Pilot of a Maternity & Neonatal Independent Senior Advocate (MNISA) role: A rapid mixed-methods evaluation

Study protocol (version 1.1, 16/09/2024)

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SCIENTIFIC ABSTRACT

Background:

Various reviews of maternity services and previous research have highlighted that there is a need to improve the safety and quality of maternity and neonatal care. This is due to systemic failings and safety incidents resulting in avoidable adverse outcomes for mothers (e.g., maternal death or serious injury) and babies (e.g., stillbirth, neonatal death or serious injury).

Many factors have been suggested to contribute to these failings, including systemic/structurally-driven factors (e.g., underfunded healthcare system), organisational factors (e.g., leadership, management and culture, issues with collaboration and multidisciplinary working), staff factors (e.g., training and skill gaps), and factors related to a lack of family involvement (e.g., service-users not being supported to fully participate in decision making). In addition, women and families often feel ignored and not listened to, that their adverse outcomes have not been fully investigated or explained, and that opportunities to promote change and improvements are missed.

The Ockenden review (published in 2022) highlighted a need for women and families to be listened to, heard, and their concerns acted upon. It specified that an independent senior advocate role must be created. This led to the development of the Maternity and Neonatal Senior Independent Advocate (MNISA) role, which is currently being piloted across 16 Integrated Care Boards in England. The intended purpose of the role is for MNISAs to support women and families who have experienced an identifiable adverse outcome so that they are listened to, heard and their feedback used to influence change within the system, and to help them to navigate investigation or complaints processes (including NHS and non-NHS processes e.g., NHS complaints, NHS Resolution Early Notification scheme, Maternity and Newborn Safety Investigations) and signpost them to services as appropriate. However, as this is a new service, there is not yet evidence on stakeholder views and experiences, impacts and costs of the role.

Aims and objectives:

This mixed-methods rapid evaluation aims to evaluate the pilot implementation of the MNISA role in England, including:

- Family, MNISA, and wider staff (network, ICB, trust staff) experience,
- National stakeholder views of implementation,
- Implementation (including how the service is used, whether it is implemented as intended, variation, barriers/facilitators at a national, system and local level)
- Cost and impact,
- Potential equalities and/or inequalities related to access, experience and outcomes (where possible).

Methods:

To evaluate family members' experience of receiving support from MNISAs, we will aim to conduct interviews with families who have received support from MNISAs (n=15-35), and families who have been eligible, but who have not accessed the service (e.g., n=3-5).

To evaluate national stakeholders' views of early implementation, we will analyse relevant documents and conduct 3-8 interviews with national stakeholders (e.g., policymakers, commissioners, regulators, programme leads, third sector organisations).

To evaluate how the service is implemented and MNISAs' experience of the role, we will analyse relevant documents relating to the role (e.g., job descriptions, standard operating procedures, local service plans, equality impact assessments, communication guidelines/documents), conduct in-depth interviews (n=15-20) and an in-person workshop with MNISAs.

To evaluate wider staff perceptions and experiences of working with MNISAs, we will interview up to 30 wider staff (network, ICB and trust staff) across 8-10 areas (1-3 interviews per area).

To evaluate workload, impact and cost of these services (including but not limited to cost of investigation), we will analyse combinations of data being collected by NHSE specifically for the pilot and existing data on maternal and neonatal outcomes. Short-term costs will be estimated using data about the resource use and unit costs which are publicly available. Long-term costs will be calculated using the logic model that we will develop, and which will combine costs and relevant consequences (e.g., baby/ family events) using information from the different data sources that will be sought. Some impacts on parents and families receiving support and on wider system change will not be observable over the course of the study, so we plan to outline recommendations for how this could be carried out in further rollout of the programme.

These methods will also be used to explore issues of equality and inequality (e.g., to look at whether there are any differences in who is accessing the service or how families find the service).

Qualitative data will be analysed rapidly using inductive thematic analysis and Rapid Assessment Procedures. We will then conduct in-depth analysis using deductive thematic analysis. We will analyse quantitative data on MNISA caseload to assess existing workload of the MNISA's and to compare with the potential workload reported in national data. We will analyse differences in potential and actual workload by specific patient characteristics in order to investigate where there may be inequalities in accessing MNISA services. Qualitative and quantitative data analysis will be triangulated to fully understand implementation of the MNISA service.

Patient and Public Involvement and Engagement:
Comprehensive PPIE involvement is an important part of our research, and lived experience has been and will continue to influence and shape the project throughout. Three of our project core team members are public contributors. We also held a PPIE workshop with 5 members of the public in July 2024 to discuss the project design and data collection plans. We have and will continue to engage with the wider RSET PPIE panel and wider members of the public throughout the project. Discussions have informed our research design and will also inform data collection, analysis and write up.

We have also taken strategies to ensure equality, diversity and inclusion is central to our work (including during the development of our core project team, PPIE activities, and research activities).

Timelines for delivery:
This rapid study will be conducted between April 2024 and June 2025, with the following milestones:

- *April-July 2024* - Develop study and submit ethics;
- *July-September 2024* – Obtain ethics approval;
- *October 2024-April 2025* – Data collection and analysis;
- *May-June 2025* – Write up findings and formative feedback;
- *June 2025*– Report findings to NHS England;
- *July 2025 onwards* – Submit final report for NIHR, publish peer reviewed journals and other outputs.

Anticipated impact and dissemination:
Throughout the project we will share formative and final findings with those taking part and others interested in the topic. We will publish findings in academic journals, submit a final report to our funder and a final report to NHS England. We will present formative and final findings to various stakeholders throughout the project (including the public, family members, policymakers, service commissioners, inquiry/review teams, healthcare professionals, charities) and will develop various outputs (e.g., slide sets, short reports, blogs) that will be tailored to different audiences as appropriate. Dissemination activities developed for members of the general public and/or families will be co-produced with our PPIE contributors and will be written in plain English.

Findings will help to influence policy making decisions, particularly around whether the MNISA role will continue to be implemented and rolled out more widely, and if so, how the role will be implemented in future.

PLAIN ENGLISH SUMMARY

Why is this study needed?

- In 2023-2024, the Maternity and Neonatal Independent Senior Advocate role (also referred to as Maternity and Neonatal ISA or MNISA) was trialled in 16 areas of England.
- MNISAs support families after the death or serious injury of a baby, or death or serious injury (e.g., intensive care admission) of a mother during NHS care.
- The purpose of these independent advocates is to
    i. support and advocate for women, birthing people and families so that they are listened to, heard and their feedback used to bring forward change to help make maternity care better and safer.
    ii. Help families to navigate complicated systems and processes which happen after these incidents.
- But, we don't yet know what different people think about this role, how much it costs and whether it works.

What do we aim to do?

This rapid evaluation aims to study the pilot of the MNISA role in England.

We aim to evaluate:

- The experiences of women, birthing people and their families.
- Whether the service is equally accessible to different groups of families.
- What those involved in developing the service, those involved in regulating maternity and neonatal care, policymakers and charities think of the MNISA role.
- How the service is used.
- How MNISAs experience the role.
- What different members of staff who work with or alongside MNISAs (e.g., managers, midwives, health visitors, investigators) think of the role and working with MNISAs (e.g., including what works well and what may be challenging).
- Different people's views on impacts of the role (e.g., women and families, MNISAs themselves, staff at regional, ICB or trust level who work with or alongside the role).
- How much the service costs (financially), and what funding is needed for the role.
- How services in the future can measure how effective they are.

What do we plan to do?

To understand family members' experience of receiving support from MNISAs, we will aim to speak with 15-35 families who have received support from MNISAs, and up to 5 families who have not accessed the service.

To understand national stakeholders' views of early implementation (i.e. the delivery of role and pilot so far), we will analyse relevant documents and speak with 3-5 national stakeholders (e.g., those involved in developing the service, regulators and charities).

To understand how the service is used and how MNISAs find the role, we will look at relevant documents relating to the role (e.g., guidance, training materials), and speak with MNISAs through 15-20 individual conversations and an in-person workshop.

To understand what wider staff think about the role and working with MNISAs, we will speak with up to 30 staff members (in a wide range of different roles) who work with or alongside MNISAs in 8-10 areas (1-3 staff members per area).

To understand how many families want and need support from a MNISA, what funding is needed for the role, and whether the service has been successful in supporting families and driving improvements, we will analyse existing data and electronic health records.

These methods will also be used to look at whether the role can be accessed equally well by families from different backgrounds.

Patient and Public Involvement and Engagement:
Throughout planning this study, we work closely with public and patient representatives, and wider public members and stakeholders throughout the project. This includes parents with relevant lived-experiences and various charities that support families. Three of our core project team members are patient and public contributors. We also held a PPIE workshop with 5 members of the public in July 2024 to discuss the project design and data collection plans. Additionally, we will hold further conversations with members of the public with relevant lived experience to gather feedback on our study at various points during the project. These inputs and discussions have informed and shaped our approach to the study design and will continue to inform data collection, analysis and write up of findings.

When do we aim to complete the study?
We will complete our study by June 2025.

Our proposed timeline is below:

- *April-July 2024* - Develop a study and submit study for ethical approval
- *July-September 2024* – Obtain ethics approval
- *October 2024-April 2025*– Collect and analyse data (interviews and workshop)
- *May-June 2025* – Write up findings
- *June 2025*– Report findings to NHS England
- *July 2025 onwards* – Submit final report for NIHR, publish peer reviewed journals and other outputs.

Sharing what we know:

Throughout the project, we will regularly share findings with those who take part and other people interested in this role or supporting families who have experienced the death or serious injury of their baby or death or serious injury of the baby's mother. We will publish findings in academic journals, submit a final report to our funder (the NIHR) and a report to NHS England. We will also work with our patient and public contributors to co-produce other ways to share findings with families and members of the public (e.g., infographics, animations, blogs, short articles).

Why is this research important?

It is important to understand what has worked well and what might need to be improved about the MNISA role so far. This will help to inform decisions about if and how the role should be used across England in future.

RESEARCH PROTOCOL

1. BACKGROUND AND RATIONALE

1.1 Background

Previous research has highlighted the high-risk nature of maternity and neonatal care; stemming from the unpredictability of pregnancy, labour and birth, and the speed at which life-threatening events can occur.[1, 2] However, within the United Kingdom, many inquiry reviews, have taken place in recent years (e.g., independent review of maternity services at Shrewsbury and Telford Hospital NHS trust,[3, 4] Morecambe Bay,[5] and Northwick Park[6]) and policy reports[7-10] have highlighted criticisms and systemic failings in maternity and neonatal care that have led and continue to lead to avoidable safety issues. These inquiry reports took place due to families who were affected by avoidable safety issues refusing to accept what they had been told and pushing and fighting for change.[35, 32, 33] Additionally, evidence indicates that safety events, resulting in serious incidents (resulting in serious harm or death[11]) are particularly evident in the maternity and neonatal healthcare space.[1, 2] Inquiry reviews, together with previous evidence, indicate a need to improve safety and quality of maternity and neonatal care[3-10]; as avoidable safety events have devastating outcomes for both families and staff.[12]

Within maternity and neonatal services, adverse outcomes include maternal adverse outcomes, and neonatal adverse outcomes (see Table 1 for recent statistics). Adverse outcomes can have both physical and psychological impacts on women, birthing people and families.[13-16] In terms of maternal adverse outcomes, one example is maternal mortality.[3, 4, 7] This has been defined as: *"death while pregnant or within 42 days of the end of pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes"*[7] (page 4). Mortality may be directly related to pregnancy, labour or postnatal complications (<42 days) or indirectly resulting from existing conditions or conditions that developed during pregnancy.[7] Maternal deaths have been found to be rare adverse outcomes in some countries, e.g., Australia,[17] while previous research has indicated that almost 50% of maternal deaths may be avoidable.[1] Other maternal adverse outcomes include severe maternal morbidity, such as postpartum haemorrhage,[17-21] hysterectomies, multiple organ dysfunction, and Intensive Care Unit admission.[1]

Neonatal adverse outcomes may include perinatal mortality (stillbirths and early neonatal deaths).[1, 3, 4] Stillbirths have been defined as *"the death of a baby after 24 weeks of pregnancy before or during birth"*[7] (page 4); and can occur prior to labour (antepartum stillbirth), or at the time of birth (intrapartum stillbirth).[7] Previous research indicates that stillbirths may occur in 1 out of 200 pregnancies in high income countries.[22] Neonatal death has been defined as *"the death of a live born baby in the first 28 days of life"*[7] *(page 4)*. Other neonatal adverse outcomes include those resulting in neonatal morbidity and/or lifelong disability, including hypoxic ischaemic encephalopathy (brain injury),[3, 4] cerebral palsy,[1] brachial plexus injury,[1] and shoulder dystocia.[1]

Table 1. Available statistics outlining number of adverse outcomes in England or the UK

Type of adverse outcome	Adverse outcome	Statistic [Reference]
Maternal	Maternal mortality	272 in the United Kingdon from direct or indirect causes from 2020 to 2022[23]
	Admission to critical care from obstetrics	1,485 in England 2022-23[24]
Neonatal	Stillbirth	2,276 in England in 2022[25]
	Neonatal mortality	1,683 in England in 2022[25]
	Hypoxic brain injury	About 1,155 in England in 2022-23[26]

Evidence highlights inequalities in adverse outcomes that disproportionately affect different groups, including regarding different ethnicities and levels of deprivation.[7, 27, 28] For example, research has shown that babies of Black ethnicity (7.52/1000 births) and babies of Asian ethnicity (5.15/1000 births) are more likely to die than babies of White ethnicity (3.30/1000 births).[29] Also, research has shown that stillbirth rates are higher for babies born to mothers living in the most deprived areas.[29]

The processes, pathways and reporting requirements (locally, regionally and nationally) vary according to the adverse outcome. For example, certain patient safety incidents (early neonatal deaths, intrapartum stillbirths, severe brain injury in babies born at term, maternal deaths in England[30]) are reviewed by Maternity and Neonatal Safety Investigation (MNSI, formerly HSIB)[31] where families consent for a review to take place, a national strategy of independent investigation initiated with the aim of improving maternity safety. Maternal deaths, stillbirths, and infant deaths are reported to the MBBRACE (Mothers and Babies: Reducing Risk through Audit and Confidential Enquiries)[32] UK reporting system, with this programme responsible for collecting national information. The Perinatal Mortality Review Tool (PMRT)[33] is integrated within the MBBRACE-UK programme and supports standardized perinatal mortality review across maternity and neonatal units. All child deaths are reviewed by the multi-agency Child Death Overview Panel (CDOP).[34] All neonatal and maternal deaths should also undergo medical examiner review and some cases will be referred for coroner review (where appropriate). Reporting processes also exist within the Local Maternity Neonatal System (LMNS) and Neonatal Operational Delivery Network. Local governance processes that might be initiated following an adverse outcome include incident reporting (e.g., Patient Safety Incident Response Framework; PSIRF[35]), and learning from deaths and mortality review processes.

