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Pharm-CONNECT

Continuity of Care in General Practice Multidisciplinary Teams: Understanding the Impact of Pharmacy Roles and Measuring Continuity Across the Wider Team

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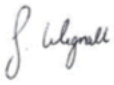
The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

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: 

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1. BACKGROUND

Continuity of care in general practice is essential for improved patient outcomes and clinician satisfaction. However, continuity is declining, partly due to the rise in multidisciplinary teams (MDTs). Traditional definitions focusing on the GP-patient relationship no longer reflect current practice, as pharmacists and other professionals play increasing roles in patient care.

1.1 Continuity of care in general practice

Continuity of care matters in general practice for patients, and for their health outcomes. Patients value having a personal, one-to-one relationship with a clinician, and feel that continuity means that their clinician knows them, gives clear and consistent advice, and leads to a reciprocal relationship based on trust and respect.(1) GPs also value providing continuity of care, and it can increase clinician job satisfaction through a perception of being able to provide better and more tailored care.(1)

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, better medicines management and deprescribing of medication in the elderly. (2-4) However, continuity of care is declining in UK general practice, and one of the challenges to maintaining continuity of care includes the increasing multi-disciplinary team-based model of care within primary care.(5, 6)

Continuity of care in general practice has traditionally been defined in terms of relational continuity, or the ongoing interpersonal and therapeutic relationship between a specific GP and a patient built up over time. With the increasing use of multidisciplinary teams, GPs are now only responsible for 44% of patient contacts in general practice.(7) There is therefore a need to better understand how the changing landscape of the general practice workforce is impacting on continuity of care, and how to measure continuity within the wider practice team.

1.2 The increasing multidisciplinary team in general practice

General practice has increasingly worked under a multidisciplinary team (MDT) model. One of the first widespread additions to traditional GP and nursing teams were clinical pharmacists with the launch of the 'Clinical Pharmacists in GP Practices scheme' pilot in 2016-17, following the publication of the General Practice Forward View (GPFV). This scheme offered an investment to integrate over 2000 clinical pharmacists into general practice by 2020.(8) An increasing shift towards MDT working was then underpinned by the NHS Long-Term Plan which offered funding for a greater range of allied health professionals to offset a projected gap between supply and demand in primary care. The subsequent Additional Roles Reimbursement Scheme (ARRS) provides primary care networks (PCNs) with funding for roles such as clinical pharmacists, nurse practitioners and social prescribers as part of the general practice team.(9)

Clinical pharmacists in particular have been taking an increasing role in general practice since the 2016 GPFV pilot. As part of the ARRS funding, clinical pharmacists in general practice were able to transfer across as PCN pharmacists and were amongst the first roles agreed by NHS England for recruitment into general practice through the ARRS.(10) Likely due to the GPFV and early adoption of pharmacy roles to the ARRS, clinical pharmacists and pharmacy technicians have comprised the majority of professionals that are funded under the ARRS, with over 8000 pharmacists recruited into general practice since 2019.(11) Clinical pharmacists and pharmacy technicians have continued to expand their clinical role, particularly in long-term condition care, in general practice, and in some practices, will have a particular role in managing patients over time.(12)

An increasing team-based way of working in general practice means that traditional ways of looking at continuity of care just in terms of the relationship between a GP and a patient do not reflect current practice. Ladds and Greenhalgh described a new conceptual framework for continuity of care to describe not just the challenges, but the opportunities for continuity of care with increasing team-based working.(13, 14) This framework describes not just relational continuity, but informational continuity and 'distributed work', which is the totality of tasks undertaken by a multidisciplinary team (MDT) of clinical professionals to coordinate patient care. Their paper gives the example of a patient with multimorbidity who sees their long-term GP to manage their chronic illness, but also the practice clinical pharmacists for medication reviews, with members of the team working together through the electronic record and multidisciplinary discussions to coordinate care and gain an understanding of what care is being provided and potential gaps.(13) This conceptualisation of continuity of care mirrors that of Shortell, who defined continuity of care across different professionals as 'the extent to which services are received as part of a coordinated and uninterrupted succession of events consistent with the medical care needs of patients'.(15)

