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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** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 15/10/2024	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 18/11/2025	**Condition category** Other	[_] Individual participant data [X] 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

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
336527

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Other

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

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
31/07/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Exeter
Stocker Road
Exeter
England
EX4 4PY

Sponsor information

Organisation
University of Exeter

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

Individual participant data (IPD) sharing plan

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.1	19/06/2024	15/10/2024	No	No