Within the NHS, there have been numerous broader policy innovations that have aimed to improve safety of health care services. These include initiatives to improve openness, such as the Freedom to speak up Guardian role (which aim to support healthcare workers and trusts to raise concerns and to learn from these concerns; evaluated in[36, 37]), statutory duty of candour (prompting healthcare organisations to inform and apologise to patients/families when something goes wrong), 'fit and proper persons test' (rigour checks on suitability of candidates for executive and non-executive roles), patient safety collaboratives (shared learning across regions) and sign up to safety (organisations working together to reduce

avoidable harm and excess mortality) (as discussed and evaluated in [38]). Within the maternity space specifically, the Maternity and Neonatal Safety Improvement programme[39] aims to improve safety and outcomes of maternal and neonatal care by reducing variation, providing high quality healthcare and contributing to reducing rates of maternal and neonatal deaths, stillbirths and brain injuries by 50% by 2025 (in line with ambitions outlined in the NHS Long term plan[40]). Whilst strategies have been implemented to improve maternity care, adverse outcomes continue to occur;[5, 41] some of which have been demonstrated to be preventable.[42] Reports have highlighted that despite attempts to improve maternity care, the numbers of stillbirth and neonatal mortalities have not improved in the UK.[7]

Avoidable safety events resulting in adverse outcomes have led to a large scale of harm caused to families receiving maternity care.[12] This is evidenced by reports that have outlined the scale of litigation relating to obstetric and maternity care. For example, recent statistics indicated that the number of obstetric claims in 2022/2023 made up a small number of overall clinical claims in the NHS (13.1%), but accounted for the majority of notified clinical claims in terms of value (64%, £5.9 billion (GBP)).[12]

Previous research has outlined a framework of safety features in maternity units, e.g., commitment to safety and improvement at all levels; technical competence; teamwork; reinforcing of safe, ethical and respectful behaviours; multiple problem-sensing systems; systems and processes designed for safety which are regularly reviewed; and effective coordination and ability to mobilise quickly.[43] However, previous research has outlined numerous systemic, organisational and individual factors that may contribute towards adverse outcomes within maternity and neonatal services and pathways received by families who have experienced these adverse outcomes. In terms of systemic/structural factors, these have included: wider NHS structural changes and budget cuts leading to underfunded maternity workforces;[44] variations in maternity and neonatal service provision nationally;[45] lack of national oversight[46] or guidance;[46] inconsistent governance processes for reporting, investigating and learning from adverse outcomes and maternity changes;[3, 4, 44] systemic preferences regarding the promotion of vaginal births in order to maintain low rates of caesarean sections[3, 4, 47], issues with data collection via national datasets[46] and the absence of national screening for certain conditions e.g., Vasa Previa.[48] From an organisational perspective, factors have included: issues with high turnover and lack of continuity of leadership and management of maternity services ,[3, 4, 49] power imbalances and hierarchy imbalances in maternity services;[50] issues with multidisciplinary engagement and collaboration in maternity/neonatal service provision[1, 3, 4, 46, 50-52]/serious incident investigations;[3, 4] staffing and resource issues (understaffed, high workload, lack of training for dealing with safety critical scenarios, lack of resources);[45, 46, 49, 52, 53] failures in processes relating to the management of labour,[3, 4, 53] inadequate facilities (lack of privacy/equipment)[46] and inadequate follow up support for those who have experienced adverse outcomes.[3, 4] In terms of staff factors, previous research has outlined: training and skill gaps;[3, 4, 49, 52] lack of regular monitoring of patients and risk assessments,[46] resulting in escalation delays or failures;[3, 4, 51] staff not listening to women and families,[3, 4] perhaps due to a lack of time and skills;[47] challenges relating to whistleblowing, e.g., lack of support and protection, and inadequate action in response to complaints[54]; low staff morale;[49] and lack of kindness and compassion from some staff.[3, 4] Increasing social and medical complexities of those going through pregnancy may affect the management of pregnancies. [2, 49] Furthermore, factors

related to a lack of family involvement outlined in previous research have included variation in advice received by staff throughout the pregnancy journey;[53] and the healthcare system not allowing families to fully participate in decision making.[47]

These factors have contributed towards women, birthing people and families feeling ignored.[2-4] Furthermore, they have contributed to families feeling concerned that adverse outcomes have not received appropriate and full investigation, and that families have not been given meaningful or appropriate explanations when adverse outcomes have occurred.[8, 9] Recent media reports commenting on the most recent inquiry at Nottingham University Hospitals NHS Trust have also illustrated examples of situations whereby safety issues have been covered up by hospitals and families have been blamed or lied to.[55] Additionally, previous research has identified many issues with the care families receive following an adverse outcome, with research on family experience echoing many of the aforementioned factors relating to the importance of communication, trained staff, appropriate maternity environments and provision of sensitive information.[56] Furthermore, despite the many benefits of including parents in reviews of adverse outcomes and healthcare harm events more broadly (e.g., improving quality and future safety), and despite parents wanting to be included (with the proviso of sensitive, compassionate and open and honest communication),[42] findings from previous research have highlighted that many review processes and inquiries in the maternity and neonatal space may not inform families about investigations taking place[57] and that review processes often do not include families.[42, 57] However, there is currently ongoing work evaluating open disclosure (discussions between patients, families and health care providers) about incidents resulting in harm whilst receiving maternity care.[58] This study will offer insight into how to improve open disclosure processes within these services in future.[58]

These findings are comparable with healthcare harm investigations more generally – which have been found to overlook patient and family perspective.[11] Previous research has highlighted that patients and families want to be involved in strategies that may improve patient safety and service improvements,[59, 60] but that the involvement of patients and families is sometimes marginalised by healthcare services.[38]

The Ockenden review of maternity services at Shrewsbury and Telford Hospital NHS Trust (published in 2022) outlined several Immediate and Essential Actions to improve maternity and neonatal care.[3, 4] One Immediate and Essential Action (IEA) specifies that *"Maternity services must ensure that women and their families are listened to with their voices heard"*, and that *"Trusts must create an independent senior advocate role"*.[3, 4] This recommendation was made due to findings indicating that parents' voices were not being heard (see previous paragraph).[2-4] Following this, NHS England developed the Maternity and Neonatal Senior Independent Advocate role (also referred to as Maternity and Neonatal ISA or MNISA).[61, 62] This role is currently being piloted across 16 Integrated Care Boards.[61, 62] The MNISAs' role is intended to support and advocate for women and families who have experienced an identifiable adverse outcome, so that they are listened to, heard and their feedback used to bring forward change to help make maternity care better and safer. To help women and families to navigate processes and systems, and signpost them to further services as appropriate and advocate for learning and change.[62] The adverse outcomes included within

the scope of this role for the initial pilot phase are: i) Stillbirth (after 24 weeks of pregnancy), ii) neonatal death, iii) maternal death, iv) unplanned or unexpected hysterectomy (within 6 weeks of birth), v) maternal admission to critical/intensive care and vi) neonatal brain injury that has been diagnosed or suspected, including hypoxic-ischaemic encephalopathy (HIE).[62] However, as this is a new role, there is no evidence on what different people think about this role, how much it costs and its perceived impact. Therefore, a mixed-methods evaluation is needed to evaluate impact, cost and stakeholder experience from differing perspectives, and to inform whether and how this service should be rolled out in future.

1.2 Scoping phase

Within our scoping phase, we have reviewed existing evidence, and we have held ongoing discussions with a range of stakeholders, including: our Patient and Public Involvement and Engagement (PPIE) members (coordinated by our PPIE co-leads, includes our RSET public members who contribute across all RSET evaluations and project-specific PPIE contributors with an interest and/or experience in maternity and neonatal services), NHS England colleagues and the MNISA service steering group (comprising service users with lived experience), academics with expertise in maternity and neonatal research, clinicians and others involved with delivering maternity and/or neonatal services, representatives from relevant professional bodies, third sector organisations and other relevant organisations. These scoping conversations, together with a workshop (comprising our project team, PPIE members, NHS England colleagues and members of the MNISA service steering group) have informed our study design and protocol development. See Section 7 for details on how PPIE members have been involved throughout the research project to date.

1.3 Project team

This project is a collaboration between researchers from NIHR RSET[63] (NC, HW, RL, PLN, CSJ, KH, EM, NJF,SM), RSET public contributors (CM, SF, RM) and Sands (JH, KM, JS, BW). Sands[64] is a third sector organisation who work to support those affected by pregnancy loss or the death of a baby. Sands will collaborate on this study and will be closely involved in the design of the study, data collection and analysis (together with the research team) and write up.

2 AIMS AND OBJECTIVES

This evaluation aims to rapidly evaluate the pilot implementation of the Maternity and Neonatal Independent Senior Advocate (MNISA) role in England.

2.1 Research questions

We will answer the following questions:

Workstream 1. Experience of women, birthing people and families

- What are the experiences of i) families who receive support from MNISAs, and ii) families who are eligible, but have not received support from MNISAs? Iii) How does experience differ across different groups of families *(i.e. considering socio-demographic characteristics such as ethnicity and deprivation*)?
- Has the MNISA role met the objectives set out by NHS England from the perspective of families receiving their support? *(i.e. families feeling supported, heard and listened to, and MNISA role supporting individual and system level change)*

- What do these families think of the role? *(including views on independence, seniority and experience/background of advocates)*

Workstream 2. Service development

- What is the wider context for the implementation of the MNISA role in England? *(including the policy context, recent reviews/inquiries, changes to review processes/incident reporting procedures, how the role aligns/fits with wider context)*
- What were drivers for development of the role? *(including what other models were considered and rejected and why)*
- How was the MNISA role set up? *(including role of different stakeholders e.g., families, drivers for the way it was developed)*
- How was it designed to address or overcome potential inequalities?
- What are national stakeholders' views of this role? *(e.g., need/value, anticipated benefits, impacts)*

Workstream 3. Implementation and staff experience

- How has the MNISA role been implemented in England, and has the role been implemented as intended by NHS England, as outlined in the operational guidance *(e.g., considering factors such as standardisation of delivery, reporting, and monitoring)*?
- What are the factors (barriers and facilitators) influencing implementation?
- What are MNISAs' perceptions of the role and experiences of delivering support to families within this role? *(including views on training/support, recruitment, independence (as per operational guidance), person specification relating to seniority and advocacy, training, barriers and facilitators to delivery, sustainability/retention within role, scope of the role – current eligibility criteria, governance models and reporting, future implementation)*
- What are trust level and ICB level staffs' views and perceptions of the role, and experiences of working with the MNISAs? *(including views on independence, person specification relating to seniority and advocacy, training, barriers and facilitators to delivery, overlap, scope of the role – current focus on adverse outcome, governance models, future implementation)*

Workstream 4. Impact and cost

- What impact has the MNISA role had on individuals (families, staff), organisations and system level change *(including views on safety and quality improvement)*?
- What is the typical MNISA caseload and case-mix (by adverse event and source of referral), and how might these vary between MNISAs and ICBs?
- Is there quantitative evidence of inequalities of access to MNISA services?
- How does the current workload of the MNISA's compare to the potential workload of all adverse outcomes chosen for the pilot?
- What would be the workload implications of MNISA's handling a wider range of adverse outcomes?
- What is the overall current budget impact of the MNISA programme?
- What evidence is there relating to the costs associated with identifiable adverse outcomes, for which MNISA support might be provided?

- How might the budget impact of the MNISA programme be affected by:
    - A rollout of the MNISA program?
    - Expansion of the eligibility criteria for those needing support from a MNISA (wider range of adverse outcomes)?
- How might the impact of MNISA support for affected parents/families be quantified, to support a full evaluation of the effectiveness and cost of the MNISA program? What data are available and what should be captured to undertake such an evaluation?
- What are relevant outcome measures for longer-term assessments of the impact on system change? What data should be captured to undertake such assessments?