There is a gap in evidence around how additional roles in general practice, including pharmacists, are impacting on continuity of care. It is unclear if work distributed across different professionals in primary care leads to more fragmented care from the patient or clinician perspective. And while some allied health care practitioners will book their own follow-ups to try and maintain continuity of care with their patients, this continuity of care between allied health professionals and their patients is unmeasured at present because the tools developed to measure continuity of care focus on the GP-patient relationship.(16) Ladds and Greenhalgh suggest a need for further qualitative and quantitative evaluation of extended definitions of continuity of care, including distributed team-working in general practice.(13) It is important to also consider the experienced continuity of patients, which is their perception of a coordinated and smooth progression of care across different team members.(17)

1.3 Measuring continuity of care in multi-disciplinary teams

While research has demonstrated that continuity of care is associated with positive outcomes for patients, measuring continuity effectively is important in order to then

underpin any initiatives to improve it.(18) There are currently two broad approaches to measuring continuity of care: using electronic health records which provide data on which patient sees which GP, or asking patients how often they are able to see or speak to their preferred GP, which is the approach taken in the GP Patient Survey.(5)

Current tools to measure continuity of care do not take the multidisciplinary team in general practice into account (see Table 1 for a summary of common approaches to measuring continuity of care). For instance, the St Leonard's Index of Continuity of Care (SLICC) for measuring continuity of care in practices through the electronic health record assumes that the patient will have a clinical relationship with their named/list-holding GP. The Usual Provider of Care (UPC) index has been recently modified to measure team-based continuity of care. However, this approach requires each patient to be cared for by a specific, and known team, as the modified UPC was calculated by dividing the number of visits to the patient's most visited clinician team by the total number of clinician consultations they attended within the measurement period.(19) Microteams are a term used to describe the 'organisation of mini-multidisciplinary teams that may serve a particular patient group within the practice'.(20) Microteams and named teams are not widespread in their use in UK general practice, and within practices using microteams, information on which clinicians belong to each team is often not available on electronic health records to allow routine measurement.(20)

Table 1 – Common approaches to measuring continuity of care (21)

Name of score	How is continuity measured?	Benefits	Disadvantages for team-based continuity measurements
Usual provider of care (UPC)	The proportion of appointments with the most frequently seen GP	Simple to use and calculate	Requires a minimum number of consultations per patient over enough time to calculate continuity
St Leonard's Index of Continuity of Care (SLICC)	The percentage of consultations a patient has with a named, list-holding GP	Can be applied to short timescales, so can be calculated and monitored monthly	Requires a named GP and does not take into account team-based care
Continuity of Care index/Bice-Boxerman index	Measures the frequency of consultations with each care provider and the dispersion of visits between them	Takes into account continuity with more than one named GP	Requires a longer-term follow up to reach a meaningful threshold for minimum consultations

As an increasing number of appointments in general practice are conducted by the wider practice team, it is important to quantify whether patients do experience continuity of care from the wider clinical general practice team for quality improvement purposes.(21) A continuity of care measure assessing patient contacts within a multidisciplinary team might, for instance, consider GP-patient continuity weighted alongside a calculation of patient contacts with additional clinical roles within the wider team.

2. RATIONALE

This study addresses the gap in understanding how MDTs, particularly clinical pharmacists and pharmacy technicians, impact continuity of care. It also responds to the need for practical tools to measure continuity within evolving primary care teams.

3. RESEARCH QUESTION / AIMS

This project aims to better understand the impact of the widening team of professionals on conceptualisations of continuity of care and how care is coordinated through informational and distributed continuity from the professional and patient perspective. The specific objectives are, using pharmacists and pharmacy technicians as an exemplar, to:

1. Understand professional experiences of distributed and informational continuity.
2. Understand patient perceptions of continuity in MDT-led care.
3. Explore how MDT working affects relational continuity with GPs.
4. Develop recommendations for a continuity of care measure suitable for MDTs.

Outcomes

- A theory of continuity in MDT-based primary care.
- A set of consensus-driven measurement recommendations.

4. STUDY DESIGN AND METHODS OF DATA COLLECTION AND ANALYSIS

We will meet the objectives of this study through two workstreams: a qualitative study to meet objectives 1-3, and a consensus group approach to meet objective 4.

4.1 Workstream 1 – Qualitative interviews

This project will take a qualitative approach to meet objectives 1-3 and aims to develop a theoretical framework describing how GPs and the general practice pharmacy workforce provide continuity of care, the impact of clinical pharmacists and pharmacy technicians on continuity, and the patient perspectives on how their care is coordinated.

4.1.1 Sample and recruitment

We will sample GPs, clinical pharmacists, pharmacy technicians and patients from practices in the South West of England which promote a continuity of care approach through the Research Delivery Network.

