REVAL
NIHR Rapid Service Evaluation Team

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Evaluation of the enhanced model of midwifery continuity of carer

Protocol

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Contents

Evaluation summary

Title	**Rapid evaluation of the enhanced model of midwifery continuity of carer**
Background	Midwifery Continuity of Carer (MCoC) aims to provide personalised and safe care to women and their families via provision of the same midwife, supported by a small team of midwives, throughout pregnancy, birth and the post-partum period. NHS England is funding an enhanced MCoC model of care that aims to provide extra support to women and their families in the most deprived areas of England. Funding for enhanced MCoC has been allocated to 58 midwifery teams in 2022/23 with continued funding in 2023/24 (financial year). Funding is to be used, by these teams, to provide "holistic support that reduces midwives' workload and releases additional time for the midwives to care for women" (NHS 2021).
Aims	Our overall aim is to undertake a rapid formative evaluation of enhanced MCoC implementation. We will generate rapid insights into the format of care delivery and the experiences of those delivering and receiving enhanced MCoC to assess its early impacts. *Research questions* 1. Where are teams implementing the enhanced MCoC and are they focused on families in the highest decile of deprivation? 2. What are enhanced MCoC service delivery models and how have these been developed in response to service model guidance and related policies, existing MCoC services, high priority issues and specific local needs? 3. What are the barriers and facilitators to the implementation of enhanced MCoC models of care from a staff perspective and can fidelity to the model envisaged be maintained? 4. What are staff views on the acceptability of the enhanced elements of MCoC models and their experience of these, including how staff interface with other health and social care teams? 5. What evidence is there that delivery of enhanced MCoC is resulting in purposeful improvement to care delivery or leading to unintended consequences, including any early benefits or risk as judged by staff. 6. What factors are perceived to be linked to impacts of enhanced MCoC? 7. What are service user views on the acceptability of the enhanced elements of MCoC models and their experience of these? 8. What are the key theories of change, and themes within this, that are shaping current enhanced maternity continuity of carer service delivery models? 9. What may form the scope and design of a summative, longitudinal evaluation?
Design	Multi-site, multiple methodologies study. Interviews with staff, stakeholders and service users who are delivering or in receipt of the enhanced MCoC model, across nine case study sites.
Sample	The case site selection process may iterate based on information collected during the early stages of the evaluation, but we anticipate employing a maximum

	variation design to ensure meaningful variation in service types. Currently, based on scoping work, we anticipate case study sites being sampled to provide variation, where possible, in: geography; service model; previous experience in implementation of enhanced maternity services for disadvantaged and underserved groups; and local demography.
Timelines	Mapping of enhanced models and identification of case sites March 2023 to May 2023 In-depth exploration of the implementation and delivery of the enhanced model until end May 2024. Final report due 14th August 2024
Funding	This research is an independent evaluation undertaken by the NIHR Rapid Service Evaluation Team (REVAL). REVAL is funded via a competitive review process by the NIHR Health Services and Care Delivery Research Programme (NIHR151666). The views expressed in this protocol are those of the author(s) and not necessarily those of the NIHR, NHS England or the Department of Health and Social Care.

Evaluation context

UK inequalities in maternal and neonatal outcomes

There is recognised, concerning and recalcitrant inequity in maternal and neonatal outcomes in the UK. Birth data from England, Scotland and Wales (April 1 2015 to 31 March 2017) show the incidence of pre-term birth, admission to neonatal units, and stillbirth were higher for babies born to people from ethnic minority backgrounds and for those who lived in deprived areas (Jardine 2021). Whilst UK neonatal mortality is, on average, decreasing, 2019 data shows the risk of stillbirth and perinatal mortality remains disproportionately high for babies born to women living in the most deprived areas (MBRRACE-UK 2021).

UK data spanning 2016 to 2020 show that stillbirth rates for women in the most deprived quintile, geographically, were 1.9 times higher than rates for women from the least deprived quintile (MBRRACE-UK 2022). Perinatal mortality risk was also higher for babies of Black and Asian ethnic minority backgrounds relative to babies of White ethnicity (MBRRACE-UK 2021). From an intersectional perspective, these risks are cumulative such that there is an increased risk of perinatal mortality in babies from ethnic minority backgrounds who are also from deprived areas.

There are also on-going inequalities in UK maternal outcomes during and following pregnancy. UK data from 2018 to 2020 shows women of Black ethnicity were 3.7 times more likely to die during pregnancy or in the six weeks after the end of pregnancy compared with women of White ethnicity. Women of Asian ethnic backgrounds were 1.8 times more likely to die during pregnancy or in the six weeks after the end of pregnancy than women of White ethnicity (MBRRACE-UK 2022). Also reported is a widening gap in maternal mortality, observed over time, for women from ethic minority backgrounds, relative to women of White ethnicity (Knight 2020). Recognition of these inequalities alongside service-wide failings in NHS maternity care – such as those in Morecambe Bay (Kirkup 2015) – has catalysed NHS investment in improvement activities for maternal and neonatal care.

Policy context

The National Maternity Review *Better Births* report (NHS England 2016) outlines a vision for improved NHS maternity services. This was echoed in the Department of Health's Maternity Action Plan (2016) and follow-up report *Safer Maternity Care – Next steps towards the national maternity ambition* (Department of Health 2017). To deliver this vision, NHS England implemented a wide ranging maternity transformation process. This process, amongst its many ambitions, aims to improve equity and equality in maternal and neonatal care, via a range of policy initiatives and planned changes to service delivery. On-going focus on maternity services is reflected in further, wider, key policy documents including the NHS Improvement's health inequalities action plan and Core20PLUS5, echoing the link between withstanding inequalities and maternity and neonatal care.