Workstream 5. Integration of workstreams 1-3.

- How do the qualitative and quantitative findings align?
- What lessons can be learned from findings to inform whether and how this service is implemented in future?
- How can this service be further evaluated in future? *(including development of recommendations and a logic model in order to map out pathways through which impact or change may occur; given the complexities of the maternal and neonatal system)*

3. STUDY DESIGN & METHODS OF DATA COLLECTION

3.1 Design

This is a rapid mixed-methods study combining qualitative, quantitative and health economic approaches to evaluate the implementation of MNISAs in England.

Theoretical Frameworks

Theoretical frameworks for the implementation of health care services/innovations will be considered to align with the workstream research questions and objectives and prior to data collection and analysis to guide the evaluation. Examples of frameworks that will be considered include; RE-AIM[65] (a framework includes 5 key outcomes; reach, effectiveness, adoption, implementation, maintenance) and CFIR[66] (Consolidated Framework for Implementation Research).

3.2 Methods

See Figure 1 for a summary of all workstreams, and Table 2 for a summary of primary qualitative data collection methods.

Figure 1. Summary of evaluation workstreams

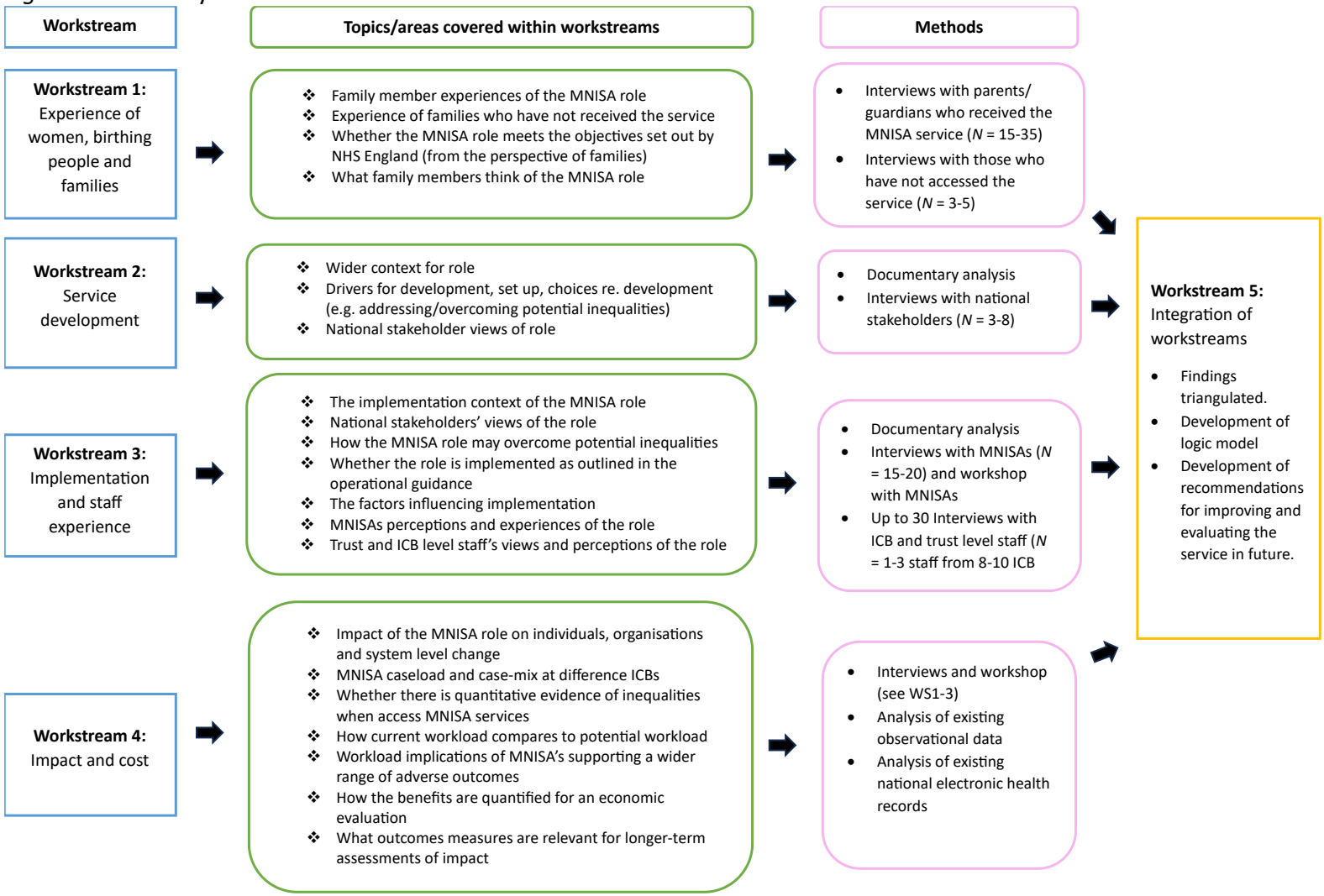

Table 2. Summary of primary qualitative data collection methods

Work stream[a]	Activity	Who we will invite to take part	Recruitment process	Who will conduct / facilitate	Approx. time	Recruitment study months
1	Interviews with families (parents/guardians/next of kin) who received service	We will aim to speak with 15-35 families (parents/guardians/next of kin) from a range of backgrounds, who have received support from a Maternity and Neonatal Independent Senior Advocate, following the experience of one of the following adverse outcomes (as specified by NHSE[62]): • *The baby died before they were born after 24 weeks of pregnancy (stillbirth)* • *The baby died in the days or weeks after they were born (neonatal death)* • *The baby's mother died (maternal death)* • *The baby's mother had an unexpected or unplanned removal of their womb (hysterectomy) within 6 weeks of giving birth* • *The mother had an unexpected admission to the critical or intensive care unit* *The baby was diagnosed with a brain injury or a brain injury was suspected, including hypoxic-ischaemic encephalopathy (HIE).*	• We will recruit via the ICBs. MNISAs will be asked to give all families a short explanation and summary of the research (supporting document to be provided by research team). • The MNISA will check with families if they would be interested in taking part in the interview. • We will also recruit via social media, and third sector or advocacy organisations. • Interested individuals will be asked to contact the researchers to indicate that they may like to participate, or (where recruited via ICBS), will have the option of asking the MNISAs to pass on their contact details to researchers	Facilitated by one Sands researcher (JH, BW) and one RSET researcher (HW/NC/RL)[b, c]	30-60 minutes	August 2024-April 2025
	Interviews with families who are eligible to receive support but have not accessed support from MNISAs	We will aim to speak with 3-5 parents/guardians from a range of backgrounds, who have experienced one of these adverse outcomes, but who have not received support from a Maternity and Neonatal Independent Senior advocate (for various reasons, e.g. we will aim to sample a mixture of individuals who were offered the service but chose not to access it (e.g. declined), and those who were not aware of the service or not referred).	• We will recruit via social media, and third sector or advocacy organisations. • If appropriate and feasible, we will also recruit via ICBs through relevant staff. • Interested individuals will be asked to contact the researchers to indicate that they may like to participate.	Facilitated by one Sands researcher (JH, BW) and one RSET researcher (HW/NC/RL)[d]	30-60 minutes	August 2024-April 2025
2	Documentary analysis	We will identify relevant national documents pertaining to the MNISA role and implementation (e.g. operational guidance, communications toolkit, training materials)	• We will ask service developers to identify any relevant documents. • We will also analyse relevant documentation available in the public domain pertaining to the role.	NC/HW/RL	N/A	August 2024 – March 2025
	Interviews with national stakeholders	We will aim to speak with 3-8 national level stakeholders (including policy makers, service developers, MNISA service steering group members, charities, other relevant organisations)	• We will directly email organisations or certain teams to invite members of their organisation/team to participate. Individuals that are interested will be asked to contact the researchers.	NC/HW/RL	30-60 minutes	August 2024-April 2025
3	Documentary analysis	We will identify relevant local level documents pertaining to the MNISA role and implementation (e.g. training	• We will ask relevant ICB/Trust level staff to identify any relevant documents.	NC/HW/RL	N/A	August 2024 – March 2025

	materials, standard operating procedures, job descriptions)	• We will also analyse relevant documentation available in the public domain pertaining to the role.			
Interviews with MNISAs	We will aim to speak with 15-20 Maternity and Neonatal Independent Senior Advocates. We will ask all MNISAs to complete a short survey prior to interviews to provide some details about their role and demographics.	• We will recruit via the MNISA community of practice. • We will invite all MNISAs to participate via email, or ask MNISAs to contact the researchers to express interest.	NC/HW/RL	30-60 minutes	August 2024-April 2025
Workshop with MNISAs	We will aim to conduct one in person workshop with Maternity and Neonatal Independent Senior Advocates.	• We will recruit via the MNISA peer network who meet on a regular basis.. • We will invite all MNISAs to participate via email, or ask MNISAs to contact the researchers to express interest.	NC/HW/RL	90-120 minutes	January 2025
Interviews with wider staff (network level, Integrated Care Board level and trust level staff	We will aim to speak with up to staff from 8-10 Integrated Care Board areas. This will include ICB level staff and trust level staff and network or regional level staff.	• We will purposively email points of contact from relevant organisations or job roles that may have interacted with MNISAs to invite members of their team/organisation to take part. • We will also circulate via the ICBs, a short email advert to staff in the ICB and associated trusts to ask for expressions of interest. • We will also recruit via relevant network level meetings. • We will also ask staff to cascade details of the interviews to other relevant staff. • Interested individuals will be asked to contact the researchers to express interest.	NC/HW/RL	30-60 minutes	August 2024-April 2025

Note. [a] For details of which research questions are covered within each workstream, please see Pages 11-12

[b] *If preferred, families will be offered a written or hybrid option to share information (i.e. to provide some responses in writing before or after the interview).*

[c] *See interview data collection section for procedures relating to debriefing and sign-posting to relevant support.*

[d] *If participants have not had access to a MNISA, researchers can signpost them to the MNISA website for their local area, in case they would like to explore accessing support from the MNISA in future.*

Workstream 1. Experience of women, birthing people and families

This workstream will be led by NC and HW with contributions from Sands and other RSET team members.

Aims

This workstream aims to evaluate family members' experiences of receiving support from MNISAs, including their views on whether the service meets the intended aims (feeling listened to and heard, and wider organisational and system level impact), views of the role and recommendations for the future role.

Design

Qualitative design, comprising semi-structured interviews.

Sample

To explore family member experience of receiving support from MNISAs, we will aim to conduct interviews with 15-35 parents and/or guardians that have received support from a MNISA. To proportionately represent families with different adverse outcomes, we will try to sample based on the proportion of people with different adverse outcomes who have accessed the service.

To explore experiences of those who have not received support from a MNISA in the ICB areas covered in the pilot, we will aim to conduct interviews with 3-5 parents and/or guardians who would be eligible for support from a MNISA but have not received/accessed the service (e.g., we will aim to sample a range of families who were offered the service but chose not to access it (e.g. declined), and those who were not aware of the service or not referred).

We will aim to purposively sample families across a range of characteristics, including adverse outcome experienced (stillbirth, neonatal death, maternal death, unexpected or unplanned hysterectomy within 6 weeks of giving birth, unexpected admission of the mother to the critical or intensive care unit, baby diagnosed with brain injury or suspected brain injury), family role (e.g., mother, father, other guardian), age, geographical area (to cover the range of ICBs included in the pilot), ethnicity, length of time engaging with the MNISA, stage in their journey following the outcome, disability, sexuality.

It is important to note that whilst we aim to recruit 35 families and have a diverse range of participants, the number of participants actually recruited may depend on several factors, including: the number of families who have experienced or accessed the service due to the relative infancy and short run-time of the pilot service, the number of families willing to engage with an interview at the time of data collection, and the diversity of the families accessing the service. It is also possible that we may receive more than 35 interview responses, due to offering a written option as well as a verbal interview option.

See Section 7 for recruitment processes.

Topic guides

Topic guides have been developed iteratively from conversations with relevant stakeholders during our scoping phase, to meet the requirements of the evaluation specification document provided by NHS England. We have obtained feedback from our PPIE contributors, NHS England MNISA service steering group service user representatives, third sector organisations (e.g., Sands), and other relevant stakeholders on these topic guides prior to their use to ensure sensitivity, appropriateness and comprehensiveness.

Interviews with those who have received support from MNISAs will cover the following topics: support received from the MNISA to date (including information, interactions, how found out about the role, further areas of support), experience of support received (likes, dislikes, if support matches expectations, relationship with MNISA, barriers and facilitators to access and engagement – including timing of support for families), whether the service meets NHS England's intended outcomes (women and families feeling heard and listened to, feeling that concerns have been acted on, perceived impact), views on the role (including whether they have time to support, views on independence and seniority, skills and experience), and reflections on future practice.

Interviews with those who were eligible to receive support but have not accessed the service will cover the following topics: awareness of the MNISA role and views and interest in the role. If individuals had been offered and declined support, they would be asked questions to help understand why and any barriers they may have experienced and what additional or alternative support or service they may have preferred or may prefer in the future. If they were interested in support but not aware of the service, they will be asked what support they would have liked to have received from a MNISA (including information, interactions, how to find out about them, what support). We will also ask them whether they think support from a MNISA could achieve NHS England's intended outcomes (women and families feeling heard and listened to, feeling that concerns have been acted on, perceived impact), and reflections on support structures that might be helpful in the future for supporting families who have been through adverse outcomes.