We will target general practices from catchment areas with higher densities of patient deprivation, or those practices identifying as part of 'Deep End' networks for recruitment to the professional and patient interviews. Mortality, hospital admissions and multimorbidity rates are higher in deprived areas, while patient satisfaction with general practice is lower in these areas, and we want to ensure we capture the experiences of those working and receiving care in this context.(22-24)

We will aim to recruit 10-15 GPs, 10-15 clinical pharmacists and pharmacy technicians and 10-15 patients. We will move away from conceptualisations of 'data saturation', which are contested within the qualitative literature, and instead of focussing on the number of interviews conducted, we will focus on the quality of the sample, the interview content, and data triangulation to enrich our findings.(25) This approach will focus on evaluations of sample size sufficiency and theme saturation in terms of data adequacy and 'information power' rather than the number of interviews conducted.(26, 27)

4.1.2 Interviews

Interviews will be conducted either in person or online, depending on the participant's preference. Face-to-face professional interviews will be carried out within the participant's place of work/general practice setting. Face-to-face patient interviews will be carried out at patient's homes. They will be led by the project post-doctoral researcher, Dr Mary Carter.

We will ask clinical staff to provide verbal 'walk throughs' of the processes they use when seeing patients, recording information and working as an MDT, and their impression of the impact on GP-patient and pharmacist-patient continuity. Specific to the pharmacy roles, we will ask which clinical activities they perform that allow them to provide continuity of care (i.e. long-term condition management). We will speak to patients about their experiences of distributed care across the multidisciplinary prescribing and medicines team.

4.1.3 Analysis

We will use a grounded theory approach to analyse the data. Grounded theory is an inductive qualitative methodology which will allow us to develop themes and generate a theory directly from what the participants have told us about continuity of care and the impact of clinical pharmacists on patient care, coordination and information sharing.(28) This approach is particularly suited to this study, as we can use a constant comparative approach (a feature of a grounded theory analysis) to inform comparisons between the interviews from different groups of participants, and to uncover the basic social processes of how continuity of care is managed across the primary care team. We will follow traditional approaches to a grounded theory analysis.(29) Broadly, the phases of a grounded theory approach involve first developing separate topic guides from the literature for each group of participants and in discussion with the research team and PPI group.

Interviews will be digitally recorded and transcribed verbatim using a Plaud Note device. The research staff responsible for analysis will read through all transcripts to check the text and to familiarise themselves with the data. The transcripts will then be coded using a 'line by line' approach, followed by axial coding to group the initial open coding into sub-themes. We will then develop overarching themes before moving to the theory generating stage by looking at the relationships between the themes and better understanding the relational nature of the themes to one another.

4.1.4 Philosophical approach

Grounded theory traditionally takes a critical realist ontological approach. We will use this philosophical approach to the interviews and analysis in the project, as it will allow us to focus on understanding different roles in general practice, the meaning of these roles, and the relationships between them.(30)

4.1.5 Outcome

The outcome of the qualitative stage of this project will be the generation of a data-driven theory exploring and explaining processes of continuity of care and the impact of pharmacy roles in general practice.

An added benefit of taking a grounded theory approach is that we will develop a working theory of team-based working in general practice based on our interviews with this professional working group. New data and evidence can be used to adapt and update the theory in future work. Our final theoretical conceptualisation will become a workable entity which can be tested in other populations, i.e. other ARRS team members working in general practice (e.g. physiotherapists, nurse practitioners) to see if it is relevant, reliable and valid.

4.2 Workstream 2 – Consensus group (Nominal Group Technique):

The second part of this project aims to meet objective 4 of the study, and will use a consensus group method to develop recommendations to determine how to measure continuity of care across an MDT.

4.2.1 Initial data gathering

We will conduct a focused review of the literature to identify and consider whether or how existing measures can be used or adapted. We will seek advice from our collaborators, Dr Kate Sidaway-Lee and Sir Denis Pereira Gray, who have developed and reviewed ways of measuring continuity of care in practice.(21)

4.2.2 Method – Nominal Group Technique (NGT)

The Nominal Group Technique (NGT) is a structured, multi-step facilitated group meeting used to elicit and prioritise responses to a specific question from groups of people with specific insights into the problem and aims to develop consensus in a topic area.(31) Formalised methods like the NGT are useful when organising subjective judgements on a

topic on which a group of people may have a diverse range of opinions. The NGT has been successfully adapted for use on virtual platforms.