Midwifery continuity of carer

One aspect of the maternity transformation process is a focus on the midwifery continuity of carer model (MCoC). This service delivery model aims to provides consistent, personalised and safe care to women and their families via management from the same midwife (supported by a small team of midwives) throughout pregnancy, birth and the post-partum period. In the UK, inequalities in maternal and neonatal outcomes are likely preceded by inequalities in access to midwifery care by

people from lower socio-economic areas and ethnic minority groups (Raymont Jones et al 2023). As such, the rationale underpinning the MCoC model aligns with reducing inequities in service delivery and health outcomes through a focus on issues including barriers to care, and wider social inequalities. (Raymont Jones et al 2015, Raymont Jones et al 2020, Hadebe et al 2021).

Enhanced midwifery continuity of carer

NHS England is currently funding an enhanced MCoC model of care that builds on the standard MCoC model. Enhanced MCoC aims to provide extra support to women and their families in the most deprived areas of England. This support is given via additional funding to local maternity systems (LMS) based on numbers of women living in the most deprived 10% of neighbourhoods. Currently, funding for enhanced MCoC has been allocated to 58 community-midwifery teams within 23 LMSs in 2022/23. Funding is to be used by midwifery MCoC teams to provide "holistic support that reduces midwives' workload and releases additional time for the midwives to care for women" (NHS 2021). The funding can support an additional band 4 NHS maternity support worker, e.g. for interpretation or breastfeeding support, link workers or administrative staff. Other use of funding, including working with local third-sector organisations, is also possible.

The rationale for the enhanced MCoC approach reflects insights from evaluations of standard MCoC models that women living in more deprived areas receiving MCoC may benefit from improved access to and engagement with maternity services, relational continuity with midwives, and wider services situated near to where women live. The enhanced model funding may increase capacity and options to support access to continuity of care, specific elements of care and/or increase access to additional holistic support. Change may then be mediated via relationship building, utilisation of local resources, interpreter services, access to antenatal education and wider practical support (Raymont Jones 2019).

Implementation of the enhanced MCoC model links to NHS England Equity and Equality guidance for LMS (NHS England 2021b). The guidance has two key improvement aims relating to equity and equality for mothers and their babies and NHS staff, these are:

- equity for mothers and babies from Black, Asian and mixed ethnic groups and those living in the most deprived areas; and
- race equality for staff.

Guidance includes a focus on accelerating preventative programmes that engage those at greatest risk of poor health outcomes. Enhanced MCoC models, alongside traditional continuity of care, are identified as a key intervention within the guidance to address the causes of addressing perinatal mortality and morbidity outcomes for Black, Asian and Mixed ethnic groups and born to women living in the most deprived areas, where LMS may consider other protected characteristics and inclusion groups. Smoking-cessation, increased rates of breastfeeding and culturally sensitive support are also identified as key to addressing perinatal mortality and morbidity for babies from these groups.

Proposed evaluation

The NIHR-funded Greater Manchester Rapid Service Evaluation Team (REVAL) has been asked to design and conduct a rapid evaluation into delivery of the enhanced MCoC model. We propose a rapid formative evaluation that can inform on-going learning and decision-making for NHSE, and can serve as a basis for future longitudinal evaluation.

The formative evaluation aims to explore how the enhanced model of MCoC is being implemented. We will consider how local contextual issues impact on service implementation and on the acceptability, experience and sustainablity of the service, from the persective of service users and staff. As formal enhanced MCoC activity is set to start for most teams early in the evaluation period, it is unlikely we can explore changes in longer-term clinical outcomes, however we will seek to explore how the model may lead to improved clinical outcomes through the development of a theory of change. We will use learning from the formative evaluation to consider what a future longitudinal evaluation could involve.

Our overarching evaluation questions are as follows:

- Where are teams implementing the enhanced MCoC and are they focused on families in the bottom decile of deprivation?

- What are enhanced MCoC service delivery models and how have these been developed in response to service model guidance and related policies, existing MCoC services, high priority issues and specific local needs?

- What are the barriers and facilitators to the implementation of enhanced MCoC models of care from a staff perspective and can fidelity to the model envisaged be maintained?

- What are staff views on the acceptability of the enhanced elements of MCoC models and their experience of these, including how staff interface with other clinical and social care teams?

- What evidence is there that delivery of enhanced MCoC is resulting in purposeful improvement to care delivery or leading to unintended consequences, including any early benefits or risk as judged by staff?

- What factors are perceived to be linked to impacts of enhanced MCoC?

- What are service users' views on the acceptability of the enhanced elements of MCoC models and their experience of these?

- What are the key theories of change and themes within this that are shaping current enhanced maternity continuity of carer service delivery models?

- What may form the scope and design of a summative, longitudinal evaluation?

These questions will be explored via three consecutive workstreams and a fourth workstream that spans the evaluation period:

- Workstream 1: mapping current enhanced MCoC service delivery models;
- Workstream 2: staff insights into the delivery and impact of enhanced MCoC;
- Workstream 3: service user insights into enhanced MCoC models of care; and
- Workstream 4: Exploring enhanced MCoC access and informing the design of a future evaluation.

Links with other evaluations

We are aware of, and in contact with, other evaluation teams commissioned to undertake MCoC-related research. We have mapped concurrent evaluations and aimed to maximise complementarity. This awareness of related activities will be maintained through-out this enhanced MCoC-focused evaluation. We will ensure any synergies are capitalised on and work is not duplicated.