Prior to the interview, participants will be asked to complete a socio-demographic questionnaire (including gender, age, sexual orientation, area of the UK they live in, ethnicity, first language, relationship status, category of adverse outcome). However, if preferred, researchers can go through this with participants during the interview.

During a pre-interview conversation or the interview itself, we will give families the choice on whether they would like to speak about the details of the event that led to their adverse outcome. We will emphasise that researchers are happy to listen if they would like to share, but that sharing this information is completely voluntary. We will also be flexible around how participants want to share information, e.g., solely taking part verbally, solely taking part in writing, or a hybrid option whereby they provide some responses in writing (either before or after the interview) and some responses verbally during an interview, if they choose to.

Data collection

Once interested individuals contact the researchers, the researchers (NC/HW/RL) will ask some basic eligibility questions (whether they have received support from a MNISA, which

ICB they are in, and whether they are over the age of 18) and will provide information sheet and consent forms. We will offer the option for information sheets and consent forms to be translated, if needed. Potential interviewees will be informed that taking part is completely voluntary. If interviewees are interested in taking part, they will be asked to provide electronic, written or audio-recorded verbal informed consent prior to taking part in the interview. Prior to the interview, participants will also be asked to complete a short socio-demographic survey.

Participants will be offered the option to take part in the interview online (via teams), over the telephone, or via written response via a secure electronic survey link (REDCap). The written response option is consistent with similar projects that have offered alternative methods of interview participation.[67] Interviews will be scheduled at a time of day to be agreed by participants. If English is not a participant's first language, we will offer interpretation services so that they can take part in the interview. Each interview will be jointly facilitated by a researcher from Sands (JH, BW) and a researcher from RSET (NC, HW, RL), and participants will be informed of the interview arrangements prior to the interview and arrangements will be flexed according to preferences. We will offer participants the option to have an informal call with the researchers prior to the formal interview to provide an opportunity for them to share their experiences and events leading to the adverse outcome (should they wish to). This will last between 20-30 minutes, will not be part of the formal data collection and will not be recorded. The formal interview that focuses on the experience of the MNISA role will last between 45-60 minutes. However, if participants choose not to have two separate conversations, we will explain to participants that interviews may take between 30-90 minutes depending on how much they would like to say. Interviews will be semi-structured, audio-recorded on an encrypted dictaphone (subject to consent), transcribed verbatim by a professional transcription service, anonymised and kept in compliance with the General Data Protection regulation (GDPR 2018) and Data Protection Act (2018). Any interview responses via electronic survey will be directly returned to the study team for analysis, electronically through REDCap. Participants will be informed that they are free to withdraw up to two weeks after the date of their interview. If families would like to provide further information following an interview, we will offer them a short follow up interview or give them the option of adding any additional information via the secure electronic survey link.

As the interview may involve family members potentially discussing distressing and/or traumatic events and adverse outcomes, we will implement the following data collection protocols to support and safeguard participants:

- Before the interview:
    - We will offer family members the option to be interviewed together (e.g., both parents), to both take part but separately, or for one family member to take part on behalf of the family.
    - We will offer different modes of participation depending on what the families feel most comfortable with (telephone, online, written via secure survey link).
    - We will offer the option for information sheets and consent forms to be translated, and for an interpreter (professional or family member) to be present during the interview, if English is not the participants' first language.

- We will ask participants if they would like to receive the interview questions in advance of the interview so that they have time to prepare.
- We will explain that participants can pause or stop the interview or skip questions at any time without reason.
- We will offer flexibility for when interviews are conducted.
- When discussing the timing of the interview, we will prompt participants to actively consider what support they will have around them that day and to consider planning whether they would like support available to them in the hours following the interview.

- During the interview
  - At the start of the interview, we will have an initial chat with participants about the study and what it will entail, we will ask them if they have any questions or concerns and if they are happy to continue and for us to start recording.
  - We will let participants know that we will not expect families to share the details of the event that led to their adverse outcome, but instead that it is completely up to them whether they would like to share this information, and whether they want to do so in the interview, or in advance in writing. We will emphasise that the researchers are happy to listen if they would like to share.
  - We will ask participants if they would like to take a short break after the first few questions in the interview (particularly due to these questions giving families the option for participants to share their experiences of the events leading to the adverse outcome if they would like to).
  - If interviewees become upset or distressed, we will offer the option to pause or stop the interview (including the recording). The researcher and participant will collaboratively decide whether they should continue the interview. If the participant is unable to continue, the researcher offers to contact a family member or friend. The researcher does not provide mental health advice but instead directs participants to relevant support services and encourages participants to contact their GP. Participants are never left in a distressed state.
  - To safeguard participants, if interviewees report any information during interviews or when in contact with researchers that indicates that they or others are at risk of harm, we will speak to participants about our need to escalate this and will escalate this accordingly (see section 11.2 on ethics). This will be outlined in participant information sheets.

- After the interview
  - At the end of the interview, we will verbally debrief participants and as part of this we will:
    - Ask participants if they are happy for us to follow up with them via email (or another preferred method) after the interview to check that they are okay.
    - Check if they have someone to talk to following the interview if needed. The researcher will offer to contact a family member or friend on their behalf if needed.
    - If they do not have someone to talk to, or if they are distressed, the researcher will not provide mental health advice but will instead direct

participants to relevant support services. This includes signposting them to the Sands helpline (who have been briefed about research activity beforehand), other support services (e.g. other relevant charities such as Petals specialist counselling service). The researcher will also encourage the participant to contact their GP. Participants are never left in a distressed state.

- Provide participants with a debrief form (see Appendix 3) following each interview, which signposts to local MNISA webpages outlining sources of support in their local area, and key charities that they can contact for further support. We will develop different versions of debrief forms so that each family receives support that is appropriate for the adverse outcome that they have experienced.
- If participants have not had access to a MNISA, researchers can signpost them to the MNISA website for their local area, in case they would like to explore accessing support from the MNISA in future (e.g., through self-referral).However, it will be explained to participants that we cannot guarantee that they will be offered support from their local MNISA service.
- If families request access to their transcript, we will fully anonymise and check this for accuracy prior to securely sharing this with them.

- As a research team, we will regularly check in with those conducting interviews (from RSET and Sands), to debrief and discuss where appropriate, to ensure that our researchers are well supported. Researchers will be signposted to relevant support services as appropriate where needed (see Section 11.2 on Ethics). We will also check that the professional transcription service has appropriate debriefing protocols or policies in place, and that research team debriefing and peer support extends to the analysis and write-up phases of the evaluation.

These protocols are summarised within our distress protocol, which outlines to researchers exactly what steps must be taken in the event of a participant becoming distressed.

As a thank you for participating in the interview, families will be given a one-off £25 voucher. This was felt to be appropriate following feedback from our PPIE contributors (study collaborators and attendees of our PPIE workshop).

Data analysis

To analyse findings from this workstream, and the other qualitative workstreams (2,3), we will use a medium Q thematic analysis approach,[68] combining inductive thematic analysis and the use of a coding framework.[69]

Data collection and analysis will be carried out in parallel, using Rapid Assessment Procedure (RAP) sheets.[70] Qualitative data will be analysed by named researchers in the Rapid Service Evaluation Team (HW, RL, NC) and Sands (JH, BW). Researchers conducting interviews will take real-time notes and will input these notes into Rapid Assessment Procedure sheets following each interview. The categories used in the RAP sheet will be based upon the interview topic guides. There will be flexibility to add categories during the research process.

Once notes have been inputted into the RAP sheets, researchers will use inductive thematic analysis[69] to inductively code these notes and develop initial themes and sub-themes. This rapid analysis will be used to share interim findings with key stakeholders throughout the study.

Following the rapid analysis, an in-depth analysis will be undertaken. Researchers will use the initial themes and sub-themes developed during the rapid analysis to develop a coding framework. This coding framework will be applied to interview transcripts. The coding will be used to develop the final themes and sub-themes relating to family experience.

For this evaluation and the other qualitative workstreams (2,3), we will identify relevant theoretical frameworks to guide analysis, prior to undertaking the analysis.

We will aim to undertake cross-case comparisons across the different ICBs and different family characteristics (e.g., to explore barriers/inequities relating to access, use and experience). Interpretation of findings and write up will be discussed and agreed with the study PPIE group, advisory group and wider team prior to finalising.

Workstream 2. Service development

This workstream will be led by HW and NC with contributions from other RSET and Sands team members.

Aims

To evaluate the way in which the service has been developed (including the wider context for implementation, drivers for development, other models considered/rejected, set up of the role and drivers for the way in which it was developed, strategies to overcome inequalities and national stakeholder views).

Design

Qualitative design, including documentary analysis and interviews with national stakeholders.

Sample

Documentary analysis

To understand the MNISA role and its implementation at a national level, we will analyse relevant key documents pertaining to the role and implementation (e.g., considering factors such as standardisation of delivery, reporting, and monitoring). Whilst not an exhaustive list, this may include operational guidance, communications toolkit, relevant reports relating to the set-up/design of the role, and training materials. See Section 7 for recruitment processes.

Interviews

National stakeholders

To explore the wider context for the implementation of MNISAs, national stakeholder views and how the MNISA role was set up to address or overcome potential inequalities, we will conduct interviews with 3-8 national stakeholders. Though not exhaustive, this may include those working in policy roles, commissioning roles, programme leads, regulatory roles (e.g., CQC), public inquiry and review teams, professional organisations, third sector organisations

and training organisations. We will aim to recruit individuals across a wide range of different roles to ensure representativeness of findings. See Section 7 for recruitment processes.

Topic guides

Topic guides have been developed iteratively from conversations with relevant stakeholders during our scoping phase, to meet the requirements of the evaluation specification document provided by NHS England. We have sought feedback from our PPIE contributors and relevant stakeholders on these topic guides to ensure appropriateness and comprehensiveness.

National stakeholder interviews will cover the following topics: the interviewees' role and how it links to the MNISA role, the broader maternity and neonatal context and how the MNISA role fits in, the reasons/drivers for implementing the MNISA service, other models considered/rejected, how it was developed (including drivers) and whether/how it was designed to overcome inequalities, set up of the role, views on the aims/purpose, implementation and role specification, barriers and facilitators to implementation, access and engagement (including timing of support for families), and perceived impacts.

Data collection

For national stakeholder interviews, researchers (NC/HW/RL) will identify relevant organisations or job types that may have a view on the MNISA role. Researchers will email these organisations to ask for expressions of interest from their organisation/team in taking part in an interview. Researchers will then send information sheets and consent forms to those that express interest. Potential interviewees will be informed that taking part is voluntary. If interviewees are interested in taking part, they will be asked to provide electronic, written or audio-recorded verbal informed consent prior to taking part in the interview. The interviews will take place either online, or over the telephone. Each interview will last between 30-60 minutes, will be semi-structured, audio-recorded on an encrypted Dictaphone (subject to consent), transcribed verbatim by a professional transcription service, anonymised and kept in compliance with the General Data Protection regulation (GDPR 2018) and Data Protection Act (2018). Interviews will be scheduled to take place during regular working hours, as staff are not being compensated for their study participation. If interviewees would like to provide further information following the interview, they can send further feedback in writing, or researchers will arrange a short follow-up interview. Participants will be informed that they are free to withdraw up to two weeks after the date of their interview.

Data analysis

We will undertake the same analysis approach used in workstream 1. See Workstream 1 for details.

Workstream 3. Implementation and staff experience

This workstream will be led by HW and NC with contributions from other RSET and Sands team members.

Aims

To evaluate implementation and stakeholder experience of the MNISA role (including implementation of the role, including barriers/facilitators and intended vs actual implementation, staff experience of the role, perceived impacts of the role, and inequalities).

Design

Qualitative design, including documentary analysis, interviews with a range of stakeholders and a workshop with MNISAs.

Sample

Documentary analysis

To understand the MNISA role and it's implementation at local levels, we will analyse relevant key documents pertaining to the role and implementation. Whilst not an exhaustive list, this may include local training materials, standard operating procedures, job descriptions, and webpages. See Section 7 for recruitment processes.

Interviews

MNISAs

To explore implementation and staff experience of the MNISA role, we will conduct interviews with 15-20 currently or previously employed Maternity and Neonatal Independent Senior Advocates. All MNISAs interviewed will be asked to complete a short questionnaire outlining key details of their role, implementation and demographic characteristics. We will also aim to conduct one in-person workshop with as many MNISAs as possible. This will be held during a regular MNISA in person meeting day.

There are currently 14 MNISAs operating in the role across 16 Integrated Care Boards[61, 62]; with remaining MNISAs still to be recruited and/or start working with families. Therefore, this sampling approach enables us to capture views from the majority of MNISAs. As we may not be able to recruit all MNISAs to take part, we will purposively select MNISAs to ensure representation from individuals with a wide range of characteristics, including: the model of MNISA employment (e.g., ICB or external organisation), geographical area, time since implementation, background of the MNISA (e.g., clinical vs non-clinical) and type of contract (e.g., fixed-term or zero hours).

See Section 7 for recruitment processes.

