IMPPP

Improving Medicines use in People with Polypharmacy in Primary Care

(IMPPP)

Phase 1 Protocol

CONTENTS

BACKGROUND AND CONTEXT.

Over time, the number of medicines that people are prescribed has risen sharply.[1] It is known that the more medicines that a patient is prescribed, the higher their risk of being prescribed potentially problematic combinations and of being harmed.[2,3] There is limited evidence that interventions involving medication review in people with polypharmacy improve patient outcomes, although there is some inconsistent evidence that prescribing is improved.[4-7] The IMPPP study is an NIHR Health Services and Delivery Research Programme funded project to develop and optimise a complex intervention to improve prescribing and other outcomes in people with polypharmacy. IMPPP has three phases.

1. Phase 1 is to design the intervention drawing on evaluation of two related interventions in NHS Scotland.
2. Phase 2 is to implement and optimise the intervention in pilot practices in NHS England.
3. Phase 3 is to evaluate the optimised intervention in a definitive cluster-randomised controlled trial with parallel process evaluation in NHS England.

Phase 1 is led by University of Dundee. Phases 2 and 3 is led by University of Bristol. This protocol is for phase 1 only (there will be a separate protocol, governance and ethics process for phases 2 and 3).

PHASE 1 STUDY AIM AND OBJECTIVES

The overall aim of the whole IMPPP study is to develop and evaluate an intervention to optimise medication use for patients with polypharmacy in a general practice setting.

The specific objective for phase 1 is to develop and refine the intervention components in a mixed methods study, building on existing work in Scotland.

To meet the phase 1 objective, we will develop and refine key intervention components, building on experience of implementation of informatics tools to support NHS-led polypharmacy interventions (POEMS, P-DQIP [previously known as DQIP2]) in two Scottish Health Boards, in order to develop and refine the intervention for use in subsequent phases of the project. This will specifically include establishing the best approach to case finding, as well as identifying appropriate screening and recording standards for guiding medicines optimisation.

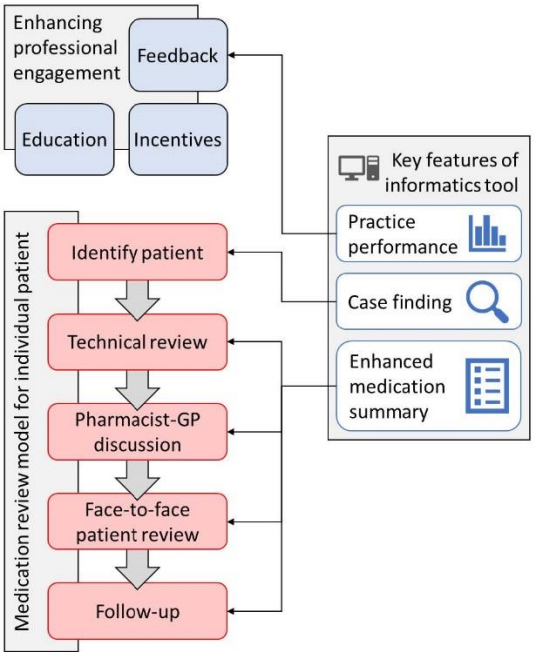
PHASE 1 STUDY METHODS

The overall design is a mixed-methods study in 2 Scottish Health Boards that are implementing existing polypharmacy interventions that include various blends of the potential IMPPP intervention components.

POTENTIAL INTERVENTION COMPONENTS

The potential components which will be examined in phase 1 are summarised in figure 1. The two core components are interventions to enhance professional engagement (education,[8,9] incentives[10] and feedback[11]) and the informatics tool which as well as providing feedback to practices additionally has a case-finding tool to identify patients and will create the enhanced medication summary to support review.

FIGURE 1: POTENTIAL IMPPP INTERVENTION COMPONENTS MAPPED TO POEMS AND P-DQIP



Components in POEMS

- Education via multiple workshops
- Various and variable incentives for review
- Case finding (pre-determined by Health Board)
- Enhanced medication summary available as printed document, not integrated with GP record
- Mixed pharmacist-led and GP review

Components in P-DQIP

- Education via mix of workshops and outreach
- Small financial incentives to attend education
- Feedback
- Case finding (practice can tailor easily)
- Enhanced medication summary integrated with GP record but printable if required
- Pharmacist-led review

QUALITATIVE METHODS

Sampling

We will purposively sample from practices in the two health boards to include those with variation in the informatics tool being used, the type of education received, the size and structure of payment, and how reviews were organised (e.g. primarily GP-led vs pharmacist-led). We will sample healthcare professionals with variable engagement with polypharmacy review, as well as patients who have had a review. Patients will be identified and initially approached by practices, and invited by letter to contact the research team if they are interested in taking part after reading the participant information sheet.