Evaluation structure and use of theoretical frameworks

All work will be guided by the Health Disparities Framework (Kilbourne et al 2006). We will draw on the key proponents of this Framework: detection of health disparities (including definition and defining relevant populations); understanding the determinants of health disparities; and intervention to reduce health disparities and evaluation of these. This framework recognises that the determinants of health inequalities are multi-level and any evaluation seeking to understand these must focus not only on the individual recipients of care, but on clinical encounters, the providers and the ways services are shaped by the wider health system in which they are delivered. This approach underpins our evaluation framework and guides development of the logic model (see below). Use of this framework links well to our planned use of the Consolidated Framework for Implementation Research (CFIR); we will use the recently updated framework, (Damschroder 2022) with reference to Normalisation Process Theory (NPT) where relevant.

We will also draw on previous evidence synthesis that has developed a Context-Mechanisms-Outcomes framework for MCoC to draw out specific themes relevant to: 1) how changes in maternity care may be realised for women with social risk factors, and 2) an intersectional perspective on inequities in maternity care. Current theories from this work have been grouped under headings of: Resources (access; education; interpretor services; practical support; continuity of care; relational support); Candidacy (experiences of negative assumptions by healthcare professionals; experiences of surveillance rather than support) ; and Relationships (trust-building) (Raymont Jones 2019). These are fed into the approach and data collection methods for Workstreams 2 and 3.

Whilst the target group for the enhanced model is defined by NHSE - as those living within the highest decile of deprivation (based on postcode), an intersectional lens highlights that high levels of deprivation may interact closely with other forms of socially situated inequalities, namely on the basis of ethnicity, migration status and other social risk factors. This is reflected in the setup of the enhanced model, which, in theory, recognises the intersect between withstanding inequalites and other forms of social marginalisation. As such, our evaluation incorporates approaches that allows analyses to capture how intersectionally experienced factors may impact on maternity care for those living in the most deprived areas.

Scoping and initial theory of change model

The research team has undertaken an informal and rapid scoping review of published research on MCoC models in high-income countries delivered to disadvantaged and ethnic minority communities. We combined MCoC-related search terms developed by the NIHR Policy Research Unit in Maternal

and Neonatal Health with search terms related to underserved, deprived and ethnic minority populations (search available on request, run October 2022).

The search identified 921 citations for individual studies plus 56 citations for systematic reviews. Screening these citations for those relevant to MCoC in underserved groups specifically, resulted in 20 studies that were considered in this scoping work[1]. A further study was included after being flagged to the evaluation team.

We summarise key early insights in relation to key scoping questions which we addressed using available information.

How have MCoC models been adapted to reduce inequity in high income countries?

Whilst services which replicate the enhanced MCoC model are not discussed explicitly in the literature, one Australian study (Hartz et al 2019), discusses a MCoC model alongside 'wrap-around' services, which may be the closest manifestation of an 'enhanced' MCoC model identified in the literature. The model includes link workers and administrative capacity, which provides additional support around cultural relevance, cultural safety and cultural sensitivity. The rationale behind a focus on cultural needs is echoed in other studies in which translation support and cultural representation through a MCoC model is reported to be important for under-served groups, in particular ethnic minority women (Kelly et al 2014).

What theories of change are driving MCoC service models aimed at underserved groups?

The rationale underpinning the MCoC model aligns with reducing inequities in service delivery and health outcomes through a focus on issues including barriers to care, wider social inequalities, unmet needs etc. However, definitions of midwifery continuity of carer and theories of change related to MCoC models that specifically consider reduction of health inequalities are limited (Raymont Jones et al 2020), and the mechanisms through which better outcomes could be achieved through continuity of care models in specific groups is not clearly identified in the literature (ibid).

Is there any evidence MCoC models in high income countries have benefited underserved groups?

The literature demonstrates that MCoC models (also sometimes referred to as 'caseload midwifery') could have positive impacts on birth, neonatal, and perinatal outcomes for underserved groups (Cummins et al 2022, Hadebe et al 2021, Turienzo et al 2019, Donnellan-Fernandez et al 2018, Gibbins 2022, Hartz et al 2019), as well as improvements in health behaviours, including smoking cessation, amongst women (Gibbins 2022). However, many of these studies are conducted in specific settings and contexts i.e., in Australia, with Indigenous groups (Cummins et al 2022, Kelly et al 2014, Turienzo et al 2019, Donnellan-Fernandez et al 2018, Gibbins 2022, Hartz et al 2019) and have limitations including small sample sizes. There is limited evidence from the UK, with small comparative studies suggesting that ethnic minority and socially disadvantaged women and women with social risk factors who receive MCoC models of care may have better birth outcomes than those who did not have continuity of care (Raymont Jones et al 2015, Raymont Jones et al 2020). The model was reported to have the greatest impact in the highest risk populations (mothers in areas of more deprivation (measured by IMD) and those from ethnic minority backgrounds (Hadebe et al 2021).

[1] Two of the full articles were unable to be located for further review.

A further study (Homer et al 2017) retrospectively assessed maternal and perinatal outcomes from families who had received maternity care by a London-based team of midwives aiming to provide continuity of carer. This team was active in a deprived area of London from 1997 to 2009. The report describes data from 2568 women of whom 58% were from Black and Asian ethnic minority backgrounds. The study is not comparative per se but reports low rates of preterm birth and perinatal mortality relative to rates reported elsewhere for babies born to women from deprived areas and/or of Black or Asian ethnic minority backgrounds.

Draft logic model

We have collated the information provided by LMS leads to NHS England, on receipt of the enhanced MCoC funding. These forms have preliminary details of how the funding is to be used within each midwifery team, the type of service provided, and target populations for the model. This information, alongside other scoping work and supporting discussion with a range of stakeholders and members of our advisory panel, has informed development of a draft logic model for enhanced MCoC (Appendix 1). This model will be developed alongside our understanding through the proposed evaluation and reflexive edits will be made throughout each stage of the evaluation.

