## Study Protocol

# Models of Antenatal Care:

# a pilot study to explore a new quality care framework

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| Study Acronym | **MAC-Qual** |
| Sponsor | **University of Dundee-NHS Tayside** |
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| Funder | **NHS Tayside** |
| Chief Investigator | **Dr Andrew Symon** |
| REC Number | |
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**PROTOCOL APPROVAL**

**Models of Antenatal Care: a pilot study to explore a new quality care framework**

**Signatures**

**By signing this document I am confirming that I have read, understood and approve the protocol for the above study.**

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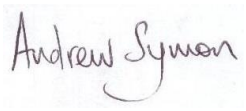
| **Andrew Symon** |  | 26th August 2016 |
| Chief Investigator | Signature | Date |
| Individual Responsible for Statistical Review | Signature | Date |

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## LIST OF ABBREVIATIONS

| | |
|---|---|
| GCP | Good Clinical Practice |
| SMF | Study Master File |
| SOP | Standard Operating Procedure |
| CRF | Case Report Form |
| CNORIS | Clinical Negligence and Other Risks Scheme |
| RA | Research Assistant |

**SUMMARY**

Systematic reviews (e.g. Sandall et al. 2015) [1] have demonstrated a link between midwifery-led continuity of care models and improved Clinical, Psychosocial and Organisational (CPO) outcomes, including preterm birth and breastfeeding rates. However, the underlying causal mechanisms within these models are not understood, and trial reports rarely detail all the relevant contextual factors for the intervention and control groups [2]. This pilot study will test the use of focus groups with service users and providers across NHS Tayside and NHS Fife in an exploration of their perceptions of the antenatal care model with which they are familiar. The focus groups will use as their starting point the Quality Maternal and Newborn Care (QMNC) Framework published in The Lancet Series on Midwifery [3]. While this Framework for quality care is well-evidenced and peer reviewed, it has yet to be determined how service users and providers in different care models understand or experience the components and characteristics of care which the Framework describes. These pilot focus groups are therefore needed to explore how service users and service providers perceive or understand how the characteristics of care specified in the Framework apply to the model of care with which they are most familiar. Analysing these interviews will help us to understand better how to design larger-scale fieldwork that will result in development of a care model evaluation toolkit. This will allow us, other researchers, the NHS and policy-makers to assess service provision across a range of settings, models of care and regions.

This pilot study will be conducted in three varying care model settings within Tayside and Fife: in-hospital continuity midwifery; out-of-hospital continuity midwifery; 'standard' care with no or little prescribed continuity element (which in practice often means in-hospital obstetric-led), and will be guided by Patient and Public Involvement. We emphasise that while settings and care models overlap, they are not synonymous. 'Continuity' is not restricted to midwifery care; and 'standard' care varies according to local circumstances.

# 1 INTRODUCTION

## 1.1 BACKGROUND

The UK fares worse than some comparable countries in key perinatal outcomes, e.g. preterm birth [4]. This outcome alone entails significant clinical, psychosocial, organisational and financial burdens. There is also evidence of other significant problems within maternity care services in the UK, such as serious failures of clinical care [5] and higher rates of perinatal mortality than comparable countries [6]. Randomised controlled trials (RCTs) have established that midwifery continuity of care models contribute to fewer preterm births and fewer clinical interventions, as well as higher breastfeeding rates and improved psychosocial outcomes [1]. However, trial reports seldom explain the model's active mechanisms, i.e. how and why care is given and which aspects make a difference [2]. Understanding this is crucial to replicating and implementing cost-effective care. As a first step in developing an evaluation toolkit for antenatal service evaluation, we will explore the perceptions and understanding of service users and providers of those care characteristics deemed by the QMNC Framework to be determinative of good quality care. While these have been extensively detailed in The Lancet Series on Midwifery's Framework for Quality Maternal and Newborn Care (QMNC) [3], to date that framework has not been used to formulate a data collection instrument or evaluation toolkit.

## 1.2 RATIONALE FOR STUDY

Improving pregnancy outcomes is both a research and a policy priority [7,8,9]. There is now robust evidence that shows the constituents of quality maternal and newborn care [3]. In addition there is emergent evidence that certain models of care produce better outcomes [1], but the understanding of how to extend or replicate those models and implement quality care beyond their trial settings remains limited.. This pilot study will use the evidence contained within the QMNC Framework as a lens through which to explore service user and provider perceptions of different antenatal care models. Analysing these perceptions will help us to devise a larger-scale empirical study whose purpose will be to devise a service evaluation toolkit.

