and would follow up to obtain retrospective written consent from the birth partner for the use of footage including them, if necessary.

HCPs: We recognize that HCPs may feel reluctant to film their clinical practice for a number of reasons (although our informal discussions with HCPs at both study sites indicate positive support for the study). We propose holding meetings with all staff, through, for example, maternity unit forums, to allow for full and free discussion of the project before giving practitioners an opportunity to opt in. Posters about the research study will also be placed around both study locations, to ensure that non-clinical staff (for example, cleaners and administrators) are also aware of the study. We will make it clear that opting-in will mean that HCPs consent to being recorded in whatever form (video or audio) that the particular women they are caring for have consented to. When a consented woman is admitted to a maternity unit, recording will only be initiated if HCPs who have opted in to the study are available to provide care. However, it is possible that staff who have not previously consented will still have to enter a room to provide care during labour. Recording signs will be placed on the doors to highlight that recording is in progress and that no footage of staff will be used in the study unless written consent is given by the staff member. Consultant midwife team members or the UoY researcher (as practicable) will follow up with staff post-recording to confirm whether they are happy to provide retrospective consent for the use of the footage, or that they do not want footage to be used.

7.3.3. Withdrawal of consent

We have given parity on the time limit for withdrawal of consent for all participants as 6 weeks post-birth. This time limit corresponds to the time when the woman will be asked to complete the post - natal questionnaire. This seems to us to be a natural cut off point for consent to be withdrawn by the woman as her attention will be directed toward the project once again. Accordingly, HCPs and birth partners can also withdraw their consent at any time up to 6 weeks post birth. In the event that HCPs withdraw their consent we will edit the footage accordingly, if practicable, or delete the data. In the event the birth partner considers withdrawing their consent, we would ask them to first discuss this with the woman they accompanied. If the birth partners' consent is withdrawn we will edit the relevant footage if practicable, or delete the data.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

We are aware that in recordings of birth, we may witness poor practice and/or abuse of HCPs. Prompted by our discussions with PPI, we will make explicit to participants (through information sheets) our legal responsibilities to report actionable practices to relevant authorities.

8.2 Research Ethics Committee (REC) review & reports

Before the start of the study, approval will be sought from an NHS REC for the study protocol, informed consent forms and other relevant documents e.g. advertisements. Approval will also be confirmed by the University of York Economics, Law, Management, Politics and Sociology REC.
Substantial amendments that require review by the REC will not be implemented until the REC grants a favourable opinion for the study.
All correspondence with the REC will be retained.
An annual progress report (APR) will be submitted to the NHS REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

8.3 Peer review

The study has been subjected to high quality peer review as part of the application for NIHR funding. Five independent experts have provided anonymous feedback on the study design.

8.4 Patient & Public Involvement

As noted previously, we very much appreciate and welcome the involvement of service users in the development, implementation and dissemination of the research. Our engagement with service users has helped us to more fully frame the relevance of our proposed study for women and their partners/families. In recognition of this, one of our co-applicants (Laura Cook) is a PPI member, and

is a full member of the research team, with a specific role to provide guidance in designing, implementing and disseminating research that emphasises service-user voices and concerns.

In addition, we have set up project-specific PPI groups (one at Sheffield and one at Calderdale) to advise on:

1. The research design and development of participant information resources (e.g. information sheets and consent forms);
2. Advising on matters that arise (e.g. difficult scenarios);
3. The reporting of the research by reviewing the interim and final project reports;
4. The dissemination of research findings by contributing to the project website, information for service users, and planning and running the dissemination workshops for health care practitioners.

8.5 Regulatory Compliance

Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will apply for NHS permission from the site management organisation, HEI or NHS Research & Development (R&D).
For any amendment that will potentially affect a site's NHS permission, the Chief Investigator/ Principal Investigator or designee will confirm with that site's R&D department that NHS permission is ongoing.

8.7 Data protection and patient confidentiality

All investigators and study site staff must comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.
The study involves the collection of multiple forms of participant data, the storage and security arrangements for which are as follows:

Expression of interest forms

These will contain women's contact information. They will be collected during women's visits to the hospital by the Research Midwives and stored securely. Both Research Midwives (at NHS Trusts) and the UoY researcher may need to use the contact details recorded on the 'expression of interest' forms in order to conduct follow up telephone calls and make arrangements to consent women into the study. Any 'expression of interest' forms collected and used by the UoY researcher in follow up/consent will be stored securely (in a locked drawer is a locked office) at the University of York.

Consent forms

Women and birth partners: Consent forms will be filled out at the consenting meeting and one copy will be given to the woman. Duplicate copies will be stored as relevant in the site file at the corresponding participating Trust by RMs and/or by the UoY researcher (in a locked drawer in a locked office).

HCPs being recorded: Consent forms will either be filled out prior to recording or post recording (in the case of staff who were not previously consented). They will be stored in the site file at the corresponding participating Trust by Consultant midwife team members and/or by the UoY researcher (in a locked drawer in a locked office).