We require, however, further information which we will obtain via additional mapping.

Workstream 1: Mapping enhanced MCoC service delivery models

Timeframe: 3 months – March to May 2023

Sense making and mapping

We will meet with regional midwifery leads to explore key contextual factors surrounding implemention of the enhanced model nationally and regionally. These sense-making discussions will help the REVAL team understand further how support is organised and functions in each region, as well as to gather any 'soft intelligence' relating to sites who are delivering the enhanced model.

We will conduct informal 'mapping' consulations with 23 LMS leads representing the 58 community teams funded to develop their enhanced MCoC model in the first cohort of funding. The information gathered during these informal consultations will be used to record additional information on the components of each enhanced MCoC model and give a clearer overview of how services have been developed, designed, implemented and targeted to specific population groups. We will also elucidate whether the enhanced MCoC services aim to reach those in the most deprived decile and if target population representing intersecting inequities on the basis of ethnicity, migration status, English language profiency, etc.

The consultation will focus on understanding:

- An outline of the planned or active enhanced MCoC services including key components and how funding is used to support these. We will ask if any documents detailing service specification can be shared with us;

- Which groups the enhanced MCoC models aims to target (see WS4 where we will aim to use rountine data to then report on who does access services);
- Whether the enhanced models proposed are new or have been active in each team prior to this enhanced MCoC funding;
- If and how services are recording relevant outcomes (in addition to clinical data recorded nationally) and measuring user experience information;
- Anticipated timelines for enhanced MCoC implementation across the individual teams.

These are not formal interviews and are in-confidence for internal purposes only. The information provided will help us (REVAL) shape and frame the data collection for the deep dive case study phase. We will ask to record the discussions, which will be via Teams, Zoom or the phone, but if individuals would prefer to talk without a recording this is also possible. If an individual is uncomfortable with the recording process at any time during the discussion, then we will stop the recording. All audio files will be deleted after our note taking process is complete.

Data will be mapped to present (a) the geographical spread of enhanced MCoC service delivery; (b) a brief summary of current formats of enhanced MCoC service delivery (from which a taxonomy of models will be constructed); and (c) previous experience teams may have in delivering elements of midwifery services targeted at specific underserved groups.

We will also consult with a purposive sample of teams who are eligible (n=125) for the enhanced MCoC funding but who have not taken up the offer at this point, or withdrew from the process. This will allow us to gain initial information on potential inhibitors and facilitators to implementation.

Group deliberation

We will organise a feedback session with wider stakeholders, especially NHS England Maternity Transformation Programme, to consider the data collected during the mapping, and how insights impact on workstream 2 and 3.

Workstream 1 Deliverables

Workstream 1 will allow us to:

- Describe types of enhanced MCoC models of service delivery, producing a taxonomy of models that have been implemented in this cohort of funding;
- Outline the approaches taken to shape the format of service delivery to meet local need and how teams anticipate models may impact on factors associated with reducing inequity and inequality in maternity services for defined target groups;
- Describe outcome data collection at a team level including whether experience outcomes are being measured using a patient reported experience measure; and
- Further shape the next steps of the evaluation as required.

Workstream 2: Exploring implementation and delivery of the enhanced model: insights from staff and key stakeholders

Timeframe: Until May 2024

Identification of case sites

We will use the taxonomy, developed in Workstream 1, to develop a sampling strategy to select 'case sites' for in-depth exploration. The case site selection process may iterate based on information collected during Workstream 1, but we anticipate employing a maximum variation design to ensure variation in service types and taking into account characteristics that might influence access and experience of delivery at the local level. We anticipate having nine case study sites, but this will be considered again following Workstream 1. Currently, based on scoping work, we anticipate case study sites being sampled to provide variation, where possible, in the following areas:

- **Geography:** including spread and environment e.g. to include urban and rural teams;
- **Service model:** type of enhanced offer; details of previous model/activities, variations with LMS that have multiple teams across multiple trusts
- **Previous experience**: previous experience in implementing enhanced maternity services for disadvantaged and underserved groups;
- **Local demography:** variations in local patient populations and target populations for care;

We will also consider case study sites' involvement in existing research as part of the sampling process. There may be cases were it makes sense to involve sites that are involved in other evaluations to allow triangluation, and where this is not onerous. Final selection will be discussed and agreed with the NHSE team and we will seek to avoid duplication and evaluation burden by coordinating with the activity of the other concurrent evaluations.

Case study set-up

A REVAL team member will be allocated to each site to build relations with key contacts in each site. A case site initiation meeting will be set up with the key enhanced MCoC team contact to explain the anticipated activities and manage expectations about what will be involved and agree appropriate communication activities. This meeting will also be an opportunity for the evaluation team to gather further information on local contextual information and implementation progress.

We will also discuss the availability of any relevant documentation that may be accessible for the team to review, to enhance our understanding of local service design, development and current activities.

Interviews

We will aim to interview samples of stakeholders at each case study site. Through a purposive snowball sampling appraoch, we will start with designated contacts at each site and seek to sample interviewees including Trust staff such as: senior local midwifery leads and other service managers; midwives from the relevant teams; obstetricians who work with the relevant team; enhanced MCoC non-midwifery workers and professionals. We will also interview where relevant other stakeholders external to Trusts including primary care staff, mental health staff, health visitors and representatives

from voluntary sector organisations. To recruit staff participants, information sheets about the evaluation will be emailed to relevant staff. Community-based partner organisations will be drawn on to disseminate information to key stakeholders about the evaluation, where approproriate. The interviews themselves are likely to be conducted remotely.