Alternative group processes for consensus building include the Delphi technique and the Consensus Development Conference. The Delphi technique is a multi-stage survey technique for decision making and involves rounds of anonymised survey responses. The consensus development conference involves several days of meetings to seek general agreement on a topic. The advantages of the NGT are that it combines idea generation and problem solving into one short group process which encourages participation of each group member, and avoids problems such as dominant personalities within group meetings.(32)

4.2.3 Participants

NGT approaches typically require a sample of people who have experience, expertise and insight into the problem being explored. For this project, participants will include:

- GPs
- Pharmacists and pharmacy technicians working in General Practice
- Pharmacy medicine optimisation leads, workforce leads, or primary care leads
- Researchers/academics and data scientists using big data and looking at continuity of care for research purposes
- Other participants, including other ARRS role team members, as identified during the project development phase and from PPI input

Individuals within the NGT must be able to 'speak a common language', so groups should avoid mixing participants from different roles/professional backgrounds where language, attitude and culture can inhibit group discussions. We will consider alongside advice from our collaborators how to split the NGT groups by role.(32) We will take the results of our NGT meeting to our PPI group for advice and tailoring.

4.2.4 How to develop the nominal question

An appropriate question, or questions, need to be developed for the nominal group to address. In this project, our initial question is: **what do we need to measure, what information or data do we need to measure, or how do we measure continuity of care across a multidisciplinary team**? We will conduct further development work to refine and test this question by speaking to our experienced collaborators (Kate Sidaway-Lee, Sir Denis Pereira Gray, David Bearman, Victoria Lings and the project patient mentor). The question development phase is important as a good question can provide a lot of conceptual detail about the matter being examined, however, a poor question will provide a lot of detail about something in which the organiser is not interested. We will test out the questions with our collaborators before it is used in the NGT group.

4.2.5 Process of an NGT

The meetings (up to two meetings) will be facilitated by the project post-doctoral researcher. We will use a modified NGT approach which involves sending members a review of published literature or a summary of continuity in general practice and how it is

measured prior to the meeting, alongside a short video explaining the purpose of the NGT and procedure to ensure a smooth implementation. These pre-meeting preparation steps can give participants a change to reflect on aspects of the main questions they will encounter in the NGT, which speeds up the process and prepares them better for the session.(33)

Steps in an NGT meeting are summarised below in Table 2: (31, 32)

Table 2: Steps in an NGT meeting

Step	Activity
1	Introduction
2	Presentation of the nominal question
3	Silent generation of ideas in writing • Typically around 15 minutes, in silence
4	Round robin feedback from group members to record each idea in a succinct phrase on a flip chart/virtual flip chart • The organiser asks each person in turn to share one item during the silent period • The contribution is written down using the phrase used by the participant
5	Group discussion of each idea in turn for clarification and evaluation • Typically around 30 minutes
6	Individual voting on priority ideas with the group decision being derived through rank-ordering or rating • Ranking to select the top ten ideas • Voting on the top ten ideas
7	Feedback of results, further discussion and re-voting • Discussion of the vote – the top ten items are listed on a flip chart in order of the most votes cast • Re-ranking and rating revised 'top ten' items
8	Conclusion of the nominal group

The introduction includes an explanation to the participants that subjective feelings are as important as factual statements. Each participant is invited to introduce themselves.

The individual ranking of items (step 6 above) is completed on a personal priority sheet. Each person ranks their top 10 items in order of priority, with 10 points to the most important item and 1 point to the least important item. The re-ranking exercise (step 7) involves the members again using a personal priority sheet in another rating procedure. Each person assigns a written value (100) for the most important item and a value between 0-100 for the remaining nine items. The NGT then concludes with a final ranked prioritisation list, which in this project, will reflect the ideas and processes important for measuring continuity of care across multidisciplinary teams in general practice. The NGT

approach has been successfully used as an online/virtual meeting, an approach we will use to help coordinate participating professionals and patients.(34)

4.2.6 Outcome

Following on from the NGT, we will use the priority scored items to consolidate recommendations for a measure of continuity of care relevant to multidisciplinary models of primary care service delivery. We will aim to use the results of the NGT meeting to develop an approach to measuring continuity of care across multidisciplinary teams in general practice. This approach will be further developed and tested through future funding applications.

5. STUDY SETTING

5.1 Workstream 1

General practices in South West England, including practices from deprived areas and those prioritising continuity.

The Research Delivery Network (RDN) will identify general practices (according to the study sampling frame) to approach 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.

