

The Core Study - Exploring the implementation of maternity and neonatal multi-professional training in England

Submission date 08/11/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/11/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/07/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This project seeks to evaluate an NHS England initiative to improve the organisation and delivery of staff training in maternity and neonatal services. There is widespread concern about the quality and safety of maternity and neonatal services in England. There are worrying inequalities in outcomes. Reports repeatedly indicate the crucial role of skilful and knowledgeable staff, working well together. Yet it is known that training is not always prioritised within busy maternity and neonatal services and that there is variability in such training. To address this, NHS England launched a 'Core Competency Framework' (December 2020) to support the organisation of effective training for all maternity and neonatal staff. The Framework includes suggested training modules. The second version of the Framework (December 2023) built on this, with a training needs analysis tool that calculates the number of days of training each staff group should receive and a 'how to' guide. It also highlighted key 'best practice' principles: service user involvement; learning from local feedback/incidents/good practice; multidisciplinary team learning; and shared learning across Local Maternity and Neonatal Systems. The Framework is intended to drive improvement in maternity and neonatal care, but its impact is currently not known. Although some basic measures are now monitored (e.g. number of staff attending training), there is no built-in evaluation. This means there is no national-level insight into how the Framework is delivered, and its impact on organisational, team and individual skills and knowledge. Nor its impact on the quality of care and outcomes, particularly for those most at risk of poor outcomes. This project aims to fill that gap by exploring the implementation, operation and impact of the Framework. There is widespread support for this study amongst service user representatives. An advisory group, local service user panels and local and national Forums built into our evaluation design will create spaces in which service user questions and concerns can be heard. Stakeholder perspectives will be gathered through three linked pieces of work (Work Packages (WP)).

Who can participate?

The study will invite staff from across all 121 maternity and neonatal units in England, who take a lead on the CCF in their NHS Trust to complete an online survey about the way the CCF is implemented in their organisation. Part of this study will be based in six NHS Trusts across

England that will remain anonymous. Maternity or neonatal staff, and service users representatives, who are responsible for the planning or delivery of the CCF, from the NHS Trusts, will participate in interviews, observations, and a meeting to learn about, and feedback on, their local data. Service users who gave birth at each of the six NHS Trusts to take part in small group discussions or interviews will also be invited.

What does the study involve?

A national survey will be conducted to gather views about the Framework's implementation across England's maternity and neonatal units. The study will undertake ethnographic research to explore in detail implementation at six selected sites; this will also include local service user focus groups drawn from groups most at risk of poor outcomes. Joint interpretive forums will be held at the local and national level, which will help to make sense of the data and feed into the development of a logic model and implementation toolkit for NHS England, to support the next version of the CCF (December 2026). A short animation will be created offering service user perspectives on maternity and neonatal staff training, to increase NHS engagement with this initiative. The project team has worked with NHS England, and their service user group, on the study design; NHS England supports our planned evaluation. Findings and an implementation toolkit will be shared at regional and national conferences and publish at least two high-impact academic papers.

What are the possible benefits and risks of participating?

There are no direct benefits to those participating, but it is hoped their input will help improve multi-professional maternity and neonatal training in future. Reflecting on issues relating to maternity and neonatal care can sometimes prove challenging for women and members of staff alike. In group discussions or interviews, the team researchers, who are experienced in handling conversations of a sensitive nature, will ensure that participants have opportunities to pause, stop, re-schedule, or withdraw from the group discussion or interview. Systems are in place to ensure participants receive confidential support.

Where is the study run from?

The study is run by researchers based at King's College London and will be conducted across six NHS Trusts in England.

When is the study starting and how long is it expected to run for?

The study started in September 2024 and will run until June 2026

Who is funding the main study?

The study is a Health and Social Care Delivery Research Programme funded by the National Institute for Health and Care Research.

Who is the main contact?

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Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

337557

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

NIHR159486

Study information

Scientific Title

Improving maternity and neonatal care in England: a formative evaluation of the implementation of the Core Competency Framework to improve multi-professional practice

Acronym

The Core Study

Study objectives

To explore and enhance the implementation and impact of the Core Competency Framework (CCF) in England as it seeks to reduce variation in maternity and neonatal care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 06/02/2025, HRA North West - Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8290; gmeast.rec@hra.nhs.uk), ref: 24/NW/0384

Study design

Multi-site mixed methods observational study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Multi-professional maternity and neonatal training

Interventions

A mixed-methods national online survey will be distributed on two occasions (around one year apart) among all maternity and neonatal units in England.

An ethnographic study will be conducted in six NHS Trusts in England, comprising (1) interviews with NHS staff and service user representatives involved in the planning and delivery of the Core Competency Framework (CCF), (2) non-participant observations of staff interactions relating to training, the collection of training-related documentary evidence from each participating NHS Trust, (3) group discussions or interviews with local service users, and (4) a local joint interpretive forum meeting that is offered to each participating NHS Trust at which local data is presented and the opportunity given to reflect on this data. An animation representing data from service user interviews will be developed.

Finally, a national joint interpretative forum meeting will be held to present synthesised study findings and explore how best to align a future version of the CCF with national policies and strategies relating to improving CCF implementation and maternity care provision.

Intervention Type

Other

Primary outcome(s)

This is an observational study based predominantly on qualitative data to evaluate the implementation of the Core Competency Framework (CCF). Implementation will be assessed in the following ways:

1. The adoption, adaption and implementation across time, of the CCF in maternity and neonatal units in England is measured using a survey based on the TIDIER checklist and a NoMAD survey at baseline and one year
2. Staff attitudes and opinions about the CCF among the Multi-professional Education Training (MET) team and senior maternity and neonatal leaders, and its implementation in their organisation are measured using semi-structured interviews at various undefined timepoints from baseline to one year
3. Ethnographic observations of the implementation of staff training and associated training-related activities at various undefined timepoints from baseline to one year
4. Service users' perceptions and experiences of competent maternity and neonatal care that they trust and in which they have confidence are measured using semi-structured interviews at various undefined timepoints from baseline to month seven

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

30/06/2026

Eligibility

Key inclusion criteria

1. Maternity and neonatal unit organisational lead for the Core Competency Framework (CCF) v2

Participation in semi-structured interviews:

1. Take a lead role in, or support the delivery of multi-professional safety and training at one of the participating NHS Trusts
2. Are the local MNVP chair or other service users involved in training, governance lead head of service, or the local LMNS representative involved in supporting delivery of the CCF, and give consent to be interviewed

Participation in local joint interpretive forums:

1. Staff members from each of the six study sites in the MET team, senior maternity and neonatal managers, LMNS and MNVP representatives and others with a lead role in training and quality improvement

Service users:

1. Aged 18 years old and over
2. Gave birth in the past year in one of the six participating NHS Hospital Trusts
3. Willing to participate and give consent to do so

Participant type(s)

Health professional, Service user

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Does not meet the pParticipant inclusion criteria

Date of first enrolment

01/06/2025

Date of final enrolment

30/06/2026

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre
King's College London - Administrative site
James Clark Maxwell Building
57 Waterloo Road
London
United Kingdom
SE1 8WA

Sponsor information

Organisation
King's College London

ROR
<https://ror.org/0220mzb33>

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be stored in a publicly available repository (King's Open Research Data System <https://kcl.figshare.com/>) for 10 years after the end of the study. The datasets will be fully anonymised and consent will have been gained from participants for their data to be made available in this way.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes