

PPhoCUs: Polypharmacy, Pharmacists and Clinical Uncertainty – Understanding how pharmacist decision making can be improved in the context of polypharmacy

Submission date 08/10/2024	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 15/10/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/11/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study looks at how pharmacists in GP practices make decisions when helping patients who take many different medications. People who take more than 10 medicines are more likely to have serious health issues and need hospital care. The study aims to understand how pharmacists handle these complex situations and make decisions when the best course of action is unclear.

Who can participate?

Pharmacists working in GP practices and patients who have appointments with these pharmacists can participate in the study.

What does the study involve?

The study involves recording patient appointments with GP pharmacists to see how decisions are made. Both pharmacists and patients will also be invited to individual interviews to share their experiences. Pharmacists will discuss how they make decisions, and patients will talk about their experiences during their appointments.

What are the possible benefits and risks of participating?

Participants may benefit from contributing to research that could improve pharmacist training and patient care in the future. There are minimal risks, but participants might feel uncomfortable being recorded or interviewed.

Where is the study run from?

University of Exeter (UK)

When is the study starting and how long is it expected to run for?

June 2024 to September 2026

Who is funding the study?

The study is funded by the School for Primary Care Research within the National Institute for Health Research (UK)

Who is the main contact?

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Contact information

Type(s)

Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

336527

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

UoE Sponsor number: 2022-23-31, CPMS 62607

Study information

Scientific Title

PPhoCUs: Polypharmacy, Pharmacists and Clinical Uncertainty

Acronym

PPhoCUs

Study objectives

How can clinical pharmacist decision-making be improved when delivering medication reviews in the context of polypharmacy and clinical uncertainty?

1. How do practice-based pharmacists approach clinical uncertainty when conducting reviews with patients who have complex polypharmacy?
2. What influences clinical pharmacists' decision making when encountering clinical uncertainty in patients with complex polypharmacy?
3. In the context of clinical uncertainty, what is the patient's experience of care and person-centred decision making delivered by clinical pharmacists in general practice?
4. In what way do the current education pathways for pharmacists in primary care meet the perceived learning needs for pharmacists managing clinical uncertainty in practice?
5. How might the standards for ongoing clinical education for pharmacists in GP practice settings (considering both clinical supervision and formal education) be further improved to support better patient-centred decision making in the context of clinical uncertainty?

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 27/06/2024, Yorkshire & The Humber - Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 207 9722504; leedswest.rec@hra.nhs.uk), ref: 24/YH/0120

Study design

Qualitative

Primary study design

Observational

Secondary study design

Qualitative study

Study setting(s)

GP practice

Study type(s)

Other

Participant information sheet

See outputs table

Health condition(s) or problem(s) studied

Polypharmacy (10 or more medicines)

Interventions

Phase 1: Observational audio recordings of structured medication reviews between pharmacists and patients

Phase 2: Semi-structured interviews with pharmacists

Phase 3: Semi-Structured interviews with patients

Phase 4: Focus group sessions to develop new intervention targeting pharmacist management of clinical uncertainty when reviewing polypharmacy in primary care

Intervention Type

Other

Primary outcome measure

Perceptions and experiences of clinical uncertainty using audio recordings of naturalistic encounters where pharmacists review polypharmacy with patients in GP practice settings

Secondary outcome measures

1. Joint navigation of clinical uncertainty using audio recordings of naturalistic encounters where pharmacists review polypharmacy with patients in GP practice settings
2. Pharmacist perceptions of clinical uncertainty using qualitative interviews
3. Patient perceptions of pharmacist-delivered polypharmacy reviews, including shared decision making, using qualitative interviews

Overall study start date

27/06/2024

Completion date

30/09/2026

Eligibility

Key inclusion criteria

For Pharmacists (in Phases 1 and 2):

1. Registered as a Pharmacist with the General Pharmaceutical Council
2. Employed in the primary care sector, based in either a general practice or primary care network setting
3. Currently delivering or able to deliver structured medication reviews

For Patients (in Phases 1 and 3):

1. 18 years old or older
2. Prescribed 10 or more medications on repeat
3. Booked to have a structured medication review with a clinical pharmacist in primary care
4. Able to freely give informed consent

Participant type(s)

Health professional, Service user

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

For Pharmacists:

1. Pharmacists working in secondary care or community pharmacy settings
2. Healthcare professionals who are not registered pharmacists
3. Pharmacists with no experience or ability to deliver SMRs

For Patients:

1. Under 18 years of age
2. Patients who are unable to freely give consent or lack capacity
3. End of Life Care patients
4. Care Home Residents
5. Patients identified by the host research site as being unsuitable for participation by virtue of being acutely or significantly unwell, difficulties in communicating, safety issues (e.g. noted on patient records or have overtly declined to be contacted by the practice) or welfare issues

Date of first enrolment

30/09/2024

Date of final enrolment

30/01/2026

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Exeter

Stocker Road

Exeter

United Kingdom

EX4 4PY

Sponsor information

Organisation

University of Exeter

Sponsor details

University Corporate Services, University of Exeter
G14, Lafrowda House, St Germans Road
Exeter
England
United Kingdom
EX4 6TL
+44 1392 726621
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Sponsor type

University/education

Website

<http://www.exeter.ac.uk/>

ROR

<https://ror.org/03yghzc09>

Funder(s)

Funder type

Government

Funder Name

NIHR School for Primary Care Research

Alternative Name(s)

School for Primary Care Research, NIHR SPCR

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The analysis of the data arising from the study will be combined into a final thesis as part of the Chief Investigator's PhD submission. This will be placed into the University of Exeter's Open Repository (Open Research Exeter, ORE) for public access. The study data will be owned by the University of Exeter. It is also anticipated that each phase will give rise to an accompanying

formal publication in a peer-reviewed journal. As a predicate of NIHR funding, all research published will be made publicly available via open access.

Other outputs will include:

- Conference presentations
- Social media updates via X and LinkedIn
- Blogs posted on Institutional webpages
- Plain English Language summaries (co-produced with the PAG)
- Policy briefings targeting pharmacy professional groups and national bodies

The outputs from this study will seek to inform and engage:

- Primary Care Clinical Pharmacists and Pharmacy Technicians
- Patients with significant polypharmacy
- Professional groups including the Royal Pharmaceutical Society, Centre for Pharmacy Postgraduate Education and Primary Care Pharmacy Association
- Higher Education Institutions and Academics currently offering postgraduate pharmacy education
- National bodies and policy makers, such as the General Pharmaceutical Council

Intention to publish date

01/06/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available. The ethical permission granted to this project does not allow for the long term retention of sensitive data or anonymised audio recordings beyond the study end date. Interview transcripts will be retained for up to 10 years on University of Exeter servers after the conclusion of the data collection, but will not be publicly available. The ethics permission granted for the PPhoCUs study allow for University of Exeter researchers to collaborate with external researchers around the retained dataset of interview transcripts, but not for these to be freely available on a public facing website or repository.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	for Patients version 2	19/06/2024	15/10/2024	No	Yes
Participant information sheet	for Pharmacists Phase 1 version 2	19/06/2024	15/10/2024	No	Yes
Participant information sheet	for Pharmacists Phase 2 version 2	19/06/2024	15/10/2024	No	Yes
Protocol file	version 1.1	19/06/2024	15/10/2024	No	No