# Re-CONNECT

# Realist Evaluation of Continuity of Care in General Practice

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## Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor: 

Name: Suzy Wignall

Date: 13 June 2025

**Chief Investigator**

Signature:

Name: NADA KHAN

Date: 11 June 2025

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# 1. BACKGROUND

Why does continuity matter? There is good evidence that continuity of care results in better patient outcomes. Higher relational continuity of care is associated with lower mortality, fewer hospital admissions, more satisfied patients and less risky prescribing of medication in the elderly.(1-3) The patient experience demonstrates that patients value having a personal, one-to-one relationship with a GP. Patients feel that continuity means that their GPs gives clear and consistent advice, and leads to a positive reciprocal and coherent relationship based on trust and respect.(4, 5) Alongside the positive patient outcomes, higher continuity of care is associated with higher clinician productivity and fewer consultations, which can save time and resource in an already overworked general practice system facing multiple pressures.(6)

## 1.1 Competing priorities in general practice

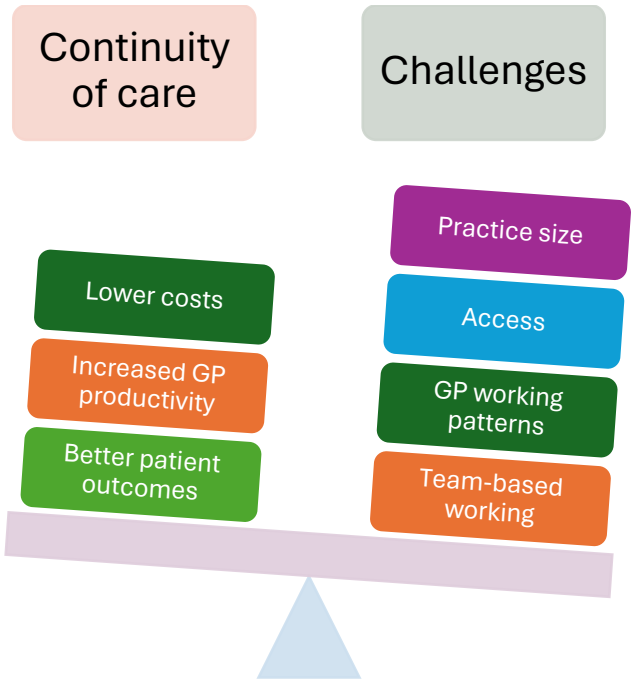
Despite these positive outcomes, relational continuity is declining in English general practice, and is less well achieved amongst practices with a high proportion of patients from minority ethnic groups or living in deprived areas.(7, 8) Whilst the benefits of continuity are understood, some commentators believe that it is no longer possible in UK general practice, despite models of high continuity in countries with similar primary care systems including Denmark and Norway.(1, 9, 10) Some practices cite perceived challenges including the recruitment and retention 'crisis' in general practice, GP working patterns, a tension between continuity and timely access to appointments, and increasing multi-disciplinary team-based models of care (Figure 1).(11)

Qualitative research examining access problems in UK general practice has shown that the depriotisation of continuity leads to increased work for staff and contributes to unmet need, especially amongst under-served patients such as those with mental health problems or people with limited English.(12) Voorhees et al described this as a paradox of access, suggesting that restoring relational continuity can improve patient satisfaction, staff retention and reduce unnecessary work.(12) A mixed-methods evaluation of continuity of care reiterated that continuity and timely access are not 'opposing principles', highlighting that continuity can be achieved without an impact to timely, high quality access to care.(11)

Some practices are able to prioritise and achieve high levels of relational continuity.(5) Up to 10% of general practices in the UK use GP personal lists with one GP responsible for a group of patients, with one practice achieving 82% of consultations between a patient and their regular doctor.(13) How have these 'outlier' practices managed to retain high levels of continuity of care, and do their outcomes relate to patient characteristics or practice circumstances over which practices have control? Understanding this is increasingly important given that in May 2024, the UK Local Medical Committees (LMC) backed a motion proposing contractual measures to incentivise continuity of care in practice. The complexity between and within different

general practices means that it is difficult to fully understand how different approaches or interventions affect continuity of care.(11)

Figure 1 - Competing interests and challenges relating to continuity of care




## 1.2 Why a realist approach?

This study will use a realist approach to evaluate how relational continuity of care is achieved within a sample of general practices. Realist evaluation is a theory-based approach that provides a framework for developing theories about how interventions work by seeking to understand what works for whom, in what circumstances, in what respects and how.(14) Realist approaches acknowledge that programmes are not successful everywhere, and work better in some circumstances and conditions than in others. The aim of a realist evaluation is to develop, test and refine theories open the black box to understand these circumstances: which mechanisms work, in which contexts, to produce which outcomes?(14)

Programmes to increase continuity of care are complex, and their success depends on how they are implemented within each general practice. Theory-driven forms of realist evaluation align with the UK Medical Research Council (MRC) guidelines for evaluating complex interventions, which acknowledges that evaluating complex interventions requires clarification of causal mechanisms and contextual factors that result in variation in outcomes. (14, 15) A realist evaluation is particularly suited to answer the main

research question in this project: why do interventions to increase continuity of care work in some general practices but not others, and for some patient groups and not others?