Data collection

We will conduct semi-structured interviews with relevant professionals (12 GPs, 8 pharmacists, 4 practice managers). Interviews will be based on a topic guide focused on professionals' perceptions of polypharmacy review including the 7-step medication review model recommended by NHS Scotland[12] (or other models used by the practice), any education and training they had received, contractual incentives facilitating or blocking review, the optimal roles of different professionals, and the benefit and problems of the informatics tools. Interview topic guides will be used flexibly and adapted over the course of the study to allow emergent issues to be accounted for. We will conduct 2 focus groups with patients (6-8 patients each) who have had a recent polypharmacy review, seeking to understand their experience of the review including the extent to which the process differed from usual care, their degree of involvement in decision-making, and their perceptions of impact. We will specifically examine how patient experience of usual care and reviews can inform intervention design in terms of eliciting and accounting for patient priorities and values (for example in the design of the educational intervention).

Data analysis

Interviews will be digitally recorded and transcribed verbatim, and NVivo used for data management and coding. Initial analysis will be thematic, based on both a priori and emergent themes, seeking to describe the implementation and experience of polypharmacy review in each practice including barriers and facilitators of successful implementation. Analysis will draw on Normalisation Process Theory[13] which we have previously found a helpful framework in this context for understanding whether and how technologies and new ways of organising care are successfully implemented, integrated and sustained in the context of existing practice work.[14,15] We will additionally specifically explore perceptions of the potential IMPPP intervention components shown in figure 1 (education, incentives, feedback, case finding, enhanced medication summary, by whom and how the review work was done).

QUANTITATIVE METHODS

Data collection

The POEMS and DQIP2 tools measure prescribing quality and safety using >100 indicators of potentially inappropriate prescribing (PIP), selected by an expert group. There is limited information about many of these indicators in terms of prevalence or variation between patients and practices. We will conduct a descriptive epidemiological analysis to explore these issues in detail. The results from this work will inform our choice of indicators for the intervention, providing information on how best to identify those patients with the most problematic prescribing as well as the problems most often encountered and most amenable to change.

Data analysis

We will examine the prevalence of PIP in total and for each individual indicator. We will also examine how such prescribing varies between patient groups (e.g. by age, by number of repeat medications), and between practices including the extent to which practices tend to have high or low prevalence on all indicators as opposed to high on some and low on others (which is important for framing the educational and feedback elements of the intervention). Finally, we will examine which measures of PIP had evidence for being amenable to change in the two Health Boards using data from segmented regression analysis of interrupted time series data (given evidence that potential for change varies between measures).

Integration of findings

The research team will develop the core intervention components for implementation in the Phase 2 optimisation study, drawing on our previous experience in the development of DQIP,[10,16] EFIPPS,[17,18] POEMS and P-DQIP, and informed by both the qualitative and quantitative findings. The qualitative findings will be used to establish facilitators and barriers to the effective delivery of the intervention, as well as which components of the intervention (and the design of those components) are considered of greatest value by users.[14] The quantitative findings will help inform the optimal approach to case finding based on focusing reviews on those at the highest risk from potentially inappropriate prescribing, and will enable us to establish which indicators to include in the enhanced medication summary to be evaluated in NHS England. In addition, these findings will help define prescribing outcomes to measure in the trial. The output from this work will be a detailed draft design of each component of the intervention, with areas of uncertainty or plausibly effective options identified.

We will then further refine each element working with separate health care professional and patient panels in England to ensure tailoring to the English context where the trial will be run. Separate panels will help avoid the well-recognised problem of professional views dominating those of patients, as well as enabling better identification of key design factors specific to the needs of the two different groups. The patient panel will focus more on patient-facing materials, patient-centred aspects of the education session (e.g. elicitation and accounting for values and priorities), and elements of the face-to-face review process. Two professional panels will be convened to explore views on all elements of the intervention. In addition, 8 think-aloud interviews (4 GPs, 4 pharmacists) will be conducted to specifically explore experience of using the informatics tools. The results of the group discussions and interviews will be used by the research team to optimise the design of all elements of the intervention prior to its pilot implementation in Phase 2.

OUTPUTS

The core output will be a fully specified intervention for piloting in phase 2, but we will formally disseminate the findings through conference presentation and peer-reviewed publication consistent with the TIDieR checklist for comprehensive reporting of intervention components. Should the trial show the intervention to be effective, then we will publish

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