# 2 STUDY OBJECTIVES

## 2.1 PRIMARY OBJECTIVE

To test the feasibility of running service user and service provider focus groups which will use the QMNC framework to explore their perceptions and experiences regarding the ***characteristics of care*** associated with different antenatal care models.

## 2.2 SECONDARY OBJECTIVES

To identify those clinical, psychosocial and organisational outcomes deemed by service users and providers to be the most relevant ones. This is in order to be able to determine the breadth of assessment needed to make comprehensive statements regarding "what works for whom".

## 2.3 OUTCOMES

### 2.3.1 Primary Outcomes

The feasibility of conducting service user and service provider focus groups which explore perceptions of the characteristics of care associated with the model of care with which they have current or recent experience.

### 2.3.2 Secondary Outcomes

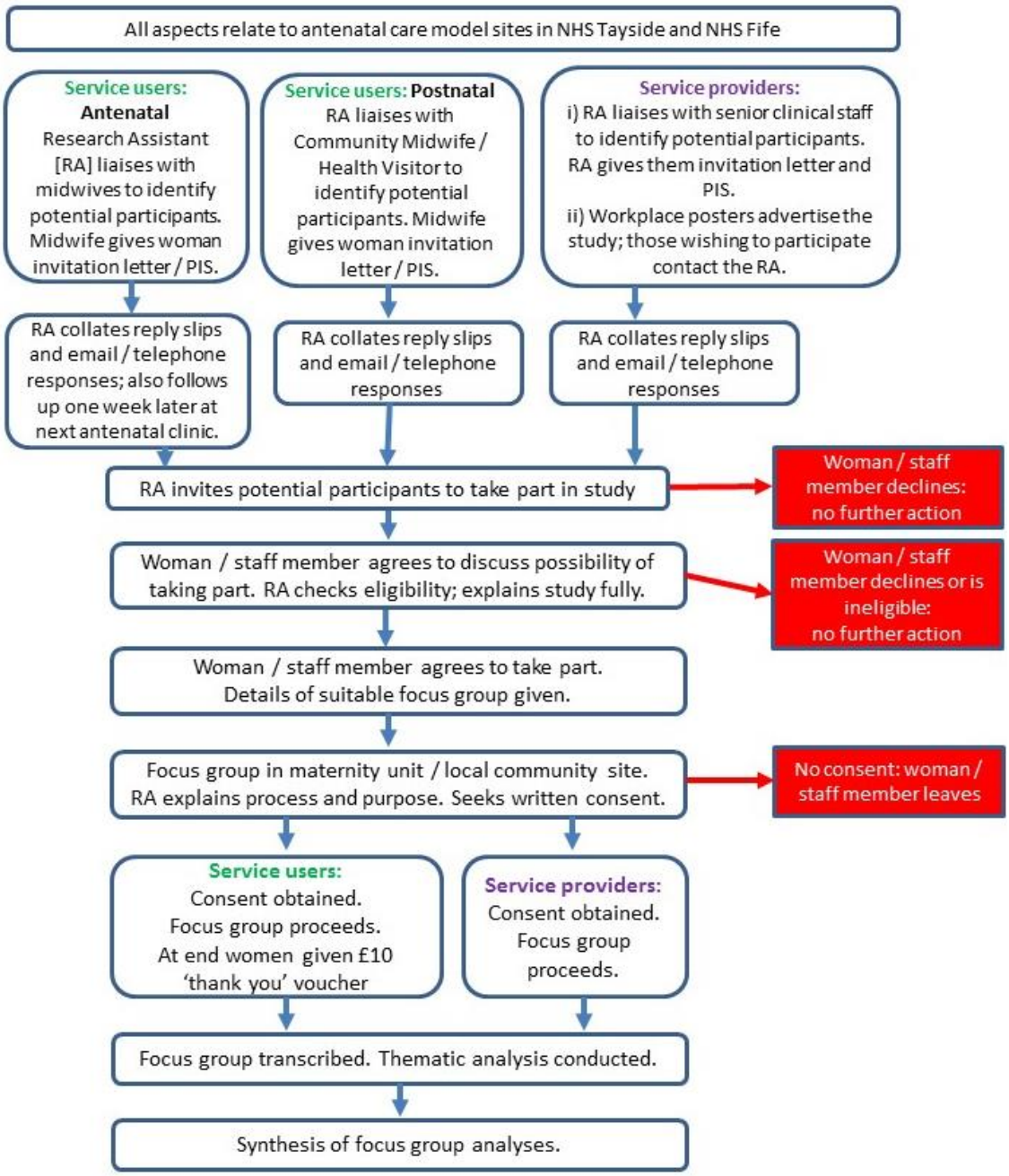
The perceptions of service users and providers of the characteristics of care provision which most deserve to be assessed routinely.