# 2. RESEARCH QUESTION / AIMS

The aim of this research project is to understand how relational continuity of care works in general practice for whom, and in what circumstances. Relational continuity is an ongoing interpersonal and therapeutic relationship between a clinician and a patient built up over many years of a seeing each other.(16) It has been described as a 'cornerstone of general practice', and is associated with positive health outcomes.(17) Whilst continuity of care is declining in the UK, some practices have been able to maintain high levels of continuity of care through different programmes and interventions.

The specific objectives of the research project are to explore, through a realist evaluation:

1. What are the contextual factors that impact on whether a general practice can provide good continuity of care?
2. How do practices that achieve good continuity achieve timely and fair appointment access (or not?)

## Outcomes

The results will help inform general practice service development and policy and will produce evidence-based recommendations to inform how the key enablers of continuity of care can be transferred to other practices.

# 3. STUDY DESIGN AND APPROACH

We will meet the objectives of this study through a realist evaluation. Realist evaluations are iterative processes typically involving multiple data sources in the field to develop, test and refine programme theories to explain for whom and in what circumstances programmes work. A recent review of interventions to improve relational continuity in the UK demonstrated different strategies including GP personal lists, appointment booking procedures, and digital solutions such as online consultation follow-ups with the same clinician. These different interventions will be explored in this study through collecting real world data from practices with high levels of continuity of care.(17)

We will develop an initial programme theory to test through fieldwork using a mixed methods approach combining ethnographic research in GP surgeries, realist qualitative interviews, GP appointment data and continuity of care measurements within practices achieving high levels of relational continuity to develop a refined final programme theory.

We will report the methods and findings of this project using the RAMESES II reporting guidelines for realist evaluations.(18)

## 3.1 Stage 1 – Development of an initial programme theory

Stage 1 of this study involves formulating an initial pilot programme theory (IPT).(14, 19) The IPT will prospectively formulate how different approaches within each general practice enhance continuity of care (outcomes). Within realist programme theories these are expressed as generative mechanisms that operate to produce the intended outcomes in specific contexts (context mechanism outcomes configurations, or CMOcs).

We will assemble a project advisory committee comprising (20):

1. The project PPI group
2. Primary care professionals interested in continuity and realist evaluation

We will discuss with the patient and public members if they want to be part of the professionals group, or if the would prefer to act as a separate advisory group. The patient mentor to this project will sit across both groups.

We will develop initial CMOcs and an IPT following:

1. A pragmatic and focused review of key documents/research on continuity. The research team is also collaborating with two groups conducting realist reviews on continuity of care in general practice. As these reviews evolve we will bring their initial programme theories to inform our IPTs
2. In-depth exploratory interviews with members of the patient and professional stakeholder groups who will be presented with evidence from the literature (step 1 above) and asked about their ideas of how different models of continuity work and why derived from their own experiences.

We will focus on contextual factors perceived to shape continuity (Table 1) in developing the IPT, which we will discuss and 'sense-check' with the advisory committee.

Table 1 – Micro, meso and macro contextual factors influencing implementation of continuity of care

| **Macro** | **Meso** | **Micro** |
|---|---|---|
| Policy<br>Resource environment<br>National and local incentives | Practice level factors<br>Size of practice<br>Practice staffing<br>Practice multidisciplinary mix<br>Patient characteristics | Capabilities, values and interests of individuals at the practice<br><br>Individual patient preferences |

## 3.2 Stage 2: Realist evaluation

Stage 2 involves testing the IPT developed in Stage 1. The project team will include a post-doctoral researcher to support this project to conduct ethnographic research in four different general practices with high levels of continuity through systems including GP personal lists, multi-disciplinary micro-teams, or buddy groups.(21) The post-doctoral researcher and project Chief Investigator (CI) will conduct observational work together in the first practice to ensure rigour and consistency in subsequent data collection

### 3.2.1 Observation and discussions

The post-doctoral researcher will observe and conduct informal conversations with practice reception, administrators and clinicians to understand the technical infrastructure, informational continuity and workflow supporting continuity. Practice staff will guide us on 'walk-throughs' of tasks supporting continuity (i.e. booking acute or routine appointments, triaging e-Consultations). The project PPI development work highlighted that some patients wait to see their regular GP but may wish to see 'any' GP for acute problems, which we will explore in terms of processes.