Once consent has been provided, each participant's interview will be guided by a role-specific topic guide. Broadly, areas covered will be informed by role and the underpinning frameworks and theories guiding the work including those shaping the exploration of implementation i.e., the CFIR (Damschroder et al. 2022) and NPT (May et al. 2009) and those supporting or expanding exploration of the implicit or explict theories of change that have shaped service model delivery.

Questions posed in the interviews will seek to understand the following:

- The rationale behind the enhanced model set-up and how this relates to the understanding of local equity issues and (unmet) need for defined target groups;
- How adopting the enhanced model has intercalated with other MCoC activity;
- Whether development activity has included external stakeholders or key groups, e.g. the voluntary sector or specialist organisations, based on local understanding of issues and defined target groups, and intersectional factors that may impact equity;
- Barriers and facilitators to the implementation of enhanced McoC models and local contextual issues;
- Staff views of the acceptability of the enhanced elements of McoC models and experiences of these, including how team staff interface with other clinical and social care teams
- Insights into how staff view processes within the enhanced McoC leading to change, in terms of care delivery, patient experience, patient and clinical outcomes;
- Information on specific data being collected to monitor changes locally as a result of enhanced McoC.
- Staff views on potential benefits and unintended consequences (considering the delivery of care, patient experence, and clinical outcomes) of implementation of the enhanced McoC model.

Data analysis

We will adopt a rapid approach to the analysis that is consistent across the case study sites. Interviews will be audio-recorded with consent, transcribed and thematically analysed using a modified framework approach (Gale 2013). This will involve:

- creating a summary template based on the topic guide, with space provided for other observations, unexpected findings and "key quotations"
- completing the summary template following each interview, using field notes from the interviewer; discussing the analysis as a research team
- iterative refinement of the template as the data collection progresses
- transferring the summary templates to a matrix

The matrix of summarised data provides a structure for analysis and interpretation which is useful for policy research and is well suited to managing large datasets such as this (Gale 2013). The coding

framework will be iteratively developed as the interviews continue, through discussion at regular analysis meetings, and through discussions with NHS England and members of our advisory group.

Workstream 2 Deliverables

Workstream 2 will provide:

- Insights into how enhanced approaches have been shaped by local understanding of equity issues and targeted improvement of factors leading to inequity;
- Insights into how teams have undertaken the process of upscaling from MCoC (where this is the case) to the enhanced model and what (new) activities this includes;
- Further insights into potential mechanisms of action underpinning enhanced MCoC models that could explain how the model could facilitate change in clinical outcomes and/or patient experience; where this links to exisiting theory;
- Insights into local progress and potential challenges and successes noted;
- Insights into any unintended consequences of local enhanced MCoC implementation;
- Understanding of staff experiences of enhanced MCoC models of care, including what is working well and where aspects may be less successful. Such insights can support teams more widely to maximise the use, where relevant, of approaches that have a good chance of success;
- Insights into the impact of the enhanced MCoC models on staff relationships and interfaces with other clinical, service, social care teams and systems (e.g place-based care and community hubs);
- Increased understanding of implementation of the enhanced MCoC model via knowledge gained on specific barriers and facilitators to implementation, which can be used to prospectively shape, design and adopt decisions going forward;
- Understanding of early impacts that can shape future evaluation activities and inform ongoing decision-making around service delivery.

Workstream 3: Exploring implementation and delivery of the enhanced model: insights from service users

Timeframe: Until May 2024

We will interview service users of enhanced MCoC services in each case study site. These interviews will focus on capturing the acceptability of the enhanced elements of MCoC models and people's experience of receiving this care.

Participant recruitment

Details of the study will be provided to users of the enhanced MCoC model by members of the enhanced MCoC team. We will use a purposive sampling approach that is considered for each team, and informed by information from workstreams 1 and 2. Our approach will ensure we access a range of local representation and patient experience and we will endeavour to use innovative approaches to facilitate recruitment amongst under-served groups, e.g. by working with community partners. Factors considered for sampling will include socio-economic status and representation of people from

ethnic minority backgrounds, as well as other social risk factors including age, English language profiency, migration status.

We will endeavour to include a range of service users, including consideration of the gestation period of participants and when in their pregnancy access to enhanced MCoC began, aiming to ensure representation of women at various stages of their pregnancy journey. If feasible, then we also plan to conduct follow-up interviews with a sub-sample of women to be able to track their journey throughout different stages of pregnancy with the enhanced model of care, to assess how the model effects care and patient experience at different stages of the pregnancy.

The interviews, themselves, are likely to be conducted remotely but, where necessary (considering social risk factors), we will faciliate face-to-face interviews. Where interpreters are required, we will assess the cost of local interpretation services to explore the feasibility of using these, ensuring that all required confidentiality and data protection requirements are met.

Each service user interview will be guided by a specific topic guide that will cover topics relevant to the research questions. This will include both positive and negative experiences of the local service, how the model has impacted on known factors associated with addressing inequities in maternity for target groups, including resouces, relationship/trust building and candidacy.

Questions to services users will be informed iteratively from the mapping work and will include factors relevant to the theory of change as it is developed. Loosely the interviews will seek to understand:

- People's priorities during their pregnancy and the challenges people face (e.g., public health education, financial advice and support, accessing other services, accessing maternity care, living costs, transport costs, lone-parenting, childcare costs)
- Whether the model has provided support related to any of these factors (e.g. advocacy of and better access to non-clinical additional services, relational support from midwives, antenatal education etc)
- Whether referred to additional service (where applicable)
- People's experience with current maternity service (relevant to the specific details of the model e.g. support from Maternity Support Worker)
- Whether elements of the enhanced MCoC model meet people's needs and priorities
- Whether service users had sufficient support from assigned midwife and team of midwives, including support staff (e.g. Maternity Support Workers)
- Where the model could further meet people's needs to address inequities
- Understanding people's experientially-informed opinions on the impacts and consequences of their current care (enhanced MCoC) (positive or negative)
- Whether care and patient experience differs from previous maternity care (where applicable)

Where applicable, these questions will be asked in follow-up interviews at two different timepoints in a sub-sample of servicer user's pregnancies.