# 3 STUDY DESIGN

## 3.1 STUDY DESCRIPTION

Qualitative descriptive approach that explores service user and service provider perceptions using focus groups.

## 3.2 STUDY FLOWCHART



# 4 STUDY POPULATION

## 4.1 NUMBER OF PARTICIPANTS

We will conduct up to ten focus groups, each with up to eight participants.

We will invite 10-12 to each focus group, as non-attendance is a recognised feature of focus groups.

Participation will only last for the duration of the focus group: there is no follow-up, but participants will be advised that an executive report will be lodged on the University of Dundee website.

## 4.2 INCLUSION CRITERIA

Service users: pregnant women in the third trimester of pregnancy who have experience of one of the specified antenatal care models / new mothers who have recently had experience of one of the specified antenatal care models.

Service providers: midwives, doctors or ancillary staff working in one of the specified antenatal care model settings.

## 4.3 EXCLUSION CRITERIA

Service users: women who are deemed unable to understand the nature of the study, or who are either emotionally or/and physically seriously unwell, will not be eligible. Women whose babies have died or who are seriously unwell will not be approached.

Those under the age of 16.

Service providers: no exclusions planned.

# 5 PARTICIPANT SELECTION AND ENROLMENT

## 5.1 IDENTIFYING PARTICIPANTS

Service users: pregnant women in the third trimester of pregnancy will be identified by community-based or unit-based midwives; new mothers will be identified by community-based midwives or health visitors. The midwife / health visitor will give or send these women an invitation letter (signed by the Head of Midwifery) and a Participant Information Sheet (PIS). They will be invited to contact the study Research Assistant (RA) if they are interested in participating: email and telephone contact details are provided in the PIS, and a reply slip is included which can be left in the antenatal clinic for the RA to collect, or given to the midwife or health visitor to forward to the RA.

Service providers: all staff members in each site will be eligible. Senior midwives (Band 7) will be asked to suggest potential participants, and posters in prominent areas will advertise the study so that others who wish to participate may contact the study team. All such staff members will be sent an invitation letter and PIS.

All potential participants who indicate preparedness to attend a focus group will be advised of the relevant date, time and venue.

## 5.2 CONSENTING PARTICIPANTS

Consent will be obtained by the relevant RA (one for NHS Tayside; one for NS Fife) for each site at the start of the focus group interview. Focus groups in Tayside will be held in Ninewells Hospital, and in the maternity units in Montrose, Arbroath and Perth; focus groups in Fife will be held in Victoria Hospital, Kirkcaldy, Queen Margaret Hospital, Dunfermline, and in a community setting in North-East Fife. At least one week will have transpired between the woman / staff member receiving the invitation letter / PIS and the focus group. The PIS will be discussed and an opportunity given for those attending to ask questions. Those willing to proceed with the focus group will be asked to sign a standard consent form.

### 5.3 SCREENING FOR ELIGIBILITY

Only service users who are under the age of 16 or who are unable to understand the nature of the study will be ineligible. This will be determined by local clinical staff, and verified by the RA.

#### 5.3.1 Withdrawal procedures

Participants will be taking part in a one-off focus group interview. All will have the right to withdraw at any stage, but in that event it would not be feasible to withdraw all the focus group data collected. Should anyone choose to withdraw then any specific contribution they had made to the discussion would be discounted, if they wish.

## 6 STUDY & SAFETY ASSESSMENTS

This is a low risk qualitative study, and we do not anticipate any risks or adverse effects for participants. We will minimise inconvenience by negotiating the time and venue for the focus groups with potential participants. The topic guide for the focus groups is derived from the well-evidenced Quality Maternal and Newborn Care (QMNC) Framework, published in the Lancet Series on Midwifery [3]. This describes characteristics of quality care. It is possible that some participants may find it distressing or uncomfortable to discuss healthcare experiences that may have been disappointing. If a participant becomes distressed during a focus group, the interviewer will check if the participant would like to take a break or leave. Contact details for local counselling services for service users, and advice about relevant professional support will be provided at each focus group.