The observational and ethnographic data will be analysed through a realist lens, with a focus on exploring how the processes and interactions observed within practices align with, challenge, or refine the initial programme theory and its associated Context-Mechanism-Outcome configurations (CMOcs). The analysis will begin with deductive coding, guided by the initial programme theory (IPT) and pre-specified CMOcs developed during Stage 1. This will involve mapping field notes and ethnographic records to specific elements of each configuration, for example, identifying contextual features, mechanisms and observable outcomes including relational or informational continuity and patient satisfaction.

In parallel, we will use inductive coding to remain open to unanticipated insights or patterns that emerge from the fieldwork. These may suggest new mechanisms, highlight additional contextual influences, or reveal previously unconsidered outcomes. Coding will take place iteratively, allowing for the emergence of refined or new CMOcs, which will be compared across practices.

### 3.2.2 Collecting documentation

The research team will collect and analyse a range of practice-level documents and protocols that relate to continuity of care and its operationalisation within the general practice setting. This may include documents such as appointment booking protocols, triage guidelines, staff rotas, internal communication policies, continuity-focused

initiatives (i.e. named GP schemes), patient information materials, and any written strategies for managing long-term patient relationships.

To ensure contextual relevance, the researcher will engage with practice staff, including administrative, clinical, and managerial team members, to understand the purpose, usage, and perceived effectiveness of each document. Staff will be asked to reflect on which documents are most relevant to promoting continuity, how these protocols are interpreted in day-to-day practice, and whether they reflect formal policy or more tacit, informal practice norms.

As part of this process, we will examine how the practice appointment system is structured, including the types and numbers of appointments available by professional role (i.e. GP, pharmacist, nurse), how appointments are allocated, and how this relates to overall capacity and workload. This will help us understand how continuity is enabled or constrained by the design of access pathways, scheduling practices, and staffing models.

Collected documentation will be analysed using a realist lens, considering how specific features of the organisational context (i.e. staffing levels, digital infrastructure, appointment configuration) may activate mechanisms such as relational trust, informational continuity or role clarity to produce outcomes related to continuity. We will code documentation against our initial CMO configurations and triangulate findings with interview and observational data to test and refine the programme theory.

This documentary analysis will provide valuable insight into the structural and procedural context of each practice, helping us to explain variation in how continuity is experienced and enacted across different settings.

### 3.2.3 Realist qualitative interviews

We will interview 3-4 staff members at each practice. We will interview individuals in the practices who understand the processes and programme to enhance continuity, and how they were implemented or have evolved, and who have specific ideas and explanations of the mechanisms that make the programme work, and will likely include GPs, receptionists or practice management.

Realist interviews are theory-driven interviews, and will be conducted by the post-doctoral researcher. The interviews will involve presenting the IPT to participants and eliciting their views on whether from their experiences, they support, reject or suggest modifying the programme theory. (22, 23) Questions will be designed to test the programme theories whilst exploring unexpected and not previously hypothesised CMOcs (theory gleaning as well as theory refinement). Interviews will be conducted face-to-face, audio-recorded and transcribed verbatim.

### 3.2.4 Practice-level data

We will access practice-level data on appointments recorded in each GP practice appointment system through the NHS Digital website through the NHS England Appointments in General Practice Dataset. (24) This publicly available dataset includes aggregated information on appointment activity by healthcare professional type (i.e. GP, nurse, pharmacist), appointment mode (i.e. face-to-face, telephone, online), and time between booking and the appointment date. These data are routinely collected and published to support transparency and service planning in general practice.

For the purposes of our realist evaluation, this information will provide valuable contextual data at the practice level, supporting our understanding of how continuity of care interacts with access and workforce configuration. By examining variations in appointment patterns across practices, we will explore how factors such as staffing mix, appointment availability, and use of multidisciplinary team members may influence the delivery and experience of continuity. These data will be used to help develop, refine, and test programme theories generated through realist interviews and other sources.

The appointment data will not include any patient-identifiable information and will be used solely for comparative and contextual analysis at the practice level. This information will help us situate our qualitative findings within broader patterns of service delivery and contribute to understanding the mechanisms by which continuity is supported or constrained in different general practice contexts.

### 3.2.5 Analysis

The research team will lead a structured process of theory generation, testing, and refinement. This will include regular analytical discussions and reflexive consideration of our positionality, recognising how our professional backgrounds, values, and assumptions may shape data interpretation and theory development. (25)

Interview transcripts and ethnographic field notes will be coded both deductively, using the initial programme theory (IPT) as a guiding framework, and inductively, allowing for new insights and unanticipated mechanisms from the data. Codes will be organised into overarching themes based on recurring patterns or explanatory relevance. As part of the iterative nature of realist analysis, we will map themes onto Context-Mechanism-Outcome configurations (CMOcs), continually refining our interpretations as new data are integrated.