Wider staff (Regional (network) level, integrated care board level and trust level)

To study implementation of the MNISA role, perceived impacts of the role and experiences of staff who work with MNISAs or families receiving support from MNISAs, we will conduct up to 30 interviews with wider staff (network level, integrated care board level and trust level staff) across 8-10 Integrated Care Board areas (up to 3 interviews per area).

As there are 16 ICBs implementing this role, this sampling approach enables us to capture views and perceived impacts from several ICBs. As we are not able to recruit all ICBs to take part within the rapid timeframe of the study, we will purposively sample ICBs to ensure

representation of ICBs with a range of characteristics, such as: the model of MNISA employment used in that area (e.g., ICB employed or external organisation employed), geographical area, single/multi trust ICB, time since implementation and level of oversight/engagement from the ICB.

Potential interviewees at network/regional level may include: Operational delivery network staff, local maternity and neonatal system staff, Maternity and Neonatal safety investigation staff, child death overview panel representatives. Potential interviewees at ICB level may include line managers, maternity and neonatal voice partnerships (MNVPs). Potential interviewees at trust level may include: heads of midwifery and neonatal services, directors, those involved in developing local policy, midwives, nurses, bereavement teams, medical examiners, family liaison coordinators, those dealing with maternity and neonatal complaints or involved with incident reporting processes.

Flexibility in our sampling approach has been informed by our scoping work which indicates that the person who will be best placed to talk about implementation, experience of, and perceived impacts of the MNISA role may differ across different ICBs and trusts.

See Section 7 for recruitment processes.

Topic guides

Topic guides have been developed iteratively from conversations with relevant stakeholders during our scoping phase, to meet the requirements of the evaluation specification document provided by NHS England. We have sought feedback from our PPIE contributors and relevant stakeholders on these topic guides to ensure appropriateness and comprehensiveness.

MNISA interviews will cover the following topics: the interviewees' role and professional background, their views on the reasons for implementing the MNISA service, how it was developed and whether/how it was designed to overcome inequalities, a description of the role (aims/purpose, tasks, caseload, training, governance, reporting), their experience of the role (whether it meets NHSE objectives, training/support, recruitment, sustainability/retention of the role, eligibility criteria, job specification, communication with other MNISAs and organisations), perceived impacts and examples of perceived impacts, barriers and facilitators to delivery, implementation, access and engagement (including timing of support for families), and key learnings. For those MNISAs who are no longer in the role they will also be asked about reasons for leaving the role and any recommendations/changes related to sustainability/retention to the role.

All MNISAs will be asked to complete a brief survey prior to the interview, which will include: their employer, previous experience/background (e.g., whether clinical/non-clinical), training received, number of families working with, length of time in the role, type of contract (e.g., fixed term or zero hours), length of time working with families, whether they think the role is meeting NHS England's objectives and whether they have seen change at individual or organisational levels) (and to provide examples).

The MNISA workshop will cover the following topics: whether the role meets NHSE's intended outcomes, the MNISA job role specification, perceived and actual impacts, influential factors, and the future of the role.

Network level, integrated care board and trust level interviews will cover: the interviewees' role and professional background, their understanding of the MNISA role and how they interact with MNISAs, their experience of the MNISA role (views, whether it meets NHSE intended outcomes, views on the job role specification, how they found working with them), influencing factors (i.e. barriers/facilitators), perceived individual, organisational and system level impacts of the role (with examples), and learnings.

Data collection

For all interviews (MNISA, wider network, ICB and trust level staff), researchers (NC/HW/RL) will identify relevant organisations, teams and job roles that are relevant to the MNISA role and email a point of contact for these organisations, teams and job roles to ask them to share details of the study recruitment with relevant members of their teams. Additionally, staff may cascade details of the study with other staff members who they think may be eligible/interested. Interested individuals will be asked to contact the researchers to express interest in taking part. Researchers will then provide information sheet and consent forms. Potential interviewees will be informed that taking part is voluntary. If interviewees are interested in taking part, they will be asked to provide electronic, written or audio-recorded verbal informed consent prior to taking part in the interview. The interviews will take place either online, or over the telephone. Each interview will last between 30-60 minutes, will be semi-structured, audio-recorded on an encrypted Dictaphone (subject to consent), transcribed verbatim by a professional transcription service, anonymised and kept in compliance with the General Data Protection regulation (GDPR 2018) and Data Protection Act (2018). Interviews will be scheduled to take place during regular working hours, as staff are not being compensated for their study participation. If interviewees would like to provide further information following the interview, they can send further feedback in writing, or researchers will arrange a short follow-up interview. Participants will be informed that they are free to withdraw up to two weeks after the date of their interview.

For the workshop (MNISAs), researchers will email all MNISAs to check if they would be happy to take part in a workshop for the study. MNISAs will be sent an information sheet and consent form in advance and asked to provide electronic or written consent ahead of the workshop. The workshop will take place in person during a regularly held MNISA meeting in January 2025. The workshop will last between 90 minutes and 2 hours. Researchers will take detailed notes during the workshop to capture key findings. Workshop group discussions will be audio-recorded on an encrypted Dictaphone (subject to consent), transcribed verbatim by a professional transcription service, anonymised and kept in compliance with the General Data Protection regulation (GDPR 2018) and Data Protection Act (2018). Participants will be informed that whilst they can withdraw from the discussion, any data provided up until that point will be retained as it would not be possible to remove individual data from a group discussion.

Data analysis

We will undertake the same analysis approach used in workstream 1. See Workstream 1 for details.

We will aim to undertake cross-case comparisons across the different ICBs. Findings will be discussed with the project PPIE contributors (CM/RM/SF), advisory group and wider team prior to finalising.

Workstream 4. Impact and cost

This workstream will be led by CSJ with contributions from other RSET team members.

Aims

Enhancing maternity services with the MNISA role demands significant resource investment, encompassing the expenses for health professionals and training providers. Provision of MNISA services might also lead to changes in health and social care services utilisation, including referral rates. This may lead to an increase in some service costs in the short term, but it may also enhance the health and well-being of family members immediately, as well as in the medium and long term. Assessing the impact relative to the cost of these roles is crucial in order to allocate health and social care resources in a way that meets families' needs. This workstream aims:

1) To qualitatively explore what impact the MNISA role has had on individuals (families, staff), organisations and system level change *(including views on safety and quality improvement)*.

2) To review the current operation of MNISA's and variations between ICBs and trusts in caseload, case type etc.

3) To explore the use of existing data to:
   a) Assess inequalities among the population receiving support.
   b) Review actual workload in comparison to potential workload,
   c) Assess the workload implications of a wider range of adverse outcomes,

4) To evaluate the costs and quantified (where possible) short-term consequences of the MNISA programme, and the potential short- and long-term effects on costs and consequences of programme rollout or expansion of the MNISA role.

5) Make recommendations about data capture and analysis for future evaluation of the impact on parents or families receiving support and on system change.

Design

This workstream will include analysis of existing observational data (aims 2, 3, 4), national electronic health records (aim 3), and findings from qualitative interviews and workshops (see WS1-3; aims 1, 4, 5).

Sample

All cases supported by MNISA's that are reported in the bespoke NHSE data collection compared to potential cases reported in hospital records (Hospital Episode Statistics).

Measures

1) Case volumes by ICB and adverse event. Other possible disaggregation by trust, ethnicity, deprivation, referral source and quarter.
2) Case volumes as specified in 1) alongside potential case volumes identified in routine hospital data (HES) and other maternal/neonatal data.
3) Measures of parent/family benefits, as identified through stakeholder interviews and workshop.

Data collection

Potential data sources include:

1) NHSE bespoke MNISA caseload data.
2) Hospital Episode Statistics (HES).
3) Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK. (MBRRACE-UK).
4) Cost data from ICBs
5) Information from qualitative interviews and workshop (see WS1-3)
6) NHS costs data (e.g., PSSRU: Unit costs of health and social care, NHS England: National schedule of NHS costs)
7) Relevant NHSE case litigation data (Potential source: NHS resolution), covering case numbers and aggregate costs (legal representation/pay-outs/other associated costs (including staff hours, and number of staff involved).

Data analysis

1) To qualitatively explore what impact the MNISA role has had on individuals (families, staff), organisations and system level change *(including views on safety and quality improvement)*.

See Workstream 1 analysis section for details.

2) To review the current operation of MNISA's and variations between ICBs and trusts in caseload, case type etc.

Descriptive analysis from the bespoke MNISA caseload data collected by NHSE.

3) To explore the use of existing data to:
    a) Assess inequalities among the population receiving support.
    b) Review actual workload in comparison to potential workload,
    c) Assess the workload implications of a wider range of adverse outcomes,

Analysis of equality of access to support will be estimated using electronic health data. To do this we will compare the case mix of individuals experiencing adverse events from hospital records with data collected by the pilot on individuals who are supported. Regression analysis

will be used to investigate the relationship between patient factors such as ethnicity and support for eligible parents/families.

Identifying differences between actual and potential caseload will be carried out with multivariate analysis, comparing hospital records with data collected by the pilot. We aim for analysis to allow for differences in numbers of adverse events between ICBs.

Analysis of the implications for rolling out the role to cover a wider range of adverse events, we will carry out a similar analysis for each proposed additional event.

4) To evaluate the costs and quantified (where possible) short-term consequences of the MNISA programme, and the potential short- and long-term effects on costs and consequences of programme rollout or expansion of the MNISA role.

Short-term costs, including the average costs of investigation and that of baby/family events, will be estimated using the above-mentioned sources of data (these will inform the resource use, the number and the type of the events, etc.) and unit costs of resources as required by the MNISA in their provision of support (*e.g.*, support and advice service consultations as provided via the Personalised Care and Support Plan) which are publicly available. In depth analysis of the costs, and the potential benefits of the MNISA program will be developed from the logic model developed in workstream 5. From this, an economic model for the current MNISA program will be developed to quantify costs for the current MNISA program, including healthcare costs associated with the adverse outcomes, associated litigation costs (e.g., legal representation and pay-outs) and long-term consequences. Sensitivity analysis will be undertaken to address the expected range of uncertainty.

The model will also be designed to explore the costs and consequence impacts of scenarios for the rollout (in terms of staff numbers, expansion of MNISA role/workload, addressing barriers or inequalities in accessing MNISA support, and the timing of programme expansion) of the MNISA program.

5) Make recommendations about data capture and analysis for future evaluation of the impact on parents or families receiving support and on system change.

These recommendations will derive from assimilating information gathered from interviews and workshops already planned for workstreams 1-3. To this end, appropriate questions will be added to the topic guides that will be developed for these interviews.

Workstream 5. Integration of data collection and findings

This workstream will be led by NC and HW with contributions from other team members.

All workstreams (1-4) will inform each other and are mutually supportive. Data collected and findings will be triangulated throughout. During this workstream, we will aim to develop a logic model of the MNISA service and will develop some recommendations for improving and evaluating the service in future. We will work together through regular full team meetings and regular sharing of findings coming out of each workstream.

4. STUDY SCHEDULE

4.1 Timeline

Study design & develop protocol: April-June 2024
Development of ethics materials and topic guides: April-June 2024
Peer review of protocol: June-July 2024
Protocol review by NIHR: June-July 2024
PPIE review of protocol: June-July 2024
Set up Project Advisory Group: June-July 2024
Ethics approval: July-September 2024
Data collection and analysis begins: October 2024
Data collection ends: April 2025
Data analysis ends: April/May 2025
Write up: May-June 2025
Submission of final report (NHS England): June 2025
Submission of NIHR final report: July 2025
Summative *dissemination: July 2025 onwards*

The study gantt chart is provided in Appendix 1.

5. ELIGIBILITY CRITERIA

5.1 Inclusion criteria

Parents/guardians (received service and did not receive service)

- Individuals who meet the criteria to be supported by the MNISA role during the pilot (including having experienced one of the exclusive adverse outcomes covered by the MNISA role).[62] These adverse outcomes include:
    - Stillbirth (after 24 weeks of pregnancy);
    - Neonatal death;
    - Maternal death;
    - Unexpected or unplanned hysterectomy (within 6 weeks of birth);
    - Women admitted to critical / intensive care;
    - The baby was diagnosed with a brain injury or suspected brain injury, including hypoxic-ischaemic encephalopathy (HIE)
- Individuals who have received support from a MNISA OR individuals who live in the ICB areas covered by the pilot but have not accessed support - for various reasons (e.g., due to being offered but declining support, not being referred to the service, or not being aware of the service).
- Over the age of 18. In this evaluation we are unable to interview participants under the age of 18, as this would not be feasible within the rapid timeframe of this evaluation.
- English speaking or able to participate in an interview with an interpreter.
- Able to provide informed consent.

Documentary analysis

Any documents pertaining to the national or local implementation of the MNISA role.

