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OPTIM-I: Optimising the use of professionally trained interpreters in maternity services of England.

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Ethical approval

Ethics approval has been received for WP1, 2 and 3 (25/WA/0098). With approval for a component of WP1 (Interviews with interpreters) received from Oxford University Ethics Committee (MS IDREC 811334) as recruitment is independent of NHS Trusts.

Version Control

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SUMMARY OF THE RESEARCH

Background: The health of all mothers and babies in England is very important and an NHS priority. People from different cultures may experience communication barriers in healthcare interactions. Language, communication and understanding information is very important for maternity care to be safe, equal and fair. For pregnant women to be equal partners in their maternity care, they need information about their pregnancy and birth, to be able to ask questions, understand the answers and know where to seek help. If there are communication needs, the midwife or doctor should book a trained interpreter for the appointment. However, we know that this doesn't always happen. Midwives told us that a lack of time, planning and money means they do not use interpreters as often as they need to. We spoke to ethnic minority women who told us about feeling scared and anxious because they did not understand what was going on, and they had to rely on family/friends or a neighbour to help interpret. The irregular or lack of use of trained interpreters increases the risk of complications and women having treatments or examinations without their consent. Professional trained interpreter use in medical communication can make the quality of clinical care the same for patients independent of language barriers.

Aim: To look at what helps or blocks the use of professional trained interpreters in maternity care by comparing practice in six different NHS maternity sites, so that women with cross-cultural communication needs can understand the care being offered and safety advice given, ask questions and give informed consent for care decisions.

Methods: Six NHS maternity sites across the country will take part in a research project. In the first stage, researchers will i) watch what currently happens in maternity care consultations, ii) talk to patients, interpreters, midwives, and other healthcare staff iii) ask maternity staff to complete a survey. In the second stage, healthcare staff and women will design a toolkit of resources over the course of three workshops. In the third stage, the toolkit will be tested in the six maternity sites. The researchers will look at how well the toolkit is working by watching consultations and, again, talking to the above groups of people. They will compare data from the first stage to after this testing stage and then improve the toolkit to make it the best it can be.

Public involvement: The women and healthcare staff we spoke to felt this project was very important for the safety and wellbeing of women and their families. NHS Trusts are keen to take part in this project, telling the research team it is a priority topic for them.

Impact/Dissemination: Throughout this research we will work closely with women, maternity care staff, interpreters and others involved in maternity care at local and national levels. Our toolkit and research findings will be shared widely beyond the staff and patients at the six sites. This will include NHS maternity services across the four nations of the UK, NHS Futures, Community

Based Organisations, Interpreting providers, Maternity training programmes, Chief Midwife's office and academics.

BACKGROUND AND RATIONALE

NHS Trusts should obtain language support through professional trained interpreters (PTIs) (1). Providers of PTIs are commissioned to deliver remote/face-to-face interpretation across the NHS. Interpreting can be booked in advance or calls made in real time. In maternity care, there is evidence that PTIs are not always used when needed. A retrospective case note review using MBRRACE-UK data about women who had died in pregnancy or up to 12 months afterwards in 2015-17, reported that none of the 17 women who required an interpreter received appropriate provision at all key points in their maternity care (2). A Freedom of Information (FOI) request from 119 NHS Trusts providing maternity care in England in 2023, measuring the demand for and provision of PTIs, found that only 56% of the 100 who responded recorded a woman's need for an interpreter. Of these, 37 Trusts recorded the information on a digital system, whilst 19 relied on documentation in paper notes meaning that if the paper notes were not available, such as during an unscheduled care encounter, there would be no alert that an interpreter was required (3). On average, across the 37 responding NHS Trusts for which data were available, around 9% of women (range 1-25%) receiving maternity care needed the services of an interpreter, representing around one woman per day. A standard maternity care pathway, (4) for a woman having her first baby and experiencing an uncomplicated pregnancy, birth and postnatal care, involves around 17 contacts between the woman and a midwife or other maternity care provider. This includes a minimum of ten midwife antenatal appointments, two ultrasound scans, care during labour and birth, discharge home followed by three postnatal community visits (5). For a woman having a second or subsequent baby, the minimum number of contacts is 14. Women whose interpreting need was recorded digitally in response to the FOI request, received an average of three consultations supported by an interpreter across pregnancy, labour and birth, and the postnatal period.

Interpreting services are vital for women who need them so that they can access information about their pregnancy and birth, be able to ask questions and understand the answers, give informed consent for investigations and treatment, and know where to seek help when needed. While it is not possible to directly measure the impact of English language proficiency on maternity outcomes, it is evident that language, communication and understanding of information is central to safe, ethical and efficient maternity care (6). Cross-cultural communication (where the maternity practitioner and the woman and/or her family do not share the same language or cultural background) adds complexity to this endeavour; a woman may not understand signs and symptoms that are cause for concern, or how to seek help and may