Data will be analysed across the practices to explore how mechanisms operate in varying contexts. We will start in the first two practices, then pause for an initial analysis before the ethnographic work in the final two practices. This analysis pause will allow us to refocus the ethnographic observation, documentation collection and realist interviews on areas where we may need to collect more data.

Throughout the analysis, we will use real-time memo writing to capture analytical insights, support theory development, and track how interpretations evolve. We will present interim analyses to our project advisory groups for feedback. This will help ensure that our interpretations are grounded, credible, and relevant to real-world practice.

We will construct narrative summaries of each CMOc, supported by illustrative quotations and observational detail to bring depth and context to the explanatory accounts. These will be synthesised into a final programme theory that outlines how, why, and in what circumstances continuity of care is supported or challenged within general practice teams. (22, 23)

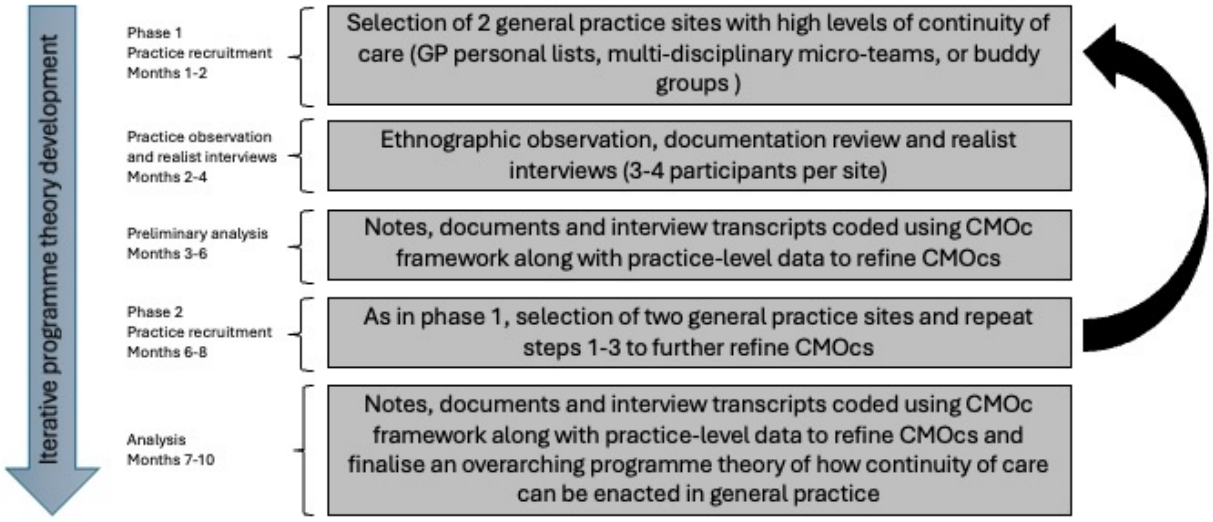
## 3.3 Stage 3

Stage 3 involves refining the IPT developed in stage 1, and informed by the data collection in Stage 2, to refine the programme theory underpinning increased continuity of care. The final programme theory will be presented at a steering committee meeting involving the PPI and stakeholder groups to ensure that the theory refinement includes and incorporates the patient and professional experience.

The programme theory will help us understand how the context can support the success of continuity of care in general practice. In this step, we will draw on the knowledge of our steering committee to draw out key principles or insights and to consider whether the same initiatives might work in other contexts (other times, places and people) with the same results. This programme theory will feed into knowledge about continuity, and will help inform future research, policy, and planned primary care incentives around continuity of care.

A summary of the study design and steps is shown in Figure 2.

Figure 2 – Study design and steps




### 3.3.1 Outcome

Following the refinement of the programme theory, we will hold a knowledge exchange day involving the stakeholders and PPI group. This event will bring additional key stakeholders (commissioners, patients, practitioners and fellow researchers) together to hear the key insights from the project and to share their experiences and perspectives. Together, attendees of this event will build a strategy on how to address key priorities collectively, including:

- How to enhance relational continuity of care in practice
- How to support the general practice workforce in delivering relational continuity of care
- How to enhance the likelihood of models that enhance continuity can support those from underserved communities

We will invite a graphic recorder to attend the meeting to produce a record of the discussions through a visual synthesis and short film of the event to disseminate the findings of the knowledge exchange day more widely.