5.2 Workstream 2

We will agree the mode of the NGT meeting (face-to face or online using Microsoft Teams) and location with all participants. Where some participants prefer a face-to-face meeting and others prefer an online meeting, we will arrange a 'hybrid' NGT meeting allowing for some participants to join remotely.

6. SAMPLE AND RECRUITMENT

6.1 Workstream 1

6.1.1 Sampling

Sites for participation in Workstream 1 will be sampled from the South West Peninsula (Cornwall, Devon and Somerset). Sites will be recruited through collaboration with the South West Research Delivery Network, targeting 'research' practices where possible) to include:

- Urban, rural and costal geographical contexts

- A variety of socio-economic locations, including areas of significant deprivation and those which are least deprived.

We will treat each practice as a 'case study', and recruit a GP, a pharmacy professional and a patient from each practice. This will allow us to compare and contrast experiences across different perspectives at each practice.

For pharmacy roles and GPs participating in the semi-structured interviews we will aim to gain a range of:

- Experience, both in terms of total years qualified and time spent practicing in a GP/PCN setting
- Ethnicities
- For pharmacy roles: qualifications (e.g. post graduate diploma, subsequent MSc beyond initial training, advance clinical practitioner status, prescriber status)

6.1.2 Size of sample

We will aim to recruit 10-15 GPs, 10-15 clinical pharmacists and pharmacy technicians and 10-15 patients. As we are aiming to include one role/patient from each practice we will therefore aim to include 10-15 general practice sites in total. We will move away from conceptualisations of 'data saturation', which are contested within the qualitative literature, and instead of focussing on the number of interviews conducted, we will focus on the quality of the sample, the interview content, and data triangulation to enrich our findings.(25) This approach will focus on evaluations of sample size sufficiency and theme saturation in terms of data adequacy and 'information power' rather than the number of interviews conducted.(26, 27) Our approach using Grounded Theory methods will also allow us to triangulate and compare and contrast the interviews between different participant groups.

6.1.3 Inclusion criteria

For patients

- Over 18 years old
- At least one GP and pharmacist appointment in the past year
- Able to freely give informed consent

Clinical pharmacists and pharmacy technicians

- Experience of caring for patients with long-term conditions and/or multimorbidity, for example in a diabetes clinic

GPs

- Experience of appointments (face-to-face/online/telephone) within the past six months
- At least one year's experience of working in general practice

6.1.4 Exclusion criteria

Patients

- Identified by practice research contact as being unsuitable for interview because of communication difficulties, welfare issues, 'decline contact' noted on patient record, lacking capacity to consent (for the patient) or safety issues (for the researcher)

Clinical pharmacists and pharmacy technicians
- No experience of caring for patients with long-term conditions and/or multi-morbidity

GPs
- Less than one year's experience of working in general practice

6.1.5 Recruitment

The South West Research Delivery Network (RDN) will support the recruitment of GP practices sites with engaged clinical pharmacists to participate in the research. This will be achieved through ongoing regular meetings with the CRN and the adoption of the Pharm-Connect study to the NIHR portfolio. 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 GPs and pharmacy staff for interviews
- Identification of patients for interviews

Patient participants

The practice study contact will coordinate a search of the practice computer system by practice staff to identify patients according to inclusion criteria.

The participating general practice (study contact or GP) will screen the list of potential participants to exclude anyone deemed unsuitable for interview on the following bases: communication difficulties, welfare issues, 'decline contact' noted on patient record, lacking capacity to consent (for the patient) or safety issues (for the researcher). Study packs containing an invitation letter, study information sheet and consent form will be posted from participating general practices until a required number of patients is reached.

Patients will be invited to contact the study researcher by email to discuss taking part in the study. The researcher will then contact the patient by phone to answer any questions and confirm that they would like to take part in the research. 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 MS forms.

The researcher will arrange an interview appointment with participants, and the mode of interview (face-to-face/online/telephone) and location, if applicable, will be chosen by the participant.

Two weeks after the study packs have been posted from the practice, the research team will send (via secure transfer) the practice study contact a list of those patients who have consented to take part in the study so that s/he knows who to remind about the study.

The practice study contact will telephone potential participants who have not made contact with the research team within 2 to 3 weeks of the mailout from the practice. This contact is to remind potential participants about the study and provide them with an opportunity to take part in the research. If the practice study contact is not able to speak with the potential participant at the first attempt, s/he will make two further attempts to do so. To preserve confidentiality, no voicemail messages will be left.

GP and clinical pharmacist participants

The practice study contact will identify potential GP and clinical pharmacist participants who will be sent an invitation email, with study information sheet and consent form as attachments.