HCP interviews: Consent forms will be filled out and the member of the research team conducting interviews will store them securely at the University of York (in a locked drawer in a locked office).

Video/audio recordings of labour

The SMOTS cameras used for recording will record onto an encrypted hard drive on a remote computer positioned in a locked office, ensuring data security. Another advantage of SMOTS cameras in terms of data security is that they are large and would be visible if being removed. Women and their partners will be shown how to operate the camera so that they remain in control of the recordings. Maternity unit staff will likewise be trained in camera operation so that they can start the recording and turn it off at a woman's request, and also so that they can show women/their partners how to use the cameras.

Once recordings are complete they will be transported to York physically on a separate hard drive and uploaded on-site to the project shared drive on the University of York's secure server by a member of the research team (most likely the RA). Raw non-anonymised video footage will be accessed only by members of the research team. All video data will be transformed to audio for the purposes of professional verbatim transcription by a transcriber who will sign a confidentiality agreement. Identifying information will be removed from the transcript and the anonymised version will be stored on the project shared drive on the University of York's secure server.

On consent forms, women, birth partners and HCPs will be given options to determine whether and in what the form anonymised video/audio footage can be shared in presentations, publications and training. The 'lowest' level of access permission given will determine the outcome, i.e. if some participants in a piece of footage want to share pixelated video footage and others are only comfortable with the publication of the written transcripts then the latter's wishes would be prioritised.

Audio recordings of interviews with HCPs

Once recordings are complete they will be labelled with an anonymous participant code and uploaded to the project shared drive on the University of York's secure server by a member of the research team. They will be transcribed by a professional transcriber who will sign a confidentiality agreement. The transcript will be stored on the project shared drive on the University of York's secure server. Audio data will not be made public, i.e. only anonymised quotations from the interview will be published.

Pre and postnatal questionnaires

Questionnaires will be labelled with anonymous participant codes. Paper versions will be stored in a locked cabinet in a locked room at the University of York. Electronic versions will be stored on the project shared drive on the University of York's secure server.

Linking file

A linking file which links participant names to anonymised participant codes will be encrypted and stored on the secure University of York server.
Only the research team will have access to data stored on the project shared drive on the University of York's secure server.

Ellen Annandale, Sian Beynon-Jones, and Clare Jackson – as permanent members of staff at the University of York - will act as data custodians.

8.8 Indemnity

1. Sponsorship by the University of York includes provision of standard indemnity insurance to meet the potential legal liability of the sponsor for harm to participants arising from the management of the research.
2. Sponsorship by the University of York includes provision of standard indemnity insurance to meet the potential legal liability of the sponsor for harm to participants arising from the design of the research.
3. NHS indemnity will meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research, which will take place on NHS sites.
4. Sponsorship by the University of York includes provision of standard indemnity insurance to meet the potential need for payment of compensation in the event of harm to the research participants where no legal liability arises.
5. Sponsorship by the University of York includes the provision of standard indemnity insurance to meet the potential legal liability arising in relation to the use of recording equipment (e.g. loss, damage, maintenance responsibilities for the equipment itself, harm to participants or site staff arising from the use of the equipment).

8.9 Amendments

The workability of the study will be kept under review via regular project team meetings, Steering Group meetings, as well as via 6 monthly reporting to/responses from the funder. Any decision to amend the protocol and whether this is a substantial or non-substantial amendment will be taken by the research team. If the decision is made to make a substantial amendment then approval for this will be sought via submitting a valid notice of amendment to the REC for consideration. Any substantive changes will be communicated in writing to relevant stakeholders (R & D departments at participating NHS Trusts). The amendment history will be logged on the project shared drive, with the most recent, approved version of the project being accessible and older versions being archived in a 'previous versions' folder, to ensure that all members of the research team are working with the most up-to-date protocol and associated study documentation.

8.10 Access to the final study dataset

Only the research team will have access to the final dataset.
All participant information sheets reflect the possibility that the dataset may be used for secondary analysis in future research.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

- On completion of the study, the data will be analysed and a Final Study Report prepared.
- The full study report will be accessible from the NIHR Journals Library
- All of the participating investigators will have rights to publish any of the study data. We will follow the authorship recommendations of the ICMJE.
- NIHR will be acknowledged as the funding body within the publications and the NHS hospital trusts will be named and acknowledged as the research sites NIHR will be notified prior to any publication of the research. One draft copy of the proposed publication will be forwarded at the same time as submission for publication or at least 28 days before intended publication whichever is earlier.

- Study participants will be able to access the outcomes of the study, for example, via the project website.
- The study protocol and full study report will be made publicly available by the NIHR Journals Library and via the study website.

9.2 Authorship eligibility guidelines and any intended use of professional writers

- Criteria for individually named authors or group authorship will be in accordance with the criteria of the ICMJE for manuscripts submitted for publication.

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