National stakeholders (interviews)

- Stakeholders that have been involved in the development, implementation and/or evaluation of the MNISA role, from a wide range of perspectives (examples may include: policy, commissioning, third sector organisation, training organisation) or stakeholders involved in maternity and/or neonatal service delivery, policy or reporting.
- Over the age of 18
- English speaking or able to participate in an interview with an interpreter
- Able to provide informed consent

MNISAs (interviews and workshop)

- Individuals currently or previously employed as a MNISA (during the pilot)
- Over the age of 18
- English speaking or able to participate in an interview with an interpreter
- Able to provide informed consent

Wider staff (interviews)

- Individuals employed in a local area covered by the pilot at network level, ICB level (who have implemented the MNISA role), or trust level in the ICB region.
- Had experience of working with or alongside the MNISA, or with families who are receiving support from a MNISA.
- Over the age of 18
- English speaking or able to participate in an interview with an interpreter
- Able to provide informed consent

5.2 Exclusion criteria

- Anyone under the age of 18 (whilst the evaluation would have liked to evaluated experiences of younger parents who may face particular challenges, this was not felt to be possible within the rapid timeframe of this study and the additional ethical considerations that would have been required);
- Anyone who cannot provide informed consent;
- Families who have experienced an adverse outcome that is not covered by the pilot criteria;
- Families who have experienced an adverse outcome but do not live in one of the ICB areas covered in the pilot.

6. RECRUITMENT AND CONSENT

Documentary analysis

To understand the MNISA role and its implementation at national and local levels, we will ask service developers and providers for relevant key documents (such as Equality Impact Assessments, local service plans, job descriptions, communications relating to the role, standard operational procedures).

Initial identification

Parents/guardians (received service and did not receive service) (interviews)

Parents/guardians (those who have received the service and those that have not had access to the service) will be recruited through the following avenues:

- Recruitment via their MNISAs (where applicable) – MNISAs will contact the families that they work with (either during a routine appointment, or in a separate conversation via telephone or email), to ask if they would be interested in taking part in an interview to share their experiences of receiving support from a MNISA. *Note. The MNISAs will know that families meet the eligibility criteria as their job role is to work with those families who are eligible for the MNISA service (as per NHSE criteria). MNISAs will be meeting with those families to provide support as part of their role. Therefore, MNISAs will not need to review any personal information above and beyond their usual professional duty to identify eligible participants. MNISAs will ask interested families to contact the researchers or will pass on contact details to researchers with families explicit consent.*
- To reach a wide range of participants (including families who have not received support from the MNISAs, and families from a range of backgrounds), we will also aim to recruit via advertisements sent out via social media, and relevant third sector or advocacy organisations. Potential organisations have been identified throughout our scoping phase and align with the adverse outcomes specified by NHSE and a wide range of families. Potential organisations will be contacted to ask if they would be willing to circulate an advert for the study, prior to recruitment taking place.

Interested individuals will be asked to email or call the researchers (NC/HW/RL) to indicate that they may like to participate. Or, where participants have been recruited through MNISAs, MNISAs may ask families if they would be happy for them to share their contact details with the researchers. Researchers will ask some basic eligibility questions, prior to sending information sheets and consent forms.

National stakeholders (interviews)

National stakeholders will be recruited by contacting relevant organisations via email and asking them to circulate the opportunity within their team to encourage relevant individuals to participate. The email invitations will emphasise that participation in the study is completely voluntary and that staff are under no pressure to participate. The scoping work conducted prior to the study will inform the purposive selection of national stakeholders.

MNISAs (interviews and workshop)

We will aim to recruit MNISAs to the interviews and workshop via the existing MNISA community of practice (where researchers will aim to present the study), and through relevant NHSE facilitated ICB meetings (specific to the MNISA role) and ICB leads. Following this, MNISAs will be asked to get in touch (via email or telephone call) if they would like to participate. The email invitations will emphasise that participation in the study is completely voluntary and that staff are under no pressure to participate. Researchers will also send an email invitation to all practicing MNISAs, with a request to let us know if they would be interested in participating.

ICB and trust level staff (interviews)

Selection of ICB areas

We will develop a short list of ICBs based on our ICB sampling framework (expressions of interest from ICBs will be initially requested via NHSE facilitated ICB meetings related to the role). Researchers will contact representatives from each ICB to find out whether they would be interested in taking part in our study.

Identification of individual participants

Once ICBs have been identified, potential participants at network level, ICB level and trust level will be identified in one of two ways: 1. We will purposively email organisations and teams representing relevant job roles that we think may have interacted with MNISAs (from our scoping work and initial interviews) to ask if they have interacted with MNISAs, and if so would they be able to circulate the details of the interviews to their team, 2. We will ask the ICBs to circulate a short email advertisement to staff in the ICB and associated trust to ask for expressions of interest from individuals who have worked with the MNISAs or who work with families supported by MNISAs, 3. We will ask relevant organisations to share details of the study with team members, and 4) we will ask staff members to cascade details of the study to other staff (where appropriate). Interested participants will be asked to contact the researchers directly by email. Emails sent to potential participants will emphasise that participation in the study is completely voluntary and that staff are under no pressure to participate.

Informed consent to participate

For all interviews (national stakeholder, MNISAs, ICB and trust level staff, parents/guardians), and the MNISA workshop, potential participants (once identified) will be sent an information sheet and given at least 48 hours to review the information and ask questions about the study or discuss the study with the researchers. If the participant agrees to take part in the study, they will be asked to provide consent via one of the following methods: i) electronic consent (via a secure electronic questionnaire – REDCap), ii) written consent (by signing a physical copy of a consent form) and returning it electronically via email or via post, or iii) audio-recorded verbal consent at the start of an interview.

7. PATIENT AND PUBLIC INVOLVEMENT AND ENGAGEMENT

Patient and public involvement and engagement (PPIE) is central to all our work at NIHR RSET, and we have a comprehensive approach to co-producing research with patients and the public. Our PPIE Co-Lead (RM) and PPIE contributor (SF) have been integral parts of the study team since its inception. Recognising the importance of service users' voices in our study, we recruited two additional individuals to contribute to the study from end-to-end. Roles were advertised via social media and targeted groups with an interest in maternity and/or neonatal services, followed by a thorough application and shortlisting process conducted with PPIE contributors (RM and SF). CM was recruited as our third PPIE contributor. We also recruited a fourth PPIE contributor, but they withdrew shortly after due to personal reasons. Those who were not selected were offered the opportunity to participate in future PPIE activities related to the study. In addition to our project team PPIE input, the study team have also worked closely with the service user representatives on the NHS England Steering Group for the service to gather their input and perspectives on the evaluation.

To date, project PPIE contributors (RM, SF, CM) and NHSE service user representatives have been actively engaged in weekly project team meetings and relevant wider meetings (e.g., attending an in-person full day workshop to discuss the study with stakeholders). PPIE contributors' feedback and suggestions have been consistently recorded in meeting agendas, raising critical questions and proposing significant improvements to the study design.

Changes made to the study protocol and study design following PPIE input and feedback so far, included:

- Mapping out complaint/investigation pathways to understand escalation.
- Making recommendations to NHS England to collect more information for inequalities analysis, including provision of an interpreter, deprivation measures, reported incidents, etc.
- Speaking to a wider range of stakeholders during the scoping phase to better understand the context and perspectives of the broader maternity and neonatal health service context.
- Exploring other sources of data to understand the impact of the MNISA role on system change, e.g., NHS Resolution, HES, PMRT, etc.

A wider PPIE scoping workshop with members of the public was held in July. This workshop included 5 individuals (from different backgrounds) with experiences of adverse outcomes during their maternity or neonatal journey and investigation and complain procedures. The workshop focused on study data collection tools (family topic guides and information sheet) – to ensure that our questions and information provided are appropriate and sensitive. Following this meeting, further changes were made, including adding additional prompts to topic guides and offering a £25 voucher as a thank you to families participating in the interviews. Additionally, we aim to recruit a public representative to the independent advisory group that is currently being established.

Throughout the study, PPIE contributors will continue to attend study meetings, review study documents, and contribute to all aspects of the study (including interpretation of findings, co-authoring articles and accessible summaries, and other dissemination activities). We may also hold additional wider PPIE workshops to discuss findings and dissemination outputs more broadly.

Furthermore, the study team will collaborate with Sands to engage wider and diverse voices. We have also started building networks with other third sector organisations with a focus on maternity and neonatal care such as Bliss, Baby Lifeline, etc., to ensure diverse perspectives and contexts are represented and to disseminate findings effectively.

Our adaptive and flexible PPIE approach enables creative involvement, inclusive opportunities, continuous improvement, and the exploration of new ways of working based on reflection. A budget has been allocated for PPIE activities, following good practices identified by NIHR INVOLVE, ensuring fair compensation and recognising the value of PPIE contributions. We will also regularly discuss the PPIE approach with PPIE contributors to gain feedback about their experiences. PPIE contributors will be supported throughout the study

by the PPIE leads (PLN, RM) and project leads (NC, HW), to ensure that any needs and/or preferences are taken into account.

8. EQUALITY, DIVERSITY AND INCLUSION (EDI)

To ensure that our project thoroughly and comprehensively considers issues of equality, diversity and inclusion (in our research questions, team composition and research approaches), we will apply our NIHR Rapid Service Evaluation Team (RSET) EDI project-specific checklist (see Appendix 2) at three stages during this project: (i) during development of the project evaluation, (ii) during data collection and analysis, and iii) following data collection and analysis. The checklist covers EDI considerations throughout the whole project, including when building the initial team, drawing on published EDI frameworks to consider EDI aspects relevant to the evaluation during the discovery and scoping phases, protocol development, stakeholder engagement, data collection, data analysis, and dissemination.

To date, we have held several broad scoping conversations with lots of stakeholders to identify potential areas of inequality that may exist within this role in relation to the service. For example, scoping conversations and previous research highlighted that some groups of parents are more likely to experience adverse outcomes due to ethnicity and deprivation related characteristics. This highlighted a need for us to ensure that we consider within this evaluation whether the service reaches those groups and how they experience the service.

We have considered research questions relating to equality, diversity and inclusion (e.g., whether/how the service was designed to overcome potential inequalities and inequities, whether the service is accessible, used and inclusive to families from a diverse range of backgrounds, who is accessing the service and how this uptake varies by different backgrounds, differences in barriers/facilitators to engaging with the service). We have taken steps to encourage diverse public voices to participate as PPIE contributors throughout this study. We have also discussed with stakeholders how to best develop a recruitment strategy, data collection materials, data collection and data analysis processes that will enable a wide range of families to participate in this evaluation (see section 12.2 for mitigation strategies relating to recruiting diverse voices).

9. FUNDING

The research costs for the study have been supported by the National Institute for Health and Social Care Research, Health and Social Care Services Delivery Research programme (Ref: NIHR156380).

The study funding will be reviewed by the UCL Research Office and is sufficient to cover the requirements of the study.

10. DATA HANDLING AND MANAGEMENT

The study is compliant with the requirements of General Data Protection Regulation (2016/679) and the Data Protection Act (2018). All researchers and study site staff will comply with the requirements of the General Data Protection Regulation (2016/679) with regards to the collection, storage, processing and disclosure of personal information, and will uphold the Act's core principles. UCL, Nuffield Trust, and University of Cambridge are joint data

controllers and processors; the UCL/UCLH Data Protection Officer is Alex Potts (a.potts@ucl.ac.uk).

10.1 Data management

Data will be managed in line with legal and regulatory requirements, including the General Data Protection Regulation (GDPR) and the Data Protection Act (2018), and necessary research approvals.

UCL, Nuffield Trust, and University of Cambridge are joint data controllers for this study. They will process, store and dispose of all data in accordance with all applicable legal and regulatory requirements, including the General Data Protection Regulation (GDPR) and the Data Protection Act (2018) and any amendments thereto. Data will not be transferred to any party not identified in this protocol and are not to be processed and/or transferred other than in accordance with the participants' consent.

In line with GDPR guidelines on data minimisation, we are only collecting personal data that is relevant and necessary for the purposes of this study.

Impact/cost data

Apart from Hospital Episode Statistics (HES), outcomes and cost-related data will be aggregated and not include patient-identifiable information, however any data used will be saved in a secure environment, with access allowed only to members of this team. Data from external sources will be securely transferred using the Data Transfer portal onto the UCL Data Safe Haven (DSH, a secure electronic environment, certified to ISO27001 information security standard and conforms to the NHS Information Governance Toolkit).

The Nuffield Trust already receive monthly updates of pseudonymised Hospital Episode Statistics (HES), and a data sharing agreement is being drawn up with NHS England which would allow the Nuffield Trust to use this data in all projects within the NIHR RSET portfolio, as required. HES data are held and will be analysed on a secure server based at the Nuffield Trust, which will act as the data processor for these data, with University College London and the Nuffield Trust acting as joint data controllers.

Although HES will be on a different server to other data sets, analyses of these data sets will be possible in isolation of each other. There will also be no common patient identifier that would enable linkage between the different data.

Access to HES will be restricted to quantitative analysts with the Nuffield Trust. Researchers with access to details and transcripts of parents, families and staff interviewed within the evaluation (WS1 and WS2) will not have access to HES and vice versa.

In any aggregated data we receive from external sources, low counts (between 1 and 9) will be suppressed, and the data will be prepared in such a way that low counts would not be deducible.

Whenever we want to use an existing local dataset as individual person records, we will carry out Data Protection Impact Assessments (DPIAs) and set up Data Sharing Agreements (DSAs)

in accordance with the HSCIC Code of Practice on Confidential Information good practice guidance. We will also ensure compliance with the Common Law Duty of Confidentiality and the Anonymisation Code of Practice.

The Nuffield Trust is ISO27001 certified, BSI Certification Number: IS 648454.

With any outputs we will follow standard constraints on disclosure control.