Data analyses

As with the staff interviews, we will use a modified framework approach (Gale 2013) for analysis of service user data with considered comparison between case study sites. Reflexivity will be ensured.

The developed analytical framework in workstream 2 (staff interviews) will be used to analyse data collected in workstream 3. Again using RAP sheets, data will be coded and categorised. If new themes emerge these will be added to the developed framework.

To gain a thorough understanding of experiences and insights from the multiple perspectives of those involved in delivering and accessing enhanced MCoC services, we will triangulate data collected from user participants with the data collected from staff members with the help of the framework matrix, developed as part of the framework method, as applied in Workstream 2.

Workstream 3 Deliverables

Workstream 3 will provide:

- Insights into women's awareness of MCoC services including enhanced elements and their experiences of accessing these**;**
- Service user experiences of enhanced MCoC models of care, including details around experiences of additional support;
- Important outcomes and priorities for service users and their views on on-going service delivery.
- Understanding of unintended consequences of the model, from a service user perspective.
- Insights into whether the enhanced model is addressing key factors associated with inequities as identified in existing theory (e.g, access and referals) and the core elements of the Health Disparities framework.

Workstream 4: Exploring enhanced MCoC access and informing the design of a future evaluation

Cross-cutting throughout project

Exploration, whilst developing this protocol alongside discussion with NHS analysts, confirms that it will not be possible to quantitatively assess changes in key clinical outcomes in this rapid evaluation. This is because: (1) the enhanced MCoC model will be recently implemented during this rapid evaluation and time is needed for longer-term outcome data to accrue; (2) the need for a developed theory of change and corresponding logic model to support longer-term evaluation; and (3) the need for careful exploration of what comparative work may be relevant and possible in any subsequent evaluation.

This rapid evaluation can, however, generate learning to shape future evaluations. Workstream 4 will cut across the proposed rapid evaluation and involve drawing together data to consider:

- An underlying theory of change model to support future evaluation;
- Initial data to explore the characteristics of women accessing enhanced MCoC services within Trust areas to explore whether enhanced models are reaching their intended target population;
- Use formative findings to shape future research questions, quantitative metrics and indicators, including those not routinely collected, with suggested design options and analytical plans that reflect required rigour and feasibility; and
- How available routine data could support future evaluation of enhanced MCoC, including what comparative analytical options may be possible.

Developing the theory of change

Across the evaluation, data collection will shaped by guiding theories and mapped against our initital logic model (Appendix 1). We aim to refine model elements to reflect developing understanding of the mechanisms of change being operationalised. The development process will be undertaken with relevant stakeholders and members of our advisory group, as well as, being responsive to other work in this area e.g. that taken by the WHO, and other clinical/academic professionals. On-going iteration of the model may shape elements of this rapid evaluation and will be used to inform future research.

Conducting initital analyses into enhanced MCoC access

After our own scoping and discussions with NHS England analysts, we have identified that the Maternity Services Data Set (MSDS) will be the most appropriate source of routinely collected data for evaluation, here. The MSDS has very accurate and complete data on characteristics of target groups, including age, ethnicity, and Index of Multiple Deprivation (available through linkage to postcode). Within the current formative evaluation, we will use these data to generate descriptive data of the women accessing enhanced MCoC services. We will run multi-level, multivariable regression analyses to see what individual (and area) level characteristics are predictive of people being on the enhanced MCoC scheme, allowing us to consider whether enhanced models are reaching their intended target population.

How available routine data could support future evaluation

As stated above, the timeframe for this rapid evaluation means that it will not be possible to quantitatively assess any change over time in key clinical outcomes. However, as the findings across the proposed workstreams enhance our understanding of key mechanisms of change, we will be able to generate a list of potential key outcomes for future evaluation. This will include longer-term clinical outcomes and process measures that may offer mechanism-based explanations of the impact of enhanced MCoC models of care on target populations and service delivery.

Based on our proposals above, where there are gaps in routinely available data, we will document these and chart where bespoke data collection may be required, informing what a mandated future minimum dataset in this area could include.

Finally, we will consider analytical options for further evaluations based on key research questions and the utility of available data. Cross-referencing insights with the MSDS, we will aim to identify potential control, or comparator, groups of people (and locations) that can be used in any long-term evaluation. It is important to establish baseline outcomes for the 'treated' and 'comparator' groups so that change can be tracked over time. The exact choice of outcomes – and, hence, comparators – will be informed by the development and refinement of the Theory of Change

Deliverables from Workstream 4

We anticipate that workstream 4 will generate:

- Evidence on whether there are associations between person and area level characteristics and enrolment on enhanced MCoC models
- A suggested theory of change model where possible from available data

- Research questions and important outcomes for further evaluation informed by staff and service user insights
- Early insights for relevant outcome measures for mothers and babies. In particular, we will establish baseline positions for those who received enhanced MCoC and potential comparators
- Consideration of future data requirements and options for data collection;
- Insights into the size of a summative evaluation and important operational details for this, including potential comparative design options and the data requirements for these.