invalidate consent. Consent is a legal and ethical principle, making permissible a wide range of conduct that would otherwise be wrongful (7). It is a positive act that goes beyond acquiescence or compliance. Standards of consent in maternity care have been reported in the literature as sub-optimal by women and clinicians (8,9). Women with cross-cultural communication needs are at risk of inadequate, unconsented care, leaving them feeling isolated, unsupported, and unable to communicate (6,10,11). The positive impact of PTIs on medical encounters is well documented, raising the quality of care to approach or equal that of patients without language barriers (10). Absent or irregular PTIs undermine midwifery care (10), act as an independent risk factor for poor outcomes (10,12), lead to suboptimal assessment of serious medical symptoms (13,14), unconsented procedures (such as episiotomy, amniotomy, internal examinations in labour) (15) birth trauma (8), and contribute to disparities in maternal mortality (2). Midwives report inefficient care and professional dissatisfaction when they cannot access timely, accurate, trusted PTIs to support women with cross-cultural communication needs (16). The 2022 RHO evidence review described a lack of consistent and high quality interpreting services to be a common issue for women without English language skills in maternity services, impacting access to and quality of care (17).

Barriers to the use of interpreters in maternity are multi-factorial and include issues of availability, quality, and organisational factors, with limited evidence from the UK setting in many areas.

Interpreter availability

Maternity professionals are not always able to book interpreters in time for appointments, booked interpreters do not always attend, or the interpreting provider is not always able to find someone who could interpret in the required language while the midwife waits on the phone (18,16). Women report infrequent use of PTIs during their care, often relying on friends or family as interpreters, compromising confidentiality and disclosure (6). A systematic review of access to maternity services among immigrant women described how women often had no other option than to arrange for family or friends to act as interpreters (18). With over 100 main languages spoken in England and numerous sub-languages, diversity of languages spoken appear to be a challenge for service providers (19,20,21). Lack of necessary qualifications, experience, or loyalty to agencies near their locations contributes to difficulty finding rare language interpreters in the UK (22). In 2020, the Migration Advisory Committee, an independent body that advises the government on migration matters, recommended adding interpreters to the Shortage Occupation List (23).

Midwives have requested access to more communicative aids for unscheduled encounters as accessing an interpreter at short notice can be challenging (16,24), which leaves midwives 'powerless to communicate with women'(16). Literature focusing on unscheduled maternity care encounters among women with cross-cultural communication needs is limited, but in one review of immigrant women's experiences of language challenges across

six countries, women described acute situations that ended in perceived forced consent as they didn't understand what was being said to them, leading to anxiety and trauma.

Interpretation and Interpreter service quality

Women have expressed concern about the accuracy of interpretation and confidentiality (25,26,27). Issues of collusion and accuracy have been identified when informal interpreters have been used in public services, resulting in errors and compromised meaning (28). In a Swedish study about midwives' experience of looking after immigrant women, midwives reported that relatives could sometimes take over conversations, resulting in errors and compromised meaning (29). Refugee women's experiences of maternity services in the UK, and other high income countries found formal interpreters were sometimes unable to understand the medical terminology used (30). This has also been found in UK primary care (31), suggesting interpreters have varying levels of preparation for their role across specialities. Agencies' requirements for the interpreters they employ are inconsistent and vary by provider (32). Interpreters themselves have described receiving insufficient preparation for their role including learning medical terminology and physiology, and guidance on how to balance 'speaking up' about patient safety while remaining impartial when facilitating communication. These tensions can impact practitioner trust in their skills (21,33), and women's preference for family to interpret (34).

Organisational factors

Midwives have described a lack of training in how to access and work with interpreters, lack of continuity in interpreter support, access to appropriate technology, and funding constraints (16,29). Inaccurate assumptions from maternity care professionals about a woman's English language ability and cultural understanding of UK maternity services can be compounded by a lack of time in consultations and forward planning (16,29).

Against a background of inconsistent PTI quality or provision, evidence of inefficient or absent systems, knowledge or support to work with PTIs as members of the maternity care team, this research will provide high quality evidence about the multi-level barriers and facilitators to provision of PTIs at each cross-cultural maternity appointment. We will use this evidence to inform the co-design of solutions to optimise the use of PTIs across the maternity pathway to

address the needs and priorities of women with cross-cultural communication needs and maternity care practitioners.

AIMS AND OBJECTIVES

The project aim is to optimise the use of PTIs across the maternity pathway so that women with cross-cultural communication needs can understand the care being offered, safety advice given, ask questions and give informed consent for care decisions.

The three objectives are:

i. To chart the context and practice of PTI use in maternity care consultations across six Trusts with diverse populations.
ii. To co-design a toolkit of resources to optimise PTI use in maternity care consultations.
iii. To implement the toolkit of resources in our six partner Trusts and evaluate its effect on PTI use in maternity consultations.

RESEARCH PLAN/METHODS

Research design and theoretical framework

This is a participatory implementation case study design (35), informed by Critical Race Theory (CRT) which alerts us to differential resource allocation along racial lines and can help us understand the broader societal context of interpreting support for ethnic minority women (36). Normalisation Process Theory (NPT) will inform investigation and support of implementation work. NPT is concerned with the work individuals and organisations do to embed and normalise complex ways of working (such as PTI use) into routine practice advocating a mixed methods approach by focusing attention on: coherence, cognitive participation, collective action and appraisal work (37), and has been successfully combined with participatory methodologies for co-design of implementation work (38). It is a participatory project; the research questions, governance, data interpretation and dissemination have been and will continue to be co-designed with women experiencing cross-cultural communication needs and maternity practitioners (38). There will be regular feedback between the fieldwork and Expert Advisory Group so that national policy leaders can support implementation work.