Interview data

Verbal consent, verbal family member interviews and staff interviews (national stakeholders, MNISAs and wider staff) (qualitative data) will be recorded on an encrypted, password-protected digital recorder (only the researcher will know the password). Family member interviews will be conducted by two researchers: one from Sands (JH, BW) and one from RSET (HW/RL/NC). Staff interview data will be collected by qualitative researchers (HW/RL from UCL, NC from Nuffield Trust).

Family member interviews, and staff interviews (national stakeholders, MNISAs and wider staff) consent forms, audio-recordings, and anonymised notes will be securely transferred using the Data Transfer portal onto the UCL Data Safe Haven (DSH, a secure electronic environment, certified to ISO27001 information security standard and conforms to the NHS Information Governance Toolkit). Once transferred onto the UCL DSH, the data will be cleared from the Dictaphone (data will be transferred and cleared at the earliest opportunity). Consent forms received via post will be returned via post to our researchers at UCL and securely transferred onto the UCL DSH. Paper copies of consent forms will be securely destroyed once scanned and uploaded to the UCL DSH. Electronic copies of consent forms received via email will be transferred onto the UCL DSH.

Digital audio-recordings of interviews and the workshop will be sent to a UCL-approved contractor for transcription (TP Transcription Limited). Transcripts will be fully anonymised (names and places) and organised by participant codes. Anonymised transcripts and other relevant data will be stored in a secure folder on UCL DSH to which only the named researchers (HW, NC, RL, JH, BW) have access.

To enable families to provide electronic consent, respond to socio-demographic questions, and/or written interview responses (if preferred), the research team will develop online survey versions of these documents using the platform REDCap. Electronic consent forms, socio-demographic questionnaires and electronic survey links will be sent directly to families via email link (see section 6 for methods of electronic, written and verbal consent). Consent forms, socio-demographic questionnaires, and interview responses received via survey link will be returned directly stored in the UCL Data Safe Haven via REDCap and will only be accessible by the qualitative research team (HW, NC, RL, JH, KM).

Only the named researchers (HW, NC, RL, JH, KM) will have access to participants' personal data (i.e. name and contact details). Quantitative analysts within the research team will not have access to this data. A password protected spreadsheet of interviewees and their contact details will also be held on the UCL DSH. Participant identifier codes will be stored in the UCL DSH and kept separate from study data.

Study documents (anonymised transcripts, written responses, socio-demographic questions etc) will be archived for a minimum of 5 years from the study end, and no longer than 10 years from the study end (in line with UCL policy). Given the sensitivities of interviews with families, researchers will delete audio-recordings from Data Safe Haven once transcripts have been received and checked for accuracy.

11. PEER AND REGULATORY REVIEW

11.1 Peer review

This NIHR RSET protocol has been peer reviewed by at least two reviewers external to UCL in accordance with UCL/UCLH and HRA requirements. We will also ask our Project Advisory Group to review the study protocol.

11.2 Ethics

A protocol and materials for this study were submitted to the UCL/UCLH Joint Research Office (JRO) for sponsorship review and then submitted through the Integrated Research application system (IRAS) for Health Research Authority (HRA) review and approval. The study has received NHS Research Ethics Committee (REC reference: 24/EE/0205) and Health Research Authority (HRA) approval, dated 04/10/2024.

We are aware of the sensitive nature of this research for organisations and individuals. The research team has experience in conducting health and care research on similarly sensitive topics. Additionally, we are collaborating with Sands on this evaluation, and they will be facilitating the interviews with family members; as they have extensive experience of conducting interviews with families who have experienced adverse outcomes.

We will maintain the independence of the research, follow an informed consent process, and maintain the anonymity of participants and organisations. We have summarised ethical considerations and how we have considered these in section 12.1 below.

11.3 Governance

We will set up a project advisory group, which will provide independent advice, governance and feedback on the project at all stages. We will aim for this group to include a wide range of stakeholders, including those within maternity and neonatal organisations (system level, regional level), regulatory bodies, third sector organisations, professional bodies, clinicians, academics and a public and patient involvement contributor with lived experience. We will aim to meet with this group 2-3 times during the project.

The research team will meet weekly to discuss project progress and any matters that arise. In addition, the project leads will report on progress to the RSET Executive Management Group monthly meetings, with a focus on progress, quality assurance, troubleshooting, and emerging learning and potential implications. The study will also be discussed at the RSET Stakeholder Advisory Board, which includes a range of clinician, academic, PPIE, and EDI experts, and meets every 6 months to offer oversight, challenge, and advice.

12. ASSESSMENT AND MANAGEMENT OF RISKS

12.1 Ethical considerations

We are aware of the sensitive nature of the topic. Whilst we are evaluating the MNISA role, we understand that when discussing the role during interviews, participants may tell us about their experiences of an adverse outcome and become emotionally distressed or upset either during or afterwards. We have created a distress protocol, which outlines to researchers exactly what steps must be taken in the event of a participant becoming distressed during the study.

We have developed the topic guides with input from our PPIE panel and Sands to ensure that the questions are sensitively presented. In our information sheets, we state that participants do not have to share their events leading to adverse outcome/s, but we are here to listen if they wish to share their experiences during the interview. We will remind participants of their right to withdraw at any time during the interview, skip past certain questions if needed, pause the interview or take a break, and offer different avenues of participation in the interview (e.g., being interviewed together rather than alone if speaking to a family). We have also developed a more detailed debrief sheet or appropriate signposting, which provides a list of local services, and different organisations that provide support for the specified adverse outcomes. For safeguarding purposes, we will also let participants know that everything they say will remain confidential unless they disclose something which puts themselves or someone else at risk and we have serious concerns for their welfare. In these situations, we will speak with them to let them know that we will need to escalate this (e.g., to emergency services in the event of an emergency). Or, if families are struggling and unsure where to go for help, we will ask for their permission to speak to MNISAs to ask them to speak with the family and/or identify additional local support services they may be able to access. Participants will be informed prior to consent that their participation in the evaluation will not impact any review or care processes and data held will be fully anonymised with the deletion of audio recordings upon receipt of an accurate transcript and identifiable details removed from all transcripts

Within this evaluation, we are collaborating with Sands. Sands supports thousands of families every year, bereaved by the death of their baby. Sands know from hearing about families' experiences over the last 40 years, the devastating and long-lasting impact of this loss on parents and family members. Sands supports research projects aiming to save babies' lives and improve care for bereaved parents. Sands have supported a wide range of research studies to involve bereaved parents in their work in a meaningful and sensitive way, particularly focusing on recruiting and advising on parent involvement in research (PPIE) and recruiting bereaved parents and family members to take part in research as participants. Sands work with research teams and other organisations to ensure that bereaved parents' voices are central to research activity and have significant experience in advising on the appropriate wording of parent-facing materials, developing sensitive recruitment strategies and ensuring data collection processes are tailored to the needs of bereaved parents. Sands often hears from bereaved parents when carrying out its own pieces of work and they have experience of surveying and interviewing parents, as well as carrying out focus groups with bereaved parents and family members. Sands will be integral throughout the whole research project, and particularly bringing their expertise to the evaluation to facilitate interviews with

families. Family members will also be signposted to the Sands helpline, following interviews, where appropriate.

In addition, we are aware that for the research team, some of the content discussed in the interviews may be sensitive and distressing. To help safeguard our team and to communicate effectively and sensitively with families, the whole project team (including named PPIE contributors) will be encouraged to attend publicly available training provided via Sands. We will also check-in regularly with each other following the interviews where we can discuss anything which we may have found distressing and debrief. Regular debriefing for research team members (including named PPIE contributors) will also be held during data analysis and write-up. We have all been made aware of the support services available at our organisation/s. We will also check that debriefing processes and policies are available within transcription services.

Staff and family members may be hesitant to provide any criticism throughout the research. However, the research team conducting the data collection (NIHR RSET and Sands researchers) are independent of those delivering care and service development/oversight, there are no right or wrong answers and information provided by individuals and sites will be anonymised. We will highlight that we want to learn about things that don't work well as well as things that work well, in order to recommend improvements in future.

In the event that during research activities a staff member expresses a wish to 'whistleblow' or 'speak up', they will be asked to refer to their local freedom to speak up or whistleblowing policy, signposted to the National Guardian's Office and will be encouraged to contact their local Freedom to Speak Up Guardian.

If families mention that they would like to raise a complaint about the care that they have received from the trust, they will be signposted to the NHS Patient Advice and Liaison service (PALS) or to the relevant ICB complaints/feedback service if the complaint relates to the MNISA service.

12.2 Risks and mitigation

There are potential risks to the project (see Table 3).

Table 3. Potential risks and mitigation strategies

Workstream	Risk	Impact	Likelihood	Mitigation
All	Delays in obtaining ethical permissions or local permissions	High	Medium	We will work closely with ICBs to identify appropriate individuals who will support local approval once HRA/NHS ethics approval has been obtained.
All	Demand on NHS workforce/non-engagement from sites	High	Medium	At each ICB site, the team will identify a key point of contact regarding participation and will be in regular contact with them. The team will produce detailed, descriptive information sheets to inform potential participants of the importance of the evaluation, why we have asked them to take part, their involvement, and associated risks and benefits. The commitment and ability to take part in this study will also be taken into account when recruiting suitable sites. The research team will seek to minimise the impact of the evaluation on the time/capacity of staff at all levels.
All	Loss of key staff	High	Medium	There is a large project team, in the event of one member leaving there is capacity and resources for this person to be replaced from the wider team or to bring other researchers in.
All	Limited ability to understand impact of role to inform policy decisions (due to early stage of role implementation).	High	Medium	Timing/phase of implementation has been factored into development or research questions and data collection materials and will be considered when sampling ICBs. WS4 will explore data capture and how impact could be quantified to support a full evaluation of the effectiveness and cost of the MNISA program, as well as relevant outcome measures for longer-term assessments of the impact on system change.
1	Difficulties recruiting families to interviews	High	Medium	The service is relatively new and therefore numbers of families accessing the service will vary across ICB areas. Therefore, there is a potential challenge that there may not be sufficient families to recruit the upper limit of 35 families for interview. The diversity of the families accessing the service may also limit the diversity of our interview sample. However, we will work closely with

				MNISAs to advertise taking part in the evaluation to families, and will offer different modes of taking part to suit different needs. We will also advertise more widely via charity routes and third sector organisations to try and access a wide range of participants. We have engaged with third sector organisations during the scoping phase and have performed a mapping exercise of relevant organisations (e.g., across adverse outcomes and different groups/communities) – we will continue to establish links with a range of organisations and groups who may be able to support recruitment of families.
2,3	Difficulties recruiting staff to interviews (national stakeholders, MNISAs, ICB, network and trust staff, national stakeholders)	High	Medium	We will present the study to national stakeholders, MNISAs, ICB leads and at relevant network meetings to ensure they are onboard. Together with the lead, researchers will present the study to staff to ensure that they are happy with the proposed approach. We will work around staff availability (with maximum flexibility) when planning staff interviews. We are offering different ways to get involved depending on the preferences of each member of staff (e.g., telephone or online interviews).
4	Low sample sizes for robust analysis of case mix and inequalities	High	High	We focus on making recommendations for how to assess potential inequalities and case mix in the longer term once sufficient data are available. There may be sufficient data to raise hypotheses for further testing. For qualitative data, further engagement across a wider network of third sector organisations particularly focused towards supporting specific groups/communities.
4	Incomplete data or poor data quality	High	High	If we receive case-level data, we will feedback any concerns we have and try to influence improved data collection.

13. RECORDING AND REPORTING OF EVENTS AND INCIDENTS

All events and incidents (and near misses) that occur to participants and/or staff that are unexpected and directly related to the research study will be reported to the Sponsor via [research-incidents@ucl.ac.uk or UCL REDCAP incident reporting form) and host sites via their Trust reporting systems and documented in the Trial Master File/Investigator Site File via study-specific incident logs (and related correspondence). This will be completed by the CI or PI. The Sponsor will be responsible for investigating, reviewing, or escalating to a serious breach if required.

13.1 Personal data breaches

Personal data breaches will be immediately reported to the UCL Information Security Group (ISG) and the UCL Data Protection Officer Alex Potts (a.potts@ucl.ac.uk) (as per form and guidance: https://www.ucl.ac.uk/legal-services/guidance/reporting-loss-personal-data), and to the Sponsor via the UCL REDCAP incident reporting form (https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo). The following information will be provided: full details as to the nature of the breach, an indication as to the volume of material involved, and the sensitivity of the breach (and any timeframes that apply). Sites will additionally follow their Trust incident reporting mechanisms and will document this within their TMF/ISFs.

13.2 Protocol deviations and notification of protocol violations

Protocol deviations are usually an unintended departure from the expected conduct of the study protocol/SOPs, which does not need to be reported to the Sponsor. The CI will monitor protocol deviations, and if found to frequently recur, will discuss in the first instance with the Sponsor to determine re-classification and reporting requirements.

A protocol violation is a breach which is likely to effect to a significant degree: –
(a) the safety or physical or mental integrity of the participants of the study; or
(b) the scientific value of the study
The CI and Sponsor will be notified immediately of any case where the above definition applies via [UCL: research-incidents@ucl.ac.uk or UCL REDCAP incident reporting form].