PPIE

As a team we have committed to ensure that we actively listen to and involve citizens in all aspects of our work. A public, patient involvement and engagmement plan for the evaluation has been developed in parternship with our REVAL public contributors.

The research team has formed an initial Public Advisory Panel. Members bring a range of skills, knowledge, and expertise and will ensure that a diverse public voice informs the evaluation that we do and the methods we use. The Advisory Panel model will be iteratively formed reflecting the nature of the evaluation (i.e. Workstreams, 1, 2, 3 & 4), where we will re-visit our Advisory Panel model throughout the course of the evaluation to include additional representation and expertise as necessary. We will consult with the Advisory Panel at regular points during the evaluation lifespan to faciliate ongoing collaboration for input and feedback into the evaluation process, including in the early stages of the evaluation seeking ongoing advice on recruitment appraoches, and development of interview topic guides.

Research Team

Jo Dumville	**Lead**
Stephanie Gillibrand	**Research Fellow**
Elaine Harkness	**Data Analysis**
Luke Munford	**Health Economics**
Penny Bee	**Qualitative and mixed methods oversight**
Nicky Cullum	**Evaluation oversight**

Proposed advisory panel

Prof Aled Jones	**Academic**
Mary Newburn	**PCIE**
Chaya Tagore	**PCIE**
Keith Reed	**PCIE**
Eileen Stringer	**Midwifery expert**

Other regular stakeholder meetings

- Monthly meetings members of the NHS England Maternity Transformation Programme Team (membership below)

Prof Trixie McAree	**National Midwifery Lead for Continuity of Carer**
Prof Jane Sandall	**Professor of Social Science & Women's Health and NHS England Head of Midwifery Research**
George Holley-Moore	**Senior Policy Lead for Midwifery Continuity of Carer**

- Attendance at NHS England's MCoC Evaluation and Research Sub-Group

Dissemination and knowledge mobilisation

To ensure relevance to national decision-making need and to maximise the impact and usefulness of findings, we intend to actively engage with key stakeholders at all stages of the research process, not only to ensure efficient use of NIHR resources, but also to maximise the impact and use of findings as they emerge. Our preference is to facilitate this relationship and to provide timely feedback loops to inform decision-making and to provide insights from the evaluation as they emerge during the life of the study. We will do this through maintaining regular contact with the NHS England Midwifery and Maternity Care, Maternity Transformation Programme Teams and via the six weekly MCoC Evaluation and Research Sub-Group meeting and through regular Teams / email contact. We will seek opportunities to share early insights with Midwifery and Maternity Care, Maternity Transformation Programme Teams, the Maternity Transformation Programme Inequalities Team, and the MCoC Evaluation and Research Sub-Group as the work progresses.

Ethical considerations

The main ethical considerations for the evaluation are recruitment, informed consent; confidentiality, anonymity and data protection:

Recruitment
The contact details of staff involved in the delivery of the enhanced model will be provided by the LMNS teams. Potential participants will then be approached initially by an e-mail invitation from the evaluation team that will include a copy of the participant information sheet and consent form. Those indicating interest in participation will then be contacted and interviews will be arranged at a time to suit the participant – verbal consent will recorded at this point (see below). Snowball sampling will be used to recruit other stakeholder participants who meet our criteria and are thought to have a perspective on the implementation of the enhanced model (e.g. key VCSE sector partners).

For service users, potential participants will be identified by the local midwifery teams within the case sites. The local teams will screen for those eligible to receive the enhanced model, based on their home postcode. Eligible service users will be approached via the local midwifery teams, who will pass on some information about the study through an invitation letter and/or ask patients to complete a

consent-to-contact form. Once the consent to contact form has been completed and securely returned to the research team, the research team will make contact with the service user and participants will be given an Easy-Read Participant Information Sheet. Community partners may also be used advertise the study to eligible potential participants.

Informed consent

All potential research respondents who are recruited for interviews will receive verbal and written information (participant information sheet) regarding the study and will be encouraged to ask questions prior to taking part. It will be made clear that participation is purely voluntary and respondents are able to withdraw from the study at any time, without giving a reason. We will obtain verbal consent before undertaking the telephone or Teams/Zoom interview which we will audio-record separately to the interview audio-recording.

Confidentiality, anonymity and data protection

With consent, all interviews will be audio-recorded using a secure University provided encrypted audio device. We will follow the University of Manchester's standard operating procedure for taking recordings of participants for research purposes: http://documents.manchester.ac.uk/display.aspx?DocID=38446). Recordings of the consent process and interviews will be transferred from the device as soon as possible to secure University servers (so that de-identified data is stored separately to consent data) and then deleted from the device. Transcription of audio-recordings will be undertaken by a University of Manchester approved external transcription company. Audio recordings will be uploaded to the transcription company via a secure server. We will remove any personal identifying information (such as names, places) from transcriptions once they are returned. We will securely destroy the audio-recording of each interview, once an interview has been transcribed and the research team has checked the transcription for accuracy.

Once a respondent enters the study, they will be provided with a unique identifier. This means that data including field notes, audio recordings, transcriptions and demographic data will be identified only by their unique identifier and not the name of the respondent. Where necessary, we may also generalise job titles to protect the anonymity of those in specialist roles or where job titles are specific to an individual organisation. The 'pseudonymisation key' to the unique identifier and respondent's details (name, contact details, site and job title), will only be accessible to members of the research team and stored electronically on a University of Manchester secure server, separate to the de-identified data. Electronic data (such as digital audio-recordings, transcriptions, field notes, and demographic data) will be stored on a University of Manchester secure server. Hard copies of consent forms and demographic data will be kept in a locked cabinet in a locked room on University premises. Once the study is finished, data will be archived securely for 10 years, after which time it will be securely destroyed.