We will use ethnographic methods (interviews, observation, document review) in six case study sites, analysing the work of communication, how it is co-ordinated, organised, delivered, and

experienced between maternity practitioners and women with cross-cultural communication needs. Our case study design will allow us to conduct detailed, in-depth comparisons across the chosen cases (sites), and analyse similarities and differences that underlie PTI use in maternity services. We will obtain a diverse sample through targeted sampling of women with specific characteristics. We will work closely with maternity staff and communicate with them about the range of women we wish to invite. Our approach is interpretive and our analytical methods largely inductive. We will work with up to 12 multi-lingual community researchers (CRs), recruited through community organisations and matched to our research site language profiles. They will interview ethnic minority women attending the maternity service who require interpreter support. The CRs will receive orientation and training in methods of consent, interviewing and cross-cultural communication and will participate in the co-design workshops. We will work with women and practitioners to co-analyse our findings. Participatory Learning and Action (PLA) research tools will be used to support co-learning in the co-design workshops as together we will critically reflect upon barriers to PTI use, share decisions on what action is required, co-design a toolkit of resources and implement them in the original case study sites. We will evaluate the impact of the toolkit to support better, sustainable approaches to PTI use that can be shared across NHS maternity and other services nationally.

This project will take place in six Trusts delivering maternity services in England. We will observe practice and speak with practitioners and women across the maternity pathway from antenatal, through acute admission in the maternity assessment unit to labour and postnatal care settings.

This project comprises three linked work packages (WP)

WP 1: Chart the context and practice of PTI use in NHS maternity services (Objective i)

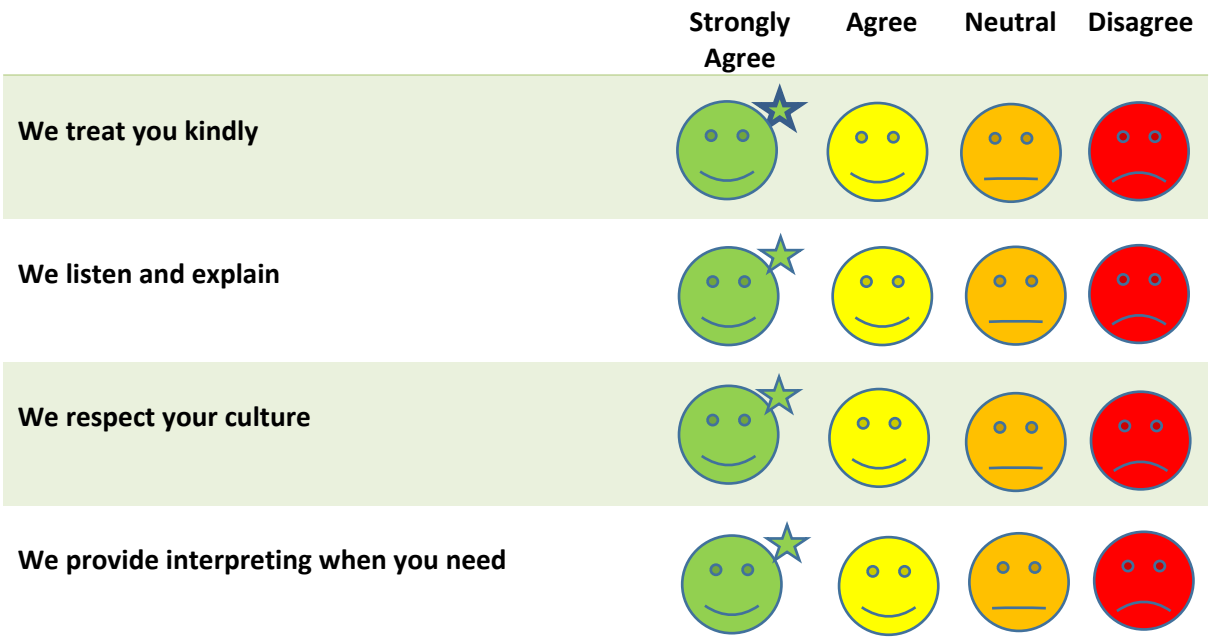
Methods: NPT informed observational fieldwork, focus groups, interviews, customised NoMAD staff survey (Normalisation Measure Development questionnaire).

Observational fieldwork: The two qualitative researchers (QRs) on the project will spend up to six weeks at each site undertaking non-participant observation (four northern sites and two Southern sites). The QRs will observe the planning, preparation and technologies central to the implementation (or not) of PTI' use in cross-cultural communication consultations. We will observe this work during antenatal, labour and postnatal care interactions between maternity practitioners and women (n=10 per site).

We will use an observation template for consistency across sites that includes the recommended 3-talk model for shared decision making (10). We will include this criteria in our observation of

consultations, remaining mindful of culture in communication content, practices and health beliefs to explore how PTI use (or not) shapes the face to face encounter between the practitioner and woman (39). To gauge satisfaction with PTI use from women whose consultation is observed, we will ask them to complete a four item visual patient reported experience measure (PREM) after their consultation. We have reviewed this measure with our lived experience group, who reacted positively, describing it as culturally acceptable and accessible for women from different cultural groups.

