

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

<b>Submission date</b> 08/10/2024	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 15/10/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/11/2024	<b>Condition category</b> 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?

Tomazo Kallis, [t.j.kallis@exeter.ac.uk](mailto:t.j.kallis@exeter.ac.uk)

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

### Contact name

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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  
res-sponsor@exeter.ac.uk

**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?
<a href="#">Participant information sheet</a>	for Patients version 2	19/06/2024	15/10/2024	No	Yes
<a href="#">Participant information sheet</a>	for Pharmacists Phase 1 version 2	19/06/2024	15/10/2024	No	Yes
<a href="#">Participant information sheet</a>	for Pharmacists Phase 2 version 2	19/06/2024	15/10/2024	No	Yes
<a href="#">Protocol file</a>	version 1.1	19/06/2024	15/10/2024	No	No