We are aware of the sensitive nature of this research for LMNS and individuals. The research team has experience in conducting research on similar sensitive topics. We will maintain the anonymity of the participating organisations and individuals and will publish findings that are anonymised and

aggregated. Individual participants are assigned a unique numerical identifier and in this instance each organisation will be given a pseudonym.

Ethics and governance approvals

The evaluation team received ethical approval (proportionate review) by the University of Manchester Ethics Committee on 22/03/2023.

HRA approval (full UREC review) will be sought ahead of any contact with individual NHS Trusts to recruit service users.

Timelines

Table 1a show the original timelines and Table 1b extended timelines (and additional 5 months). Timelines were extended in response to delays in pilot implementation, meaning more time was required for staff and service users to accrue experience of the service under-evaluation.

Table 1a: Original timelines

	2023												2024											
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
REVAL evaluation timeline																								
WS1: Scoping, mapping and case study ID																								
WS2: Staff interviews																								
WS3: service user interviews																								
WS4: Analyses and synthesis																								
Stakeholder workshop																								
Synthesis, reporting & dissemination																								

Table 1b: Revised timelines added in yellow

	2023												2024											
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
REVAL evaluation timeline																								
WS1: Scoping, mapping and case study ID																								
WS2: Staff interviews																								
WS3: service user interviews																								
WS4: Analyses and synthesis																								
Stakeholder workshop																								
Synthesis, reporting & dissemination																								

Statement of Indemnity

The University of Manchester has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

Funding

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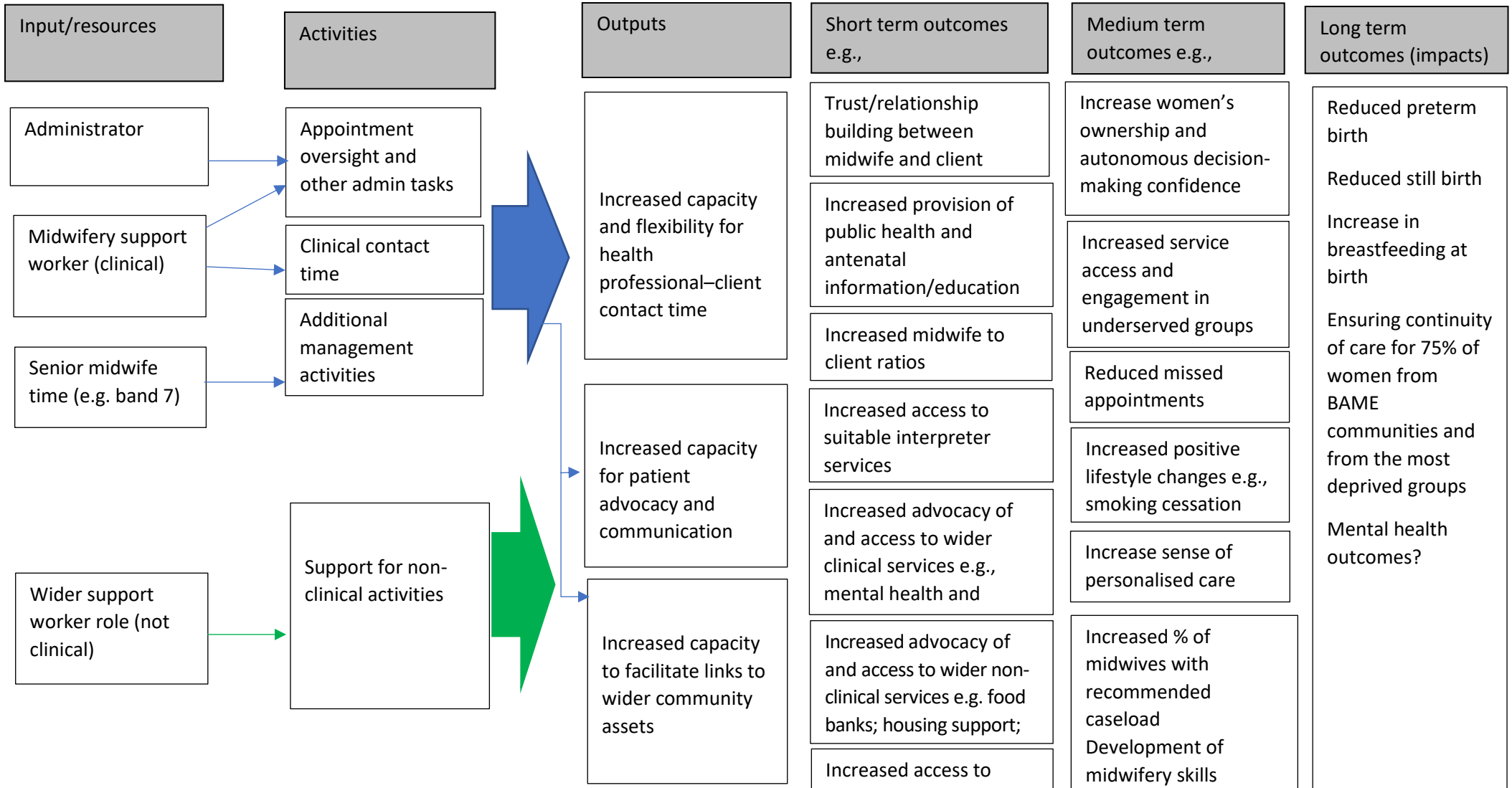
Appendix 1: Draft logic model for enhanced Midwifery Continuity of Carer



Assumptions: Enough appropriate staff; development of increased capacity as anticipated, sufficient estates resource

External factors: On-going resources; stability of policy environment