Figure 1: Visual PREM



The QRs will also have informal conversations with a range of staff at the sites to determine how interpreter need is documented; interpreter services booked and recorded, and the availability and quality of PTI provision. This could include interpreting service managers, care navigators, antenatal clinic administrators and other relevant personnel impacted by the normalisation of PTI use. The QRs will look at relevant national and local policy and audit documents to uncover multi-level influences on practice, recording observations in fieldnotes.

Interviews: We will conduct a range of audio recorded interviews to complement our observations following fully informed consent.

Women: CRs will interview up to 5 pregnant/postnatal women requiring PTI support in each site, to explore their experience of PTI provision in the pathway, and the work of families/partners/Community Based Organisations in consultations. The QRs will support the CRs at their sites to arrange the interviews and develop their skills in interviewing through

planning, review and feedback. We will ask women how their understanding of information was checked, how choices and help-seeking were discussed and we will elicit if the conduct of the interpreted consultation impacted outcomes.

Eligible women will be approached by a research midwife from their clinical care team either in the waiting room of their antenatal appointment or on the postnatal ward, to ask permission for the CR to speak with them. She will give them a translated invitation card (from a card pack with 12 language options) or a QR code linked to a YouTube video (as literacy may be an issue). This will contain an introductory phrase inviting the woman to participate in the research, making clear she can decline without impacting her care, and asking her to tell the research midwife if she would like to participate. The research midwife will arrange for the CR to contact her.

If women agree to be approached by the CR, the CR will read the translated information sheet and consent form to the participant, receive verbal consent and give a copy of the information sheet and consent form with contact details to the woman to refer to during the study. Interviews will be conducted face-to-face at the hospital or later by telephone as preferred. Interviews will be audio recorded and transcribed verbatim before being translated into English for analysis by approved university transcribers and translators. Participants will be free to terminate the interview at any time and can remove their data up to two weeks from their interview date. This will be made clear at the time of consent. Participants will receive a thank you voucher as reimbursement for their time.

Interpreters: We will recruit up to 30 PTIs across England independent of their employing agency, through social media, the Institute of Translation and Interpreting (ITI), PPI and Community Based Organisation networks. We will discuss their experiences of interpreting in maternity services in individual interviews or focus groups as they prefer. We will ask about their training preparation and support in interpreting skills, breaking bad news, seeking consent, presenting choice, speciality training in maternity vocabulary and maternity pathway navigation, psychological support systems within their organisation, the importance of cultural navigation in the interpreting relationship and accreditation/recognition processes. They will be reimbursed for their contribution.

To minimise bias and maximise experience shared, we will recruit PTIs through networks independent of NHS providers. We will seek ethical approval through the University of Oxford Ethics Committee.

Maternity Practitioners: The QRs will interview up to five maternity practitioners and other key informants at each Trust until data saturation is reached (40). Potential participants across the maternity pathway will be invited by email from the local PI to take part in a semi-structured

interview about their experience of cross-cultural communication and working with PTIs. Interested participants will be sent an information sheet and consent form and asked to contact the researcher for an interview. Interviews will be conducted face-to-face at the hospital or later by telephone/Teams as preferred following written/verbal informed consent. Participants will receive a copy of their signed consent form. Interviews will be audio recorded and transcribed verbatim. We will use an interview schedule informed by the four core constructs of NPT, while being open to arising data, to explore the distributed and patterns of work involved in implementing PTI use in maternity services.

Survey: The local PI will administer the NPT informed NoMAD survey customised to the study question to 20 maternity practitioners at each Trust to capture the impact of team and organisation processes on PTI use. The NoMAD survey assesses implementation processes from the perspective of professionals directly involved in the work.

WP 2: Co-design a toolkit of resources to optimise PTI use (Objective ii)

Method: Participatory co-design

Change ambassadors: We will collaborate with the local PI at each site to identify two change ambassadors from the maternity care team. These will be individuals with strong leadership and communication skills. We will clearly define their responsibilities and expectations. They will be mentored by the research team, from the co-design of solutions incorporating the reality of practice, to championing local implementation of solutions into the NHS. Their involvement will increase site awareness and preparation for the resource implementation. These ambassadors will act as an extension of the project team, providing two way communication between the research and practice context while acting as a point of contact for local staff. They will prepare staff at their site, support implementation of the suite of co-designed resources to the local context, and keep the implementation plan on track.

Co-design workshops: Participants (up to 25, including women of lived experience, interpreters, maternity practitioners) who express an interest in attending the co-design activities will be sent a co-design information sheet. Women will be approached through local community based organisations and interpreters who participated in an interview will be invited to the co-design sessions (ethical approval for these two groups of participants will be sought through the Central University Research Ethics Committee of Oxford University). Following discussion of any questions, attendance at the co-design will be taken as consent to participate. It will be made clear in the session ground rules that individuals will be free to leave at any time, sessions will not be recorded, or photographs taken and notes will only be taken on the discussions, not any personal or sensitive data from participants. The first workshop will present the WP1 analysis to

the co-design participants in two separate feedback sessions: 1A) in person to the women and PTIs and 1B) online to the maternity/policy professionals to allow safe spaces for discussion. The identified; multi level barriers and levers, will be prioritised by participants through consensus methods into a PLA 'wall of barriers' according to act now/act later based on policy, funding, service supports/constraints, based on adapted RESTORE methodology (41).