# 4. STUDY SETTING

We will recruit four general practices in England, including practices from deprived areas and those with high levels of continuity through systems including GP personal lists, multi-disciplinary micro-teams, or buddy groups.

Through our study contacts we are aware of practices that fit this remit, and ask the Research Delivery Network (RDN) to approach these practices to participate in the study. The project research team will liaise with the RDN and practice study contact (identified by the RDN) to ensure that inclusion/exclusion criteria for the study are fully understood.

# 5. SAMPLE AND RECRUITMENT

## 5.1 Stage 2 – Realist evaluation

### 5.1.1 Sampling

Four general practice sites for participation in the realist evaluation site work will be recruited through collaboration with the South West Research Delivery Network. We will target practices known to the research team to have high levels of continuity through systems including GP personal lists, multi-disciplinary micro-teams, or buddy groups. We will include practices across:

- Urban, rural and costal geographical contexts
- A variety of socio-economic locations, including areas of significant deprivation and those which are least deprived.

### 5.1.2 Ethnographic observation

The embedded researcher will conduct ethnographic observations and engage in informal conversations with a range of practice staff, including receptionists, administrators, clinicians, and other members of the multidisciplinary team, to develop an in-depth understanding of how technical infrastructure, informational continuity, and continuity-related workflows are enacted in daily practice. The focus will be on organisational routines, staff interactions, and socio-technical processes that shape continuity of care.

The researcher will observe:

- Reception staff as they speak to patients on the phone, triage requests, and book appointments, including how they use eConsultation systems (or similar software).
- Administrative workflows, including how clinical documents, test results, and referral information are processed, filed, and allocated.
- Team-based decision-making, such as how staff collaborate to allocate care and manage ongoing patient relationships.

The researcher will not directly observe clinician-patient consultations.

In addition to general observation, we will ask staff to guide us through 'walk-throughs' of key tasks that support continuity. These may include:

- Booking acute or routine appointments, and how these are allocated to specific GPs or members of the practice team.
- How triage systems are operated and adjusted (e.g. prioritising continuity versus availability).
- Allocation of eConsultation or online requests and how these are routed to clinicians.
- Practice meetings and/or informal team 'huddles' where staff coordinate care or review patients.
- Communication methods within the team (e.g. internal messaging, tasks, flags or summaries in electronic health records).
- Handover procedures (e.g. end-of-day summaries, covering absent colleagues).
- Use of alerts, reminders, or notes within the electronic health record to promote continuity (i.e. 'usual GP' tags).
- Any exceptions, workarounds, or local adaptations that staff use to ensure continuity for specific patients or types of care.

Fieldnotes will be written contemporaneously or shortly after each observation session, capturing descriptive detail (what is happening) as well as interpretive notes (how it may relate to continuity of care). The researcher will also reflect on their own positioning, role, and potential influence on the setting, in keeping with ethnographic reflexivity.

### 5.1.3 Size of sample for realist interviews

We will interview 3-4 staff members in each practice to a total sample size of 12-16 realist interviews. We will ask the practice to identify members of staff who have specific ideas and explanations of mechanisms enhancing continuity and how they are implemented or have evolved. We envisage that this will involve speaking to GPs, receptionists, and practice management staff.

### 5.1.4 Inclusion criteria for realist interviews

Practice staff

- Any member of staff identified by the practice who have specific ideas and explanations of mechanisms enhancing continuity and how they are implemented or have evolved.

### 5.1.4 Exclusion criteria for realist interviews

Practice staff

- No specific exclusion criteria

### 5.1.5 Recruitment

The South West Research Delivery Network (RDN) will support the recruitment of GP practices sites. A Research Information Sheet for Practices (RISP) will be developed by the research team to support with the initial recruitment of practice sites.

After initial engagement via the RDN, the RDN will e-introduce a named contact within the practice to the research team. The researcher will contact the practice to further explain the study aims and what is required from the practice, including:

- Identification of practice staff for interviews
- Explaining the ethnographic observational work

**Practice participants for realist interviews**

The practice study contact will identify potential practice staff for the realist interviews who will be sent an invitation email, with the realist interview participant information sheet.

Practice staff will be invited to speak to the embedded study researcher during the two-week observation period to discuss taking part in the study. The researcher will take verbal consent from the potential participant and the participant will be sent a link to complete the consent form digitally using Microsoft Forms. The mode of interview (face-to face/online) and location, if applicable, will be chosen by the participant. The participant may choose to conduct the interview online after the two week observation period at the practice has ended.

The practice study contact will telephone or email potential GP/clinical pharmacist participants who have not made contact with the research team within 5 days of receiving the original email about the study. This contact is to remind potential participants about the study and provide them with an opportunity to take part in the research during the two week observation period.