GPs and clinical pharmacists will be invited to telephone or email the study researcher 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 MS forms. The mode of interview (face-to face/online/telephone) and location, if applicable, will be chosen by the participant.

Two weeks after the invitation emails have been sent, the research team will send (via secure transfer) the practice study contact a list of those GPs/clinical pharmacists who have consented to take part in the study so that s/he knows who to remind about the study.

The practice study contact will telephone or email potential GP/clinical pharmacist participants who have not made contact with the research team within 2 to 3 weeks 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. If the practice study contact is not able to speak with the potential participant at the first attempt, s/he will make two further attempts to do so. To preserve confidentiality, no voicemail messages will be left.

6.2 Workstream 2

6.2.1 Sampling

Nominal group technique approaches typically require a sample of people who have experience, expertise and insight into the problem being explored. For this project, participants will include:

- GPs
- Pharmacists and pharmacy technicians working in General Practice
- Pharmacy medicine optimisation leads, workforce leads, or primary care leads

- Researchers/academics and data scientists using big data and looking at continuity of care for research purposes
- Other participants, including other ARRS role team members, as identified during the project development phase and from PPI input

We will also invite feedback on the NGT results from our PPI group, however, they will not attend the group as professional participants.

6.1.2 Size of sample

We will aim to include 8-12 professional members to the NGT meetings. The sample needs to include a range of expertise, but also a number of participants that will allow useful discussion within the constraints of a meeting.

6.1.3 Inclusion criteria

The inclusion criteria will be kept broad to allow us to include participants across general practice, pharmacy roles, primary care research and other members of the general practice multi-disciplinary team.

6.1.4 Exclusion criteria

We will exclude participants who are unable to provide informed consent to participate in the meeting.

6.1.5 Recruitment

We will use our professional networks to recruit participants to the NGT meeting. The project team is comprised of academic GPs, pharmacists and primary care researchers, and we will target specific participants working in these areas and in continuity of care measurement research and known to the research team to target for their expert advice in the NGT meetings.

The research fellow will email the known contacts with an initial invitation to participate in the NGT meeting. The researcher will take consent from the potential participant (using the consent form) and will arrange a meeting date and time suitable for participants. We are aware that it may be difficult to arrange a time suitable for all 8-12 participants and will consider whether we need to hold two different meetings to allow each participant to attend. We will agree the mode of the NGT meeting (face-to face or online using Microsoft Teams) and location with all participants. Where some participants prefer a face-to-face meeting and others prefer an online meeting, we will arrange a 'hybrid' NGT meeting allowing for some participants to join remotely.

7. ETHICAL AND REGULATORY CONSIDERATIONS

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 patient, pharmacy role and GP profiles and anonymised audio recordings from Workstream 1 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. Workstream 1 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.
- Participant disclosures
  The research topic is unlikely to provoke recall of traumatic events or upsetting memories during qualitative interviews however, due to the unpredictable nature of responses from participants, this is not a risk that can be eliminated entirely. The interviews will be conducted by an experienced post-doctoral researcher who has experience of conducting qualitative interviews and is familiar with signs and non-verbal cues that may indicate participants are in distress or significantly upset. The interviewer will proactively work to avoid and minimise any upsetting topics of discussion however, if a participant does become distressed, they will be offered the opportunity to terminate the interview at any point.
- 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 pharmacy 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. The £75 incentive for professional participants recognises the time commitment made by participants to contribute to this research study. We have also costed in time for patient participation in interviews at £50 per interview (based on NIHR Involve payment guidelines for patient and public involvement).

7.2 Research Ethics Committee (REC) and other Regulatory review & reports

Health Research Authority (HRA) approval will be sought before the commencement of any research activity 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 primary care organisations before sites commence enrolment of patients, GPs and pharmacy 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 supervisory group 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.

7.3 Peer review

The research programme underwent extensive peer review as part of the grant application process.

7.4 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.(35) 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 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. This PPI group will advise and work with us throughout the course of this project.

Specifically, the PPI group involving patients will be involved in the interview development and analysis. We will conduct 'mock interviews' with members of our PPI group to inform our patient interview guides. 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. We will also discuss the interview guides with our pharmacy lead collaborators for comment.

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.

7.5 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. 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 clinical observations in Phase 1. 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 Workstream 1 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 Workstream 1 will be retained only for the duration of the study to allow for transcription. The research team will destroy Workstream 1 recordings once transcripts have been made.