The second workshop will bring all participants together to explore these priorities and create a PLA 'tree of solutions' using participant experience and examples from the case study data. We will divide into sub-groups of five people, with each group working on one of the resources/resource themes. With the support of a group facilitator to ensure all voices are heard (for example by inviting women to contribute first, managing the group interaction to actively give space to the women to contribute), participants will review existing resources, drafting new resources as required using creative methods to support involvement at all levels of literacy. These will be formatted by the research design team, for participant refinement in workshop three.

In the third workshop participants will review and refine the developing resources in their sub-working groups, to create final draft resources in collaboration with the research design team.

Workshop four (x6) will take place in each of our six NHS sites with the two local change ambassadors and two women with experience of cross-cultural communication needs who participated in the co-design, alongside local stakeholders (e.g Equality lead, Head of Midwifery, Interpreting service manager, service leads, local maternity voices members). Using a tailored implementation approach that adapts the toolkit resources to the local context, we will present the local site level data to participants. Together participants will repeat the exercise of workshop one to create a local wall of barriers, review the toolkit of resources and populate their local tree of solutions based on the requirements of the service. Participants will add details of which resources are required, who will enact, how and when. Participants will design their own evaluation criteria within the plan, in complement to the core study criteria, to collect metrics relevant to their service that embed the new ways of working and develop a learning culture to deliver women centred care. Ongoing site feedback will be used to refine the toolkit resources in targeted online co-design sub-group meetings (Workshop 5 – up to 25 people).

WP 3: Implement and evaluate the toolkit in practice (Objective iii)

Method: Observational fieldwork, interviews and NoMAD survey.

Implementation: The local implementation plan will be executed over the following 5 months by the change ambassadors with research team support. Activities may involve presentations at

team meetings, liaising with the Trust communications team, printing/advertising of resources, co-ordinating training, running drop-in clinics and will be shaped by the plan from local workshop four. Monthly progress meetings will be held across the participating sites with the change ambassadors and research team to feedback implementation progress, identify any resource refinements required by the online co-design team, share experiences, and support each other. Ongoing site feedback will be used to iteratively refine the toolkit resources in the online co-design workshop (Workshop 5).

Evaluation: After the five month embedding period, the QR and CRs will return to each site to evaluate the impact of the toolkit against the original project objective. Data collection will proceed with targeted practice observations (n=10). These will focus on awareness and application of the toolkit; interviews with maternity practitioners and women (n=5+5) to explore effectiveness of the toolkit on consultations and shared decision making; and a repeat of the NoMAD survey with a representative staff sample (n=20) to compare results with the traffic light 'level of intervention normalisation' output of the pre-implementation phase. We will explore the effectiveness of the toolkit in improving effective PTI use in maternity pathways, noting key successes and achievements as well as obstacles and challenges.

The research team will continue to support the Trust for an additional month following evaluation to maximise sustainable practice change, patient and practitioner benefit.

Data analysis will be iterative and proceed alongside data collection, informing and guiding the direction of enquiry. The core research team will examine relationships, factors and linkages across all data episodes per site (interviews, survey responses and observations) to produce detailed and comprehensive accounts of PTI use in maternity care.

NOMAD survey: We will use traffic light coding of NoMAD survey responses as described by Lamarche (42), with the colour reflecting the mean score of respondents to provide a visual representation of how the site is normalizing (or not) PTI use at that time point. We will compare these results post implementation in the evaluation phase.

Observation and Interviews: Using thematic analysis of interview transcripts and fieldnotes (43), the NPT constructs will frame the multi-level analysis and build an understanding of the data beyond the individual data episodes, allowing us to map challenges, supports and good practice at each stage of the normalization process. CRT will be used as a sensitising concept to understand the broader context of interpretation services and racial inequalities in England and the NHS (44). The PREM will be summarised visually and numerically, and reported using descriptive statistics.

Evaluation fieldwork: Data from the evaluation fieldwork will be analysed and presented in case studies, thematic summaries, frequency, radar and traffic light charts to give project level insight into the evaluation results across the research sites. At site level, the local data will be compared with pre-implementation data and prepared in a final individualised report for each of our 6 partner Trusts. It will reflect key achievements, challenges and learning, and present a plan to maximise sustainability in the long term.

We will explore quality and process evidence from the health care professionals' perspective on the impact of the co-designed intervention. This will include for example: understanding the impact of the co-designed resources on their role; understanding their perspective on the value of the intervention; their openness to working in new ways; how easily the resources are integrated into the current maternity working culture; if they feel the resources are worthwhile; which resources are available and which have been accessed by respondents to support their practice. We will note key successes and achievements as well as obstacles and challenges.