### 5.1.6 Ethnographic observation: Observations and Informal Conversations

As part of this study, an embedded researcher will conduct non-participant observations and informal conversations with practice staff in order to understand team roles, routines, and workflows that support continuity of care in general practice. These activities will focus on staff practices and interprofessional collaboration; no clinician–patient consultations will be observed, and no patient-identifiable information will be recorded.

**Publicising the study to staff**

Before fieldwork begins, we will ensure that all staff at participating practices are aware of the study. This will include:

- A brief presentation at a team or practice meeting (coordinated with the practice study contact and management)
- Printed information sheets and posters made available in shared staff areas
- Emails sent by the practice manager or study team introducing the researcher, explaining the aims and nature of the observations, and outlining how staff can opt out

**Consent and right to opt out of observations**

Because ethnographic research involves immersion in real-world settings where obtaining written consent from every individual in every interaction may not be practical, we will adopt a tiered and ongoing permission process:

- Each participating practice will provide permission for the researcher to be present and observe day-to-day activities. This does not replace individual staff members' rights to opt out, which will be respected at all times.
- Individual staff members will be given clear opportunities to opt out of being observed or engaging in informal conversations. This includes:
    - Directly informing the researcher
    - Speaking to the practice manager or study lead, who can relay the message
    - Using a designated email address to contact the study team

The researcher will make themselves known to staff at each visit and will check in regularly to ensure ongoing comfort with their presence. Signs will also be posted in shared areas indicating when observation is taking place.

If a staff member appears uncomfortable, or asks not to be included, the researcher will respectfully step away and no notes will be taken about that interaction.

**Informal Conversations**

Informal conversations may arise naturally during the researcher's time in the practice. These will not be recorded but may be noted in fieldnotes if relevant to the research question. If a conversation moves into a sensitive area or the participant shares identifiable information about patients or colleagues, the researcher will not record this information and will remind the staff member that participation is voluntary.

Where specific insights from informal conversations are particularly relevant, the researcher may follow up with the staff member to obtain verbal confirmation that the information may be noted and used anonymously in analysis.

# 6. ETHICAL AND REGULATORY CONSIDERATIONS

## 6.1 Potential risks

Over the course of the study, we will work to align methodologies and conduct to the UK Policy for health and social care research, in order to protect members of the public and professionals involved in the research. A number of potential risks have been identified, which will require appropriate management and mitigation:

- **Data Management**
  A secure chain of data handling from the point of collection at research sites to being received, processed and stored by the research team at the University of Exeter will be in place to ensure that interview recordings are handled and stored in an appropriate manner. Field recordings will be taken using an encrypted audio recorder or through a secure University of Exeter Teams account (for remote interviews. The data extracted from realist interview audio recordings will be stored on a dedicated, secure, restricted access University of Exeter SharePoint site for the duration of the study, which only the research team and data custodian will have access to. Interview recordings will only be stored for up to 90 days after recording to allow anonymised transcriptions to be made using Microsoft Word or Microsoft Teams auto-transcibe. After this period, the recorded interview files will be deleted.
- **Time incumbency**
  Given the current pressures and demands on the health system in the UK, we acknowledge that an hour-long interview is not an insignificant time commitment for GPs and practice-based staff. The research team will make every effort to ensure that interviews take place at a time that is convenient to participants and do not impinge on daily clinical practice or work. The £50 incentive for professional participants recognises the time commitment made by participants to contribute to this research study.
- **Unintended inclusion of practice staff**
  As the researcher will be present in the day-to-day setting of the practice, there is a risk that individuals may be observed or included in fieldnotes without fully understanding that they are part of a research study. This is mitigated by practice posters, emails from practice management to all staff, regular researcher check-ins, and multiple, accessible opt-out routes.
- **Discomfort with being observed**
  Some staff may feel uneasy or self-conscious about being observed in their work environment. We will address this by providing clear and ongoing opportunities to opt out. Members of staff can either speak to the practice management or the embedded researcher to request that they are not observed at work. The researcher will end any observations if the staff members are showing any signs of discomfort.
- **Confidentiality of informal conversations**

Informal conversations may include sensitive information or identifiable content about patients or colleagues. There is a risk of accidental disclosure. To mitigate this, the researcher will avoid recording identifiable information and will not record sensitive content.

- **Perceived pressure to participate**
  Staff may feel pressure to engage with the researcher due to practice-level approval or professional hierarchies. This is addressed through a clear explanation that participation is voluntary and that opting out will not affect their role or relationships within the practice.

## 6.2 Research Ethics Committee (REC) and other regulatory review

Health Research Authority (HRA) approval will be sought before the commencement of the practice recruitment or any general practice based research detailed in this protocol. As part of this approval process, a favourable NHS Research Ethics Committee (REC) decision will need to be in place. The participant information sheets, consent forms, topic guides and other relevant documents will be submitted for review as part of this process. All correspondence with the REC will be retained for information. The REC will be informed when the study ends.