13.3 Complaints from research participants

In the first instance, research participant complaints (family members/staff/national stakeholders) will be reported to the CI/PI to investigate, as documented in the patient information sheet(s) (in this study, the term 'patient' refers to families), and to the Sponsor [UCL sponsored: via research-incidents@ucl.ac.uk, following the UCL Complaints from Research Subjects about UCL Sponsored Studies and Trials policy;]; for participants who are NHS patients, complaints will be reported to the NHS Complaints Manager at the Trust where the recruitment and study procedures was undertaken. Complaints from NHS patients are handled under NHS complaints policies and procedures, with involvement from PALS and the Sponsor where necessary.

14. MONITORING AND AUDITING

The Project Leads (NC and HW) will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality.

The Project Leads will inform the Sponsor should he/she have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

Throughout the project, we will work closely with a range of stakeholders (such as NHSE, other academics working in neonatal/maternity services, the MNISA pilot steering group, service user representatives, third sector organisations, ICB leads, regional operational delivery network and LMNS representatives) and also our project advisory group.

Our project advisory group is comprised of representatives/stakeholders with expertise relevant to neonatal and/or maternity care including professional bodies, academics, clinicians, third sector organisations and other relevant organisations. The group will meet 3-4 times over the duration of the evaluation to provide advice and feedback.

We will meet with NHSE programme leads (and selected members of the MNISA program steering group) on a regular basis throughout the duration of the evaluation (with frequency of meetings determined by the stage of the evaluation, however meetings will be held at least monthly) to understand how the pilot is progressing and to discuss any issues relating to the evaluation. The research team will also attend MNISA program steering group meetings, ICB network and MNISA peer network meetings to ensure that all stakeholders are kept up to date with the progress of the evaluation.

The research team will meet weekly throughout the duration of the evaluation. The evaluation will be discussed as a standing item at monthly NIHR RSET meetings, in terms of progress against project milestones (see timeline and Gantt chart) and to address any practical or methodological issues.

To ensure that all researchers involved in data collection and analysis are supported throughout this project, we will ensure that time is built in for reflection, debrief and discussions after data collection.

15. TRAINING

The Project Leads (NC/HW) together with the chief investigator of NIHR RSET (NJF) will review and provide assurances of the training and experience of all staff working on this study. Members of our team will attend relevant Sands training on working with those who have experienced pregnancy and baby loss.

16. INTELLECTUAL PROPERTY

All intellectual property rights and know-how in the protocol and in the results arising directly from the study but excluding all improvements thereto or clinical procedures developed or used by each participating site, shall belong to UCL. Each participating site agrees that by giving approval to conduct the study at its respective site, it is also agreeing to effectively

assign all such intellectual property rights ("IPR") to UCL and to disclose all such know-how to UCL. with the understanding that they may use know-know gained during the study in clinical services and teaching to the extent that such use does not result in disclosure of UCL confidential information or infringement of UCLIPR.

17. INDEMNITY ARRANGEMENTS

University College London as the sponsor of the study holds insurance against claims from participants for harm caused by their participation in this study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

18. ARCHIVING

The NIHR RSET team (UCL, Nuffield Trust, and University of Cambridge), and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The Project Leads (NC and HW) confirms that they will archive the study master file at UCL for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. The Principal Investigator at each participating site agrees to archive his/her respective site's study documents in line with all relevant legal and statutory requirements. Study documents (anonymised transcripts, written responses, socio-demographic questions etc) will be archived for a minimum of 5 years from the study end, and no longer than 10 years from the study end. Given the sensitivities of interviews with families, researchers will delete audio-recordings from Data Safe Haven once transcripts have been received and checked for accuracy.

19. PUBLICATION AND DISSEMINATION

We aim to present findings at relevant conferences and publish findings in peer reviewed journals. We will submit a final report to the National Institute for Health and Care Research, Health Services and Delivery Research Programme (NIHR HS&DR).

We will also share feedback regularly with key stakeholders on the progress of the study, emerging findings and recommendations/lessons learned. In addition, we will plan a range of dissemination methods to reach different audiences, including the public. These will be developed with input from the Nuffield Trust communications team and discussions with stakeholders. Findings will be shared with key audiences including families, clinicians (and others involved with the delivery of neonatal and/or maternity services), commissioners, policymakers, academics, relevant organisations. Examples of potential outputs include: peer reviewed journal articles, slide packs and other appropriate non-expert forms of dissemination (i.e. videos and blogs).

Findings from the study will be used to develop recommendations and to inform whether and how the MNISA role may be used in future. However, we acknowledge that the available evidence arising from this evaluation will not include thorough effectiveness and cost

findings, due to the timing of the evaluation and the early stage of implementation at which it will take place.

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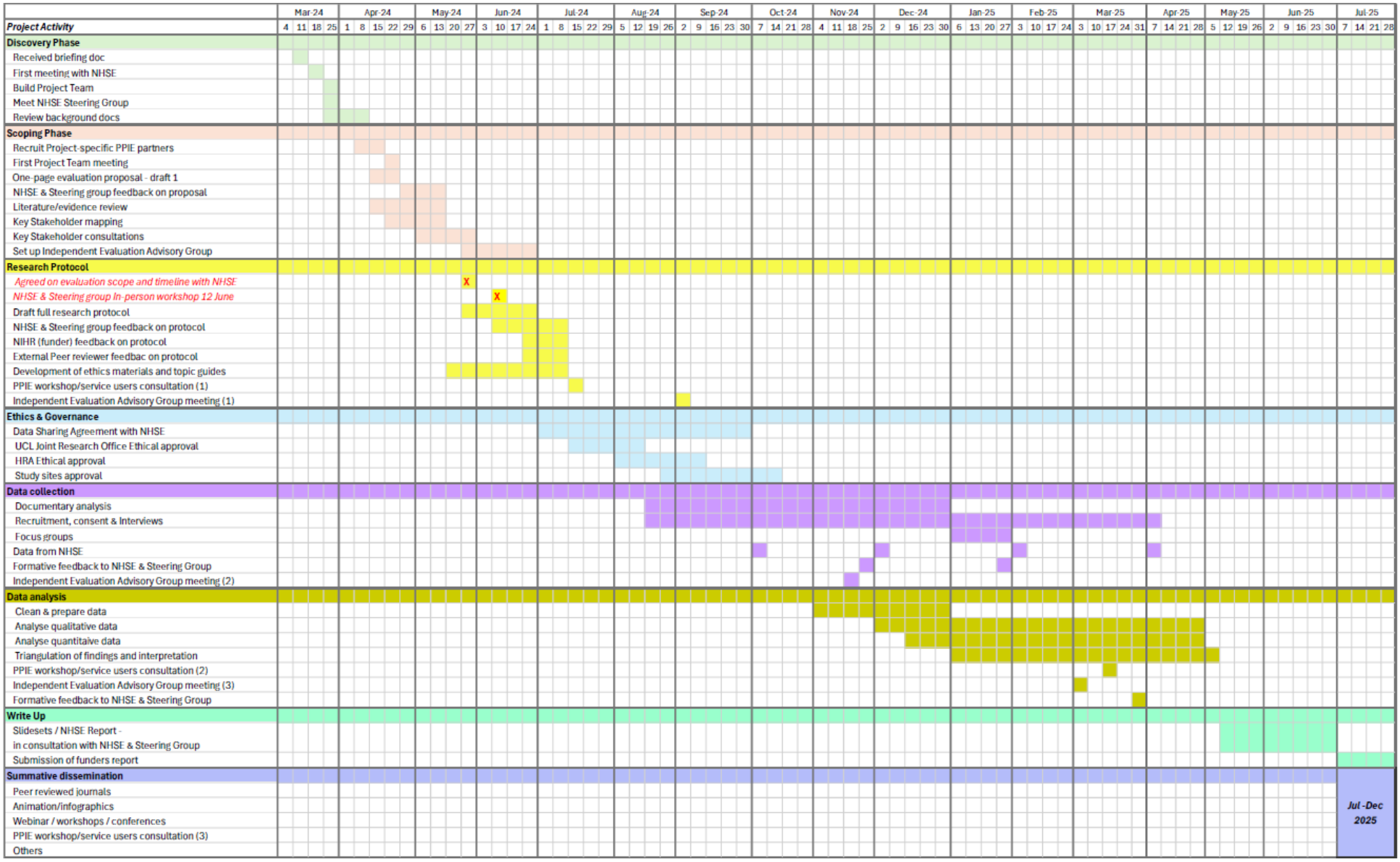
21. APPENDICES

Appendix 1. Gantt chart



Appendix 2. EDI checklist template that we will use to monitor progress on this evaluation

RSET 2 – Project specific EDI checklist

Stage of project (linked to flow chart)	**Activity**	**Done?**	**Notes on how this was considered within this project, and decisions made. If activity not considered, please briefly add details on why this was not possible in this particular evaluation.**
Building initial team	1. Ensure evaluation teams include a diverse range of team members *[e.g., gender, age, ethnicity, seniority and other characteristics*]	Yes/No/Not applicable	
	2. Ensure project steering groups include a diverse range of evidence users and healthcare professionals *[e.g., gender, age, ethnicity, seniority, role and other characteristics]*	Yes/No/Not applicable	
	3. Ensure project PPIE panel includes a diverse range of patients/carers. *[e.g., gender, age, ethnicity, experience and other characteristics]*	Yes/No/Not applicable	
Discovery and scoping	4. Consult with **PPIE group** and **evidence users** (through scoping discussions) to understand EDI implications of both the intervention and our evaluation.	Yes/No/Not applicable	
	5. During scoping conversations, the way in which PPIE members and evidence users are consulted should be adapted appropriately for each audience. *For example, it may be necessary to provide information in alternative formats other than standard text if people need or prefer that.*	Yes/No/Not applicable	
	6. Use EDI published frameworks (e.g., Health Inequalities Assessment Tool;[71] INCLUDE framework;[72] toolkit for increasing participation of Black, Asian and Minority Ethnic (BAME) groups in health and social care research).[73] *These frameworks will help ensure that our projects are designed to be inclusive and address appropriate questions (e.g., considering underserved groups and wider protected*	Yes/No/Not applicable	

	characteristics, barriers to inclusion and steps to overcome barriers).		
Protocol drafting and stakeholder engagement	7. Discuss project with **project PPIE group and project advisory group** and ensure projects address EDI issues, including: a. Whether and how different communities were involved in planning, b. Whether and how research approaches accommodate and measure potential impact on EDI considerations, c. Evaluating the intervention's impact on access, patient experience, engagement, and outcomes across different communities) d. work with stakeholders to reflect on progress of the work and ensure our findings address implications for EDI.	Yes/No/Not applicable	
Protocol drafting and data collection – **focus**	8. Develop research questions that address any issues of inequalities, inequities and disparities, as appropriate.	Yes/No/Not applicable	
	9. Identify how any relevant quantitative data reflects population diversity.	Yes/No/Not applicable	
Protocol drafting & data collection – **site recruitment**	10. Select study sites to represent a range of characteristics wherever possible (including geography, ethnicity, rurality, socioeconomic status).	Yes/No/Not applicable	
Protocol drafting & data collection –**participant recruitment**	11. Plan to recruit samples of patients, carers and staff that include a range of participants of different ages, gender, ethnicities, living circumstances, educational qualifications, work situations, and disability.	Yes/No/Not applicable	

	12. Where possible, compare our study sample characteristics to national or local populations accessing and delivering services (e.g., see[74])	Yes/No/Not applicable	
	13. To support recruitment of a range of participants, consider the following strategies and other strategies as necessary (depending on appropriateness for each evaluation and conversations with stakeholders and PPIE panel): a. Translating research materials into a range of languages or different formats where appropriate, e.g., braille, or British sign language b. Community outreach to recruit participants (e.g., through patient and staff organisations) c. Offer different modes of data collection (e.g., in person, telephone or online for interviews/focus groups/observations and online or paper surveys), d. Offer different options for participation (e.g., participant only, participant and carer, or carer only interviews) e. Offer translation services to facilitate interviews. f. Ensuring participants have reasonable access to participating in the study	Yes/No/Not applicable	

	It may be helpful to look at the NIHR's definition of underserved communities when thinking about how best to recruit different groups		
Protocol drafting & analysis - analysis	14. Use frameworks to support equity-focused analysis where appropriate (e.g., EquIR).[75]	Yes/No/Not applicable	
	15. If available, analyse data to identify differences in service use and outcomes across different population groups	Yes/No/Not applicable	
	16. Work with stakeholders **(project advisory group and PPIE)** to reflect on progress of the work and ensure our findings address implications for EDI	Yes/No/Not applicable	
Protocol drafting & Dissemination	17. Work with stakeholders **(project advisory group and PPIE)** to develop and agree a dissemination and mobilisation strategy that supports sharing findings with all relevant audiences (including diverse and underserved communities).	Yes/No/Not applicable	
	18. Work closely with stakeholders **(PPIE panel, and project advisory group)** to share findings (e.g., as co-authors and co-presenters).	Yes/No/Not applicable	
	19. If quantitative analyses of differences between population groups has not been possible, make recommendations about how to enable this for future evaluations.	Yes/No/Not applicable	
Note: Throughout all our activities, we will be facilitated by guidance on effective EDI. [e.g., National Institute for Health and Care Research. Equality, Diversity and Inclusion Toolkit 2022. Retrieved 09/12/2022 from https://www.rdsresources.org.uk/edi-toolkit] / NIHR EDI strategy (2022-2027) *https://www.nihr.ac.uk/documents/equality-diversity-and-inclusion-strategy-2022-2027/31295*			