We will look at sustainability of the local implementation plan and toolkit in the long term, and what could support its continuity. We will look at technology, training and resource constraints to normalisation of PTI use, identify areas for improvement, lessons learned and unintended consequences from the project.

PATIENT AND PUBLIC INVOLVEMENT

Research Plan Development

Women of lived experience are core to this project. The research questions, governance, data interpretation strategies and dissemination plans have been co-designed with women experiencing cross-cultural communication needs and midwives who look after these groups of women. Public co-investigator BEGUM contributed to the development of this study at stages 1 and 2, and will continue to contribute as a full member of the study team.

We developed the initial research question and design of the study in consultation with 8 women experiencing different cross-cultural communication needs from two community based organisation (CBO) lived experience groups. Pre-application discussions with women recommended using same language interviewers as essential for informed consent and authentic reporting of experiences, prompting our decision to work with multi-lingual Community Researchers (CRs). The women described how speaking with someone who spoke their own language would put them at ease and reassure them of their independence from the health care team. We have included multi-lingual CRs in the team with budget for their orientation, training and ongoing support. The women we spoke to suggested the co-design workshops - that will

include 8 women with experience of UK maternity services and cross-cultural communication needs - be conducted locally with transport costs and wrap around childcare payments in addition to the involvement payment, to support engagement. They recommended splitting the workshops into regional locations if necessary to maximise the opportunity to attend. In addition to the participatory learning and action reflections at the end of the workshop, pre-application PPI recommended signposting women to psychological support services if memories of previous trauma are triggered. We have budgeted for emergency access counselling if distress is triggered by participation in the research.

Discussion with six women from a different CBO, and our PPI co-app recommended recruitment of women for the co-design work to be done through CBOs, with a CR to accompany them at the workshop to give them confidence, reassurance and interpreting support. Interpreter support will be through an independent PTI to support them to contribute fully, unhampered by language competence. They also recommended the use of interactive methods in the workshop to support their engagement, which the PLA approach incorporates.

Plans for Patient and Public Involvement

Our public co-investigator will support involvement and engagement of our independent lived experience group alongside the PI as the voice for women in the study. We will work closely with our lived experience contributors to refine the approach phrase and information giving materials as well as sense checking findings, diversity of voices in the data, co-design participation and dissemination strategies. Our public co-investigator and the wider co-investigator group have established relationships with key community based organisations and individuals. We will build on these relationships with the aim of recruiting members to our alongside lived experience group to support us to deliver the research in the most accessible and inclusive way.

The Expert Advisory Group and Study Steering Committee both include women of lived experience of cross-cultural communication in maternity services and service user organisations. They will advise on the conduct of the research throughout. Members of the Expert Advisory Group will be invited to take part in the co-design process. We will pay members of our lived experience group for all activities they are involved in, and any associated childcare or other expenses, based on NIHR payment guidance for public involvement. For service user organisations that help recruit people with lived experience or contribute to the co-design in other ways, they will be paid at NIHR rates or their own standard rates for contributing to research if higher.

Our public co-investigator will be a member of the Co-investigator Group, attending monthly meetings. They will therefore have continuing input throughout to all aspects of the project

including design, data collection, analysis, and dissemination. Their input at these meetings (and any other input in between meetings) will be formally recorded, along with any response or change as a result, to inform reporting on the impact of PPI.

EQUALITY, DIVERSITY AND INCLUSION

Our proposed methodological approach to this question is explicitly participatory and inclusive, driven by the perspectives and priorities of those who are most involved in and affected by the interpreting service. The research questions, governance, data interpretation and dissemination have been co-designed with women experiencing cross-cultural communication needs, interpreters and maternity practitioners. We will work with up to 12 multi-lingual community researchers to interview ethnic minority women in their own language who are attending the maternity service and require interpreter support. We will review the language and cultural profiles of our sample after each site to ensure maximum diversity in our sample.

The co-design work package uses face to face, participatory, democratic, and visual methods to support engagement of women in a trusting, inclusive environment. Reflection and discussion among the research team after each workshop, to critically reflect on our inclusive approaches and language, will support team learning and refinement of working style/set up of the next activity. Participatory Learning and Action research tools will be used to support co-learning in the co-design workshops as together we will critically reflect upon barriers to PTI use, share decisions on what action is required, co-design a toolkit of resources and implement them in the original case study sites. This work package (WP2) will be co-lead by co-investigator Professor Anne MacFarlane, Co-Director of the WHO collaborating centre for participatory health research with refugees and migrants at the University of Limerick.

We have deliberately used the word ‘woman’ throughout this protocol for reasons of clarity. This should be taken to include people who do not identify as women but are pregnant and give birth.

DISSEMINATION, OUTPUTS AND ANTICIPATED IMPACT

Dissemination

Benefits will be shared with all 152 maternity units in England, 7 health boards in Wales and maternity services in Scotland and Northern Ireland. We envisage our toolkit design, documentation of our co-design and implementation journeys will offer a template for other specialities in the NHS to optimise their use of PTIs. We will enrol our policy Co-Investigator (OLAYIWOLA) to support toolkit dissemination at a national level on the NHS Futures website

and through the Maternity and Neonatal Safety Improvement Programme and Chief Midwifery Office to all NHS Trusts. We will connect with the National Diversity Council and the NHS Equality and Diversity council to disseminate our results beyond maternity services.

We will work with our CRs to write blogs and study updates on our dedicated study webpage, and involve them in the dissemination communications planning. We will also work with our network of community based organisations and the Voluntary Community and Social Enterprise alliance to cascade through information channels used by women and organisations supporting women with cross-cultural communication needs. We will produce one page summaries of the study results in multiple languages for participants who request a copy of the results.

We will liaise with the Lead Midwives for Education network to offer the toolkit for undergraduate training to target the coherence and collective action concepts of NPT among the next cohort of practitioners. We will present at conferences and via the online learning portals of the Royal College of Midwives and Royal College of Obstetrics and Gynaecology. We also anticipate disseminating information about the study findings and materials through the MBRRACE-UK report launch meeting, usually attended by more than 1000 participants and representatives of more than half of the maternity units in the UK.

Outputs

The primary output from this research will be the co-designed ‘toolkit’ of resources and implementation case studies to optimise the use of PTIs in maternity care in England. The contents will be determined by the co-design process; however some illustrative examples of these resources may include training materials for staff on how to work with interpreters, how to book an interpreter, shared decision making guide, patient decision aids, awareness raising materials for women regarding their rights to an interpreter or an alert card. Training guides, maternity pathway navigation aids or key terminology crib sheets for PTIs may also be included. The ‘toolkit’ will include practical guidance for NHS organisations about local implementation. These resources will be freely available in a central location (e.g. NHS Futures website) as well as on the websites of our partner Trusts.

Project and local level evaluation results will be shared with each partner NHS trust, partner community based organisations, national Maternity Voices Partnership, Royal College Midwives and NHS Futures. We will publish a minimum of four peer reviewed academic papers about the experience of PTIs in maternity services, the context of maternity service delivery with women experiencing cross-cultural communication needs, our co-design experience and toolkit implementation results. We will present study results at key national and international

professional and academic conferences including Health Services Research UK and City of sanctuary maternity stream.

Impact

The toolkit aims to support practitioners, PTIs and women to work together in a more informed, efficient collaboration to reduce errors, misunderstandings, anxiety, trauma and improve experiences of care and informed consent. Benefits could be realised quickly by streamlining care journeys through better understanding of care pathways and safety advice, structuring conversations to improve consent, improving quality and satisfaction for women, their families and practitioners. Initially the women, partners, PTIs and maternity practitioners in our partner Trusts will benefit from optimised PTI use in their care, before the resources are shared across NHS maternity and other health service specialities nationally to support better, sustainable approaches to PTI use. Optimising the use of PTIs offers an opportunity to reflect on the content of practice to enact best practice.

For birthing women and their families our toolkit will facilitate accurate communication and consent, safe, efficient and psychologically sensitive care for women with cross-cultural communication needs. This will have a direct impact on improving equality in outcomes for women and their babies and trust in maternity care. For PTIs our toolkit will support their work in consultations as practitioners better understand the needs of PTIs who may not have specialist maternity experience, the context and techniques of working together for the benefit of the birthing woman. For NHS midwives our toolkit will bring guidance and tools to support maternity practitioners to deliver safe, ethical, and informed care. We anticipate benefits to include improvements in timely attendance for urgent care issues in the woman/fetus that will impact regional and national morbidity and mortality statistics. For the 58 UK higher education institutions offering approved midwifery programmes, we would expect to see benefits from including the resources in cultural safety training, which will carry through into clinical practice.

We anticipate the learning from this project to be transferrable to other divisions and sections of the NHS to target more than 1,040,000 people with cross-cultural communication needs in England and the practitioners supporting them (23). Our experience of delivering a theoretically informed participatory implementation project can act as a template for researchers and practitioners committed to implementing sustainable change in clinical practice to optimise PTI use across the UK health service.

PROJECT MANAGEMENT

The Chief Investigator MACLELLAN, with the support and mentoring of Co-PI ROWE, will have overall responsibility for day-to-day management of the project. The core research team comprising MACLELLAN, Project Manager TBA, and York collaborators (SHEARD and BAZ) will meet every 2 weeks to update progress, oversee governance and delivery of study activities to meet the planned milestones. The part time ethnographer based at Oxford University will join these regular meetings once in post. ROWE and SHEARD will deliver ongoing support to MACLELLAN out with the meeting schedule. The Co-Investigator Team of MACLELLAN, ROWE, project manager, Oxford based researcher, SHEARD, BAZ, MACFARLANE, OLAYIWOLA and BEGUM, will meet monthly by video conference. This will ensure all members are kept informed of progress and have an opportunity to contribute their expertise, discuss findings and support planning throughout the project. We will convene an independent Study Steering Committee to provide overall supervision to the project and ensure that it is conducted to the standards set out in the Department of Health's Research Governance Framework for Health and Social Care and Guidelines for Good Clinical Practice. The Study Steering Committee will meet twice a year with MACLELLAN, ROWE and other team members as necessary, meeting five times over the course of the project. The Study Steering Committee will comprise an independent Chair (Dr Elizabeth Such, Nottingham University), independent members (Professor Hora Soltani, Sheffield Hallam University, Dr Will Mason, University of Sheffield, Mr Mike Orlov, Executive Director of NRPSI, Dr Brenda Kelly, Obstetrician, Oxford University Hospitals) and lay member (Diana Flores Gallardo),

MACLELLAN will co-lead WP1 with SHEARD and co-lead WP2&3 with MACFARLANE.