In the event of data being disclosed that is deemed inappropriate or where patient safety might be of concern, the PI 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.

7.6 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.

7.7 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).

8 DISSEMINATION POLICY

8.1 Dissemination policy

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

- 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 and pharmacy professional groups and national bodies

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

					Year 1												Year 2					
		Apr-25	May-25	Jun-25	Jul-25	Aug-25	Sep-25	Oct-25	Nov-25	Dec-25	Jan-26	Feb-26	Mar-26	Apr-26	May-26	Jun-26	Jul-26	Aug-26	Sep-26	Oct-26	Nov-26	Dec-26
Month		-3	-2	-1	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Cross-cutting project goals																						
	Advertise for research fellow	■																				
	Research fellow interviews		■																			
	Research fellow in post				■																	
	Start NHS ethics application	■	■	■																		
	Complete ethics application and approvals				■	■																
	Start site selection and recruitment with RDN			■	■																	
	Discuss PPI involvement strategy with PPI group				■	■																
	RCGP Annual conference workshop																			■		
	SAPC symposium/workshop																					
																	■					
Workstream 1																						
	Identify practices and GP, pharmacist and patients for interview					■	■															
	Participant interviews						■	■	■													
	Interview analysis							■	■	■	■											
	Writing up results and preparing publications									■	■	■										

Workstream 2																						
	Focussed review of continuity measures																					
	Identify participants for NGT group																					
	NGT group meetings																					
	NGT group write up																					
	Development of MDT-based continuity measure																					
	Writing grant proposal for future funding to test measure																					

References

1. Ridd M, Shaw A, Salisbury C. 'Two sides of the coin'--the value of personal continuity to GPs: a qualitative interview study. Fam Pract. 2006;23(4):461-8.
2. Delgado J, Evans PH, Gray DP, Sidaway-Lee K, Allan L, Clare L, et al. Continuity of GP care for patients with dementia: impact on prescribing and the health of patients. Br J Gen Pract. 2022;72(715):e91-e8.
3. Pereira Gray DJ, Sidaway-Lee K, White E, Thorne A, Evans PH. Continuity of care with doctors-a matter of life and death? A systematic review of continuity of care and mortality. BMJ Open. 2018;8(6):e021161.
4. Sandvik H, Hetlevik O, Blinkenberg J, Hunskaar S. Continuity in general practice as predictor of mortality, acute hospitalisation, and use of out-of-hours care: a registry-based observational study in Norway. Br J Gen Pract. 2022;72(715):e84-e90.
5. Tammes P, Morris RW, Murphy M, Salisbury C. Is continuity of primary care declining in England? Practice-level longitudinal study from 2012 to 2017. Br J Gen Pract. 2021;71(707):e432-e40.
6. Pereira Gray D, Sidaway-Lee K, Johns C, Rickenbach M, Evans PH. Can general practice still provide meaningful continuity of care? BMJ. 2023;383:e074584.
7. Beech JO-M, S.; Mendelsohn, E.; Callan, C.; Keith, J.; Fisher, R. General practice data dashboard: Monitoring data on general practice: The Health Foundation; 2024 [Available from: https://www.health.org.uk/general-practice-data-dashboard.
8. General Practice Forward View. NHS England; 2016.
9. Expanding our workforce: NHS England; 2024 [Available from: https://www.england.nhs.uk/gp/expanding-our-workforce/.
10. Loke JC, Lee KW. Additional roles reimbursement to primary care networks: an uplift or downfall of general practice partnership? Br J Gen Pract. 2024;74(738):38-9.
11. More staff in general practice, but is the emerging mix of roles what's needed? : Nuffield Trust; 2023 [Available from: https://www.nuffieldtrust.org.uk/news-item/more-staff-in-general-practice-but-is-the-emerging-mix-of-roles-what-s-needed.
12. Mann CA, C.; Boyd, M. The role of clinical pharmacists in general practice in England: Impact, perspectives, barriers and facilitators. Research in Social and Administrative Pharmacy. 2022;18(8):3432-7.
13. Ladds E, Greenhalgh T. Modernising continuity: a new conceptual framework. Br J Gen Pract. 2023;73(731):246-8.
14. Ladds E, Greenhalgh T, Byng R, Rybczynska-Bunt S, Kalin A, Shaw S. A contemporary ontology of continuity in general practice: Capturing its multiple essences in a digital age. Soc Sci Med. 2023;332:116112.
15. Shortell SM. Continuity of medical care: conceptualization and measurement. Med Care. 1976;14(5):377-91.
16. Goff M, Jacobs S, Hammond J, Hindi A, Checkland K. Investigating the impact of primary care networks on continuity of care in English general practice: Analysis of interviews with patients and clinicians from a mixed methods study. Health Expect. 2024;27(2):e14032.
17. Gulliford M, Naithani S, Morgan M. What is 'continuity of care'? J Health Serv Res Policy. 2006;11(4):248-50.