**Regulatory Review & Compliance**

The Chief Investigator (CI) will ensure that appropriate approvals and confirmations are in place with the participating general practices before sites commence enrolment of practice staff into the proposed research. Specific arrangements on how to gain approval from participating organisations will be in place and comply with the relevant guidance for NHS sites. For any amendment to the study, the CI, in agreement with the sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The CI or research post-doctoral fellow will work with sites (both the NHS sites and the research team based at the University of Exeter) to put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

**Amendments**

Any proposed substantial or non-substantial amendments to the study will be shared with the HRA and REC for consideration after discussion with the supervisory team and the sponsor. The sponsor will decide whether an amendment is substantial or non-substantial for the purpose of submission to the REC. Once approved, any participating sites, the research team and the project steering committee will be notified of any amendment details. The amendment history will be documented through retention of all documents pertaining to application for amendment and correspondence with the relevant stakeholders (i.e. the sponsor, REC, research sites) over the course of application and implementation of any amendments.

## 6.3 Peer review

The research study underwent extensive peer review from advisors internal to the University of Exeter and from the Wellcome grant panel as part of the grant application process.

## 6.4 Patient & Public Involvement

Patient and public involvement (PPI) with the proposed research will be critical to ensure that the planned research is meaningful to patients and adequately informed by representatives of patients who receive general practice-based care. We will use the Public Involvement in Research Impact Toolkit (PIRIT) which is a set of tools, including a planning tool, to help plan and incorporate public involvement in the research, and track the contributions made in each interaction and meeting.(26) The PIRIT tracking tool also provides a log to allow us to record the impact of public involvement in this project against the UK Standards for Public Involvement.

We have established a PPI advisory group across three different projects related to continuity of care being conducted in Exeter. Working with the same group of people will allow us to build longitudinal relationships and capacity within the PPI team, and better understand through different projects the patient's perspective on what is important for them in experiencing continuity. A member of the local PPI group has agreed to act as a patient mentor throughout this project to work closely alongside the research team. Together we will develop a PPIE strategy within the first three months of the project. This mentor will join the project PPI advisory group. The PPI group will be placed as equitable stakeholders, feeding directly into the development of the IPT, analysis, and development of the final programme theory to glean real-life experiences and inform interpretation of the data. For instance, we will ask members of our PPI group if they would like to be involved with transcript coding, and what training if any they need to be able to do this. We will invite interested PPI members to code selected transcripts and join the team during analysis meetings to help develop the themes, theories and approach to disseminating the results.

The PPI group will meet routinely, likely 3-4 time over the course of the study and based around the preferences of the group. We will work with our PPI group to inform our dissemination strategies across each of our continuity of care projects.

We will ensure that any public involvement in my research involves those who don't always get a voice through a variety of engagement activities. The NIHR Applied Research Collaboration South West Peninsula (PenARC) Patient and Public involvement team, who supports effective involvement and engagement of patients and public members in health research in the South West of England, have advised us throughout the project development. This team will continue to provide guidance and through their contacts, and based on the PPI development work, will link the project team in with community groups of people from marginalised and ethnic communities, people with learning disabilities, long-

term conditions and mental health issues. Throughout the course of this project, we will meet and engage with these community groups, in their own setting, to hear and learn from their experiences of accessing general practice and incorporate these insights when conducting the realist analysis. Developing a plan for making these links will be part of the project patient involvement and engagement strategy, which we will develop in the first three months of the project alongside the patient mentor.

## 6.5 Steering committee

In the first three months of the project we will convene a Steering Committee to monitor and supervise the research project. This committee will comprise of:

- A Chairperson independent of the research project
- A researcher with experience in realist methods
- The project patient/PPIE mentor
- Members with expertise relevant to this project such as health economics, health policy and health services research.
- Observers including representatives of the University of Exeter, local clinical research network and Wellcome will be invited to each meeting

The Steering Committee will meet at least once a year over the course of this research project. We will submit formal progress reports to the Committee prior to each meeting. Minutes of meetings will be sent to all members, our sponsor (the University of Exeter) and Wellcome.

## 6.6 Data protection and patient confidentiality

All research team members will comply with the requirements of the General Data Protection Regulation (UK-GDPR) and Data Protection Act (DPA 2018) regarding data collection, storage, processing, and disclosure of personal information.

### 6.6.1 Realist interviews

NHS organisations require a minimum of 256bit encryption for data security when audio recording clinical encounters. To satisfy this requirement, face-to-face Olympus DS-9500 audio recorders will be used to record the realist interviews. These recorders will have password protection for both audio recording and retrieval of recorded data.

