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

Submission date 08/11/2024	<b>Recruitment status</b> Recruiting	[X] Prospectively registered [_] Protocol
<b>Registration date</b> 12/11/2024	<b>Overall study status</b> Ongoing	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 02/07/2025	<b>Condition category</b> Other	<ul><li>Individual participant data</li><li>[X] Record updated in last year</li></ul>

# 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? Dr Rebecca Whybrow, rebecca.whybrow@kcl.ac.uk

## Study website

https://www.kcl.ac.uk/research/core-study

# **Contact information**

**Type(s)** Public, Scientific, Principal Investigator **Contact name** Dr Rebecca Whybrow

### **Contact details**

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# Additional identifiers

EudraCT/CTIS number Nil known

**IRAS number** 337557

**ClinicalTrials.gov number** Nil known

Secondary identifying numbers 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

Secondary study design Longitudinal study

**Study setting(s)** Hospital

**Study type(s)** Other

# Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

# 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 measure

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

 Ethnographic observations of the implementation of staff training and associated trainingrelated activities at various undefined timepoints from baseline to one year
 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

### Secondary outcome measures

There are no secondary outcome measures

Overall study start date 01/09/2024

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

**Age group** Adult

**Lower age limit** 18 Years

**Sex** Both

Target number of participants

**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** England

United Kingdom

**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

**Sponsor details** Room 8.11, 8th Floor Melbourne House, 44-46 Aldwych London England United Kingdom WC2B 4LL +44 (0)207 848 7306 vpri@kcl.ac.uk

**Sponsor type** University/education

Website https://www.kcl.ac.uk/

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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**

**Publication and dissemination plan** Planned publication in several high-impact peer-reviewed journals.

Intention to publish date

30/04/2027

#### 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 thei data to be made available in this way.

#### IPD sharing plan summary

Stored in publicly available repository