All focus groups will take place within a maternity unit or a public community venue, so we do not anticipate any risk to researcher safety when conducting the focus groups. We will work to the University of Dundee Fieldwork Safety Policy Arrangement (48-2010) which is based on “Guidance on Health and Safety in Fieldwork” [10].

# 7 DATA COLLECTION & MANAGEMENT

## 7.1 DATA COLLECTION

Participants will be involved in a one-off focus group discussion which will be audio-recorded. No personal contact details will be requested; participants will choose or be given a pseudonym. Those wishing to be informed of the findings of the study will be given a University of Dundee web address where a report will be placed.

All focus group data will be in the form of audio files and interview transcripts. All data will be stored securely in University password-protected computers or, if hard copy, in locked filing cabinets. As no personal data will be requested we will not need to anonymise the transcripts. Any direct quotes will use pseudonyms.

# 8 STATISTICS AND DATA ANALYSIS

## 8.1 SAMPLE SIZE CALCULATION

We will conduct ten focus groups with a maximum of eight participants in each.

## 8.2 PROPOSED ANALYSES

Focus group discussions will be audio-recorded and transcribed verbatim. A software package (NVivo) will be available for managing the transcripts.

Data will be analysed thematically using Ritchie and Spencer's framework method [11]. The analytical framework will be derived both deductively (using constructs from the QMNC Framework) and inductively (incorporating new themes that emerge from the data through open coding). This approach to analysis will enable comparison by themes across different focus groups as well as retaining the context of individual experiences. As the main outcome measure is the feasibility of conducting focus groups with these populations, we will pay particular attention to this feature. To enhance the credibility of the interpretation we will pay attention to negative or dissonant cases.

The process of analysis will involve familiarisation with all research material through repeated reading. Two researchers (the RA local to each site and a member of the research team [Symon [CI] or McFadden]) will independently code the first few transcripts before agreeing the framework to be applied to all transcripts. The analytical framework will thereafter be applied consistently.

In reporting the research we will provide sufficient contextualised participant quotes to support our interpretation. Summaries of the data and its interpretation will be discussed with the Stakeholder Advisory Group as a further strategy to enhance the credibility of the research (see 9.3).

# 9 STUDY MANAGEMENT AND OVERSIGHT ARRANGEMENTS

## 9.1 STUDY MANAGEMENT GROUP

This is a 6-month pilot project. The chief investigator (CI), supported by the research team, will be responsible for day-to-day project management, including meeting all milestones. The research team will meet monthly to discuss the conduct and progress of the research.

## 9.2 STUDY MANAGEMENT

The CI will oversee the study. A study-specific Delegation Log will be prepared for each site, detailing the responsibilities of each member of staff working on the study. Any queries will be resolved by the CI or delegated member of the study team.

## 9.3 STUDY STEERING COMMITTEE

A Stakeholder Advisory Group will meet three times (at the start, mid-point, and near the end) to agree the project protocol, monitor the progress of the research and approve the final report. The group will comprise a user representative, senior NHS personnel and an academic researcher, the CI.

## 9.4 INSPECTION OF RECORDS

The CI and all institutions involved in the study will permit study related monitoring, audits, and REC review. The CI agrees to allow the Sponsor or, representatives of the Sponsor, direct access to all study records and source documentation.

# 10 GOOD CLINICAL PRACTICE

## 10.1 ETHICAL CONDUCT OF THE STUDY

The study will be conducted in accordance with the principles of good clinical practice (GCP).

In addition to Sponsorship approval, a favorable ethical opinion will be obtained from the appropriate REC and appropriate NHS R&D approval(s) will be obtained prior to commencement of the study.

### 10.1.1 Confidentiality

As previously noted, no personal details will be requested or recoded. All data will be anonymous.

All reports, and other records will be identified in a manner designed to maintain participant confidentiality. All records will be kept in a secure storage area with limited access to study staff only. The CI and study staff involved with this study will not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the Sponsor or its designee will be obtained for the disclosure of any said confidential information to other parties.