Anonymised audio recorded files will be saved with a 7-character randomised alphanumerical filename to the dedicated SharePoint site for the purposes of transcription for the duration of the study. Extracted data from patient profiles will be anonymised and labelled with an encounter number unrelated to any patient details to link the record to the relevant audio file before being saved to the project SharePoint. A password-protected master sheet on the secure SharePoint site will contain a list of filenames of audio

recordings and anonymised patient profile filename to which each recording corresponds. All data for the study will be stored on a dedicated SharePoint site hosted by the University of Exeter, in line with the university's research storage guidance. SharePoint has the functionality to grant access on varying levels of membership to users. Access to data will be granted on a 'minimum required access' basis for members of the research team. In the first instance, this will be restricted to the chief investigator alone, but may be granted to members of the supervisory team if required. The sponsor may also be granted access if there are any ethical, governance or regulatory concerns. Anonymised transcripts of the realist interview (Stage 2) recordings and associated data extracts will be stored for 10 years in accordance with consent that was freely given to participate in the study, to allow for research beyond the scope of the proposed study to interrogate the data further using different methods (e.g. conversation analysis) or research questions. The pseudoanonymised audio recordings from Stage 2 will be retained only for the duration of the study to allow for transcription. The research team will destroy recordings from the realist interviews once transcripts have been made.

### 6.6.2 Ethnographic observations

All ethnographic observations will be treated with strict confidentiality. Observations will be recorded in a way that avoids the identification of individual participants wherever possible. Field notes will be anonymised at the point of writing, using pseudonyms or role descriptions rather than real names or identifiable information. Any potentially identifying details such as specific events, job titles, or locations will be generalised or removed during transcription and analysis to protect participant privacy.

Observational data will be securely stored on encrypted, password-protected devices and backed up on secure, University of Exeter Sharepoint servers. Handwritten notes, if taken, will be securely stored in a locked cabinet in a restricted-access office at the University of Exeter.

Only members of the research team will have access to the raw observational data. Participants will be made aware that they are part of a study involving ethnographic observation.

In any outputs (e.g. publications, presentations, reports), observational data will be reported in a fully anonymised form to ensure individuals, teams, or organisations cannot be identified. Where necessary, composite examples or paraphrased descriptions will be used to preserve anonymity while retaining the meaning and context of the data.

In the event of data being disclosed that is deemed inappropriate or where patient safety might be of concern, the CI will inform the supervisory group and report any concerns immediately to the sponsor. The data collected will remain the property of the University of Exeter. Dr Nada Khan will be the data custodian for the data collected in this study.

## 6.7 Indemnity Public Liability Insurance and Employer's Liability

Insurance is provided by Aviva Insurance Ltd through the sponsor, with full details available at:
https://www.exeter.ac.uk/departments/cgr/insuranceauditandrisk/insurancepolicies/public/ Personal professional indemnity arrangements, the Clinical Negligence Scheme for General Practice and any employer-granted vicarious liability will be applicable for staff working in or employed through general practices and primary care networks. No arrangements have been made for the payment of compensation in the event of harm to the research participants where no legal liability arises.

## 6.8 Access to the final study dataset

For the duration of the study, access to the final dataset will be restricted to the immediate research team (i.e. the CI and the research team). The retained data will be stored in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act (DPA).

## 6.9 End of study

The end of the study will be defined as the date of the last interview of the last participant to the realist interviews or the end of the ethnographic observation in the general practice sites, whichever comes last. .

# 8 DISSEMINATION POLICY

## 8.1 Dissemination policy

The protocol will be made publicly available on the research study website. As a predicate of Wellcome funding, all research published will be made publicly available via open access. Other outputs will include:

- Conference presentations
- Social media updates via BlueSky
- Blogs posted on the project webpage
- Plain English Language summaries (co-produced with the PPI group)
- Policy briefings targeting general practice professional groups and national bodies
- Dissemenation strategies as identified at the end of the project knowledge exchange day including a study infographic

The anonymised data will be deposited in a Wellcome-approved recognised data repository. We will submit the data to Figshare, which will allow access for others to view and download datasets for secondary use through a CC-BY license.

All interview transcripts and fieldnotes will be anonymised such that the participants and the practice are not identifiable. Fieldnotes will be redacted where anonymisation is not possible. Realist interview participants will complete a consent form that will describe the nature of the data sharing and their right to withdraw their data from the study at any point. Any data that is withdrawn will not be shared.

## 8.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship rights will be granted in line with the International Committee of Medical Journal Editors (ICMJE) recommendations. There is no intention to make use of professional writing services

# Gantt chart

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