Our Lived-experience Group, co-convened and facilitated by BEGUM, will meet quarterly. The project will seek input from a multi-disciplinary Expert Advisory Group who will meet annually and contribute to the co-design work. Members will comprise policy stakeholders, strategic leadership from the four nations, solution innovators and other members recommended by the co-investigator team.

PROJECT TIMETABLE

The project management plan is shown in Figure 2 below.

Project management plan for NIHR 157976

Interpreters in Maternity Services Study			2024			2025												2026												2027								
Calendar Month	Pre-		O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S
Study Month No.	grant		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
Activity																																						
Community researcher recruitment																																						
Orientation of community researchers																																						
I - Context and practice of PTI use in maternity																																						
HRA, CAG application & Local R&D approvals																																						
University ethics for PTI focus groups																																						
PTI focus groups																																						
Ethnography in 6 sites																																						
Analysis of findings from case study fieldwork																																						
II-Identify barriers to effective use of interpreters and how to remove them																																						
Workshop 1A: Prioritise with women																																						
Workshop 1B: Prioritise with professionals																																						
Workshop 2: Develop Toolkit of Resources																																						
Workshop 3: Refine toolkit resources																																						
Workshop 4: Local implementation workshops																																						
III-Implement and evaluate																																						
Implementation and embedding support																																						
Online Workshop 5: Refine toolkit resources																																						
Evaluation fieldwork & analysis																																						
Write up & National dissemination activities																																						
Project management/meetings																																						
Project Mgt Group meetings																																						
Full Co-Inv meetings																																						
Steering Group																																						
Expert Advisory Group																																						
PPI Meetings																																						

ETHICS/REGULATORY APPROVALS

This is a relatively low-risk study involving observation of maternity practitioners undertaking their usual practice, surveying and talking to them about their practice, observing and speaking with women, and co-design activities. The focus of the ethnography is the communication practices and dynamics in cross-cultural consultations. It will involve observation and interviews with staff and pregnant/birthing people in maternity settings. We received approvals from NHS REC, and HRA (25/WA/0098). We have received approval from University of Oxford (MS IDREC 811334) for the interpreter interviews and recruitment of interpreters and women to the co-design sessions. We will follow NHS and University of Oxford governance and data management procedures.

The main ethical considerations for this project are:

1. Conducting observational fieldwork in maternity settings where the researcher will be incidentally exposed to confidential information.

In the NHS sites where we are conducting our observational fieldwork, midwives will ask permission for the researcher to observe the consultation, making clear to women that they can decline without any impact on their care, and they can ask the researcher to leave at any time. If the woman consents, this will be recorded in her maternity notes alongside documentation of the name and presence of the researcher.

2. Women with cross-cultural communication issues who are approached by a research midwife for interview may not understand their right to decline.

We will design, in collaboration with our lived experience group, a short clip/introduction card as detailed in WP1 that is translated into the two chosen languages of the Trust. This introduction material will ask if the woman is willing to speak to a researcher in her own language about her experience of interpreters in maternity care. It will be made clear the researcher is independent of the care team and she can decline without consequence. It the woman agrees to the approach, the research midwife will inform the CR who will meet the woman to discuss the study, arrange a time for interview and receive consent.

3. Ensuring women with experience of cross-cultural communication issues have an equal voice in the co-design workshops.

We will ensure all women participating in the co-design workshops have interpreter support. We will pre-meet together to discuss the format of the workshops, preferred ways of working and communication or any cultural considerations to participation that need considered as well as to

meet each other in a small, friendly group. We will discuss the ground rules and interactive methods to be used that will give everyone a voice in the sessions, and introduce the women to the CR/QR group facilitators. In the actual co-design session we will repeat the ground rules/agreed ways of working with all group members and remind the CR/QRs about moderating their group to ensure full participation. The groups will be overseen by MACLELLAN and Professor MACFARLANE, who will offer additional support to the CRs as required. We will reflect with the women and QR/CRs after the session on what went well and what could be changed for the next session.

DATA PROTECTION AND PATIENT CONFIDENTIALITY

All investigators, research staff, PPI and Study Steering Committee members will comply with the requirements of the Data Protection Act 2018 and UK General Data Protection Regulation (GDPR) 2016/679 with regards to the collection, storage, processing and disclosure of data including any personal information. We will post a Privacy notice on the study website setting out the types of personal data that we will process, the purposes for that processing, storage information and the legal basis for processing. The Chief Investigator (MacLellan) is the data custodian. University of Oxford is the data controller. The processing of participants' personal data will be minimised by making use of a unique participant study number only on all study documents and any electronic database. All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

CONFLICT OF INTEREST STATEMENT

The research team have no conflicts of interest to declare.

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APPENDIX A: STUDY FLOWCHART

NIHR 157976: Optimising the use of Professionally Trained Interpreters in NHS maternity services