18. Fraser CC, G. Measuring continuity of care in general practice: The Health Foundation; 2023 [Available from: https://www.health.org.uk/publications/long-reads/measuring-continuity-of-care-in-general-practice.
19. Xu W, Yu EYT, Chin WY, Mak IL, Chan CIY, Lam CLK, et al. Team-based continuity of care for patients with hypertension: a retrospective primary care cohort study in Hong Kong. Br J Gen Pract. 2023;73(736):e807-e15.
20. Coombs C, Cohen T, Duddy C, Mahtani KR, Owen E, Roberts N, et al. Primary care micro-teams: an international systematic review of patient and healthcare professional perspectives. Br J Gen Pract. 2023;73(734):e651-e8.
21. Gray DP, Sidaway-Lee K, Whitaker P, Evans P. Which methods are most practicable for measuring continuity within general practices? Br J Gen Pract. 2023;73(731):279-82.
22. Head A, Fleming K, Kypridemos C, Schofield P, Pearson-Stuttard J, O'Flaherty M. Inequalities in incident and prevalent multimorbidity in England, 2004-19: a population-based, descriptive study. Lancet Healthy Longev. 2021;2(8):e489-e97.
23. Payne RA, Abel GA, Guthrie B, Mercer SW. The effect of physical multimorbidity, mental health conditions and socioeconomic deprivation on unplanned admissions to hospital: a retrospective cohort study. CMAJ. 2013;185(5):E221-8.
24. Beech JS, J.; Fraser, C.; Thorlby, R.; Williamson, S.; Fisher, R. Doing more for less? A mixed-methods analysis of the experience of primary care networks in socioeconomically deprived areas. London: The Health Foundation; 2023.
25. Naeem MO, W.; Ranfagni, S. Demystification and Actualisation of Data Saturation in Qualitative Research Through Thematic Analysis. International Journal of Qualitative Methods. 2024;23.
26. Vasileiou K, Barnett J, Thorpe S, Young T. Characterising and justifying sample size sufficiency in interview-based studies: systematic analysis of qualitative health research over a 15-year period. BMC Med Res Methodol. 2018;18(1):148.
27. Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies: Guided by Information Power. Qual Health Res. 2016;26(13):1753-60.
28. Glaser BGS, A.L. The discovery of grounded theory: strategies for qualitative research. New York: Aldine de Gruyter; 1967.
29. Silverio SAG, W.; Wallace, H.; Brown, J. (Re)discovering Grounded Theory for Cross-Disciplinary Qualitative Health Research. In: Clift BG, J.; Bekker, S.; Batlle, I.C.; Chudzikowski, K.; Hatchard, J., editor. Qualitative Research Symposium Edited Volume. Bath: University of Bath; 2019. p. 41-60.
30. Hoddy ET. Critical realism in empirical research: employing techniques from grounded theory methodology. International Journal of Social Research Methodology. 2018;22(1):111-24.
31. Gill PJ, Hewitson P, Peile E, Harnden A. Prioritizing areas for quality marker development in children in UK general practice: extending the use of the nominal group technique. Fam Pract. 2012;29(5):567-75.
32. Gallagher M, Hares T, Spencer J, Bradshaw C, Webb I. The nominal group technique: a research tool for general practice? Fam Pract. 1993;10(1):76-81.
33. Khurshid F, O'Connor E, Thompson R, Hegazi I. Twelve tips for adopting the virtual Nominal Group Technique (vNGT) in medical education research. MedEdPublish (2016). 2023;13:18.
34. Riley-Bennett F, Russell L, Fisher R. An example of the adaptation of the Nominal Group Technique (NGT) to a virtual format (vNGT) within healthcare research. BMC Med Res Methodol. 2024;24(1):240.
35. Free Public Involvement in Research Impact Toolkit (PIRIT) launched for public use: Wales Cancer Research Centre and Marie Curie Research Centre; 2023 [Available from:

https://walescancerresearchcentre.org/free-public-involvement-in-research-impact-toolkit-pirit-launched-for-public-use/.