### 10.1.2 Data Protection

The CI and study staff involved with this study will comply with the requirements of the Data Protection Act 1998 with regard to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. Access to collated participant data will be restricted to the CI and appropriate study staff.

Computers used to collate the data will have limited access measures via user names and passwords.

Published results will not contain any personal data that could allow identification of individual participants.

### 10.1.3 Insurance and Indemnity

The University of Dundee will obtain and hold a policy of Public Liability Insurance for legal liabilities arising from the study.

University of Dundee staff undertaking the study will hold Letters of Access with Tayside Health Board and Fife Health Board, which means they will have cover under the NHS Scotland CNORIS scheme.

**Indemnity** The Sponsor does not provide study participants with indemnity in relation to participation in the Study but has insurance for legal liability as described above.

## 11 STUDY CONDUCT RESPONSIBILITIES

### 11.1 PROTOCOL AMENDMENTS, DEVIATIONS AND BREACHES

The CI will seek approval for any amendments to the Protocol or other study documents from the Sponsor, REC and NHS R&D Office(s). Amendments to the protocol or other study docs will not be implemented without these approvals.

In the event that a CI needs to deviate from the protocol, the nature of and reasons for the deviation will be recorded in the CRF, documented and submitted to the Sponsor. If this necessitates a subsequent protocol amendment, this will be submitted to the Sponsor for approval and then to the appropriate REC and lead NHS R&D Office for review and approval.

In the event that a serious breach of GCP is suspected, this will be reported to the Sponsor immediately using the form "Notification to Sponsor of Serious Breach or Serious Deviation".

## 11.2 STUDY RECORD RETENTION

Archiving of study documents will be for a period of five years.

## 11.3 END OF STUDY

The end of study is defined as submission of the final report to the two Heads of Midwifery in the relevant Health Boards. The Sponsor, CI and/or the Stakeholder Advisory Group have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the Sponsor and REC within 90 days, or 15 days if the study is terminated prematurely. The CI will ensure that any appropriate follow up is arranged for all participants.

A summary report of the study will be provided to the Sponsor and REC within 1 year of the end of the study

# 12 REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

## 12.1 AUTHORSHIP POLICY

Ownership of the data arising from this study resides with the study team and their respective employers. On completion of the study, the study data will be analysed and a final report will be prepared.

## 12.2 PUBLICATION

The final report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study.

Summaries of results will be made available for dissemination within the relevant clinical areas (where appropriate and according to their discretion).

Lay summaries of results will also be made available on a study-specific webpage.

## 12.3 PEER REVIEW

External peer review was conducted by a senior researcher with another university. A copy of the draft protocol with her comments is held by the CI.

## 13 REFERENCES

1 Sandall J, Soltani H, Gates S, Shennan A, Devane D (2015) Midwife-led continuity models versus other models of care for childbearing women. *Cochrane Database Systematic Review* (CD004667)

2 Symon A, Pringle J, Downe S, Hundley V, Lee E, Lynn F, McFadden A, McNeill J, Renfrew MJ, Ross-Davie M, van Teijlingen E, Whitford H, Alderdice F (2016) Midwifery-led antenatal care models: Mapping a systematic review to an evidence-based quality framework to identify key components and characteristics of care. *BMC Pregnancy and Childbirth*, 16: 168

3 Renfrew MJ, McFadden A, Bastos MH, Campbell J, Channon AA, Cheung NF, Audebert Delage Silva DR, Downe S, Kennedy HP, Malata A *et al (*2014) Midwifery and quality care: findings from a new evidence-informed framework for maternal and newborn care. *Lancet*, 384(9948):1129-1145

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6 Manktelow BN, Smith LK, Seaton SE, Hyman-Taylor P, Kurinczuk JJ, Field DJ, Smith PW, Draper ES [on behalf of the MBRRACE-UK collaboration] (2016) *Perinatal Mortality Surveillance Report: UK Perinatal Deaths for Births from January to December 2014.* NPEU, Oxford

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8 Cheyne H, McCourt C, Semple K (2013) Mother knows best: Developing a consumer led, evidence informed, research agenda for maternity care. Midwifery, 29: 705-12

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10 UCEA/USHA [Universities and colleges Employers Association / Universities Safety and Health Association (2011) Guidance on Health and Safety in Fieldwork. http://www.ucea.ac.uk/en/publications/index.cfm/guidance-on-health-and-safety-in-fieldwork

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