

Background

Potentially inappropriate prescribing (PIP) (the use of medicines that introduce a greater risk of adverse drug-related events where a safer, as effective alternative is available to treat the same condition) is common in older people and can result in increased morbidity, adverse drug events, hospitalizations and mortality. (1-2) The Screening Tool of Older People's Prescriptions (STOPP) criteria is a PIP screening tool developed in Ireland. Using these criteria, the prevalence of PIP in Ireland in people aged ≥ 70 years is 36% with an associated expenditure of over €45 million (9% of pharmaceutical expenditure in that age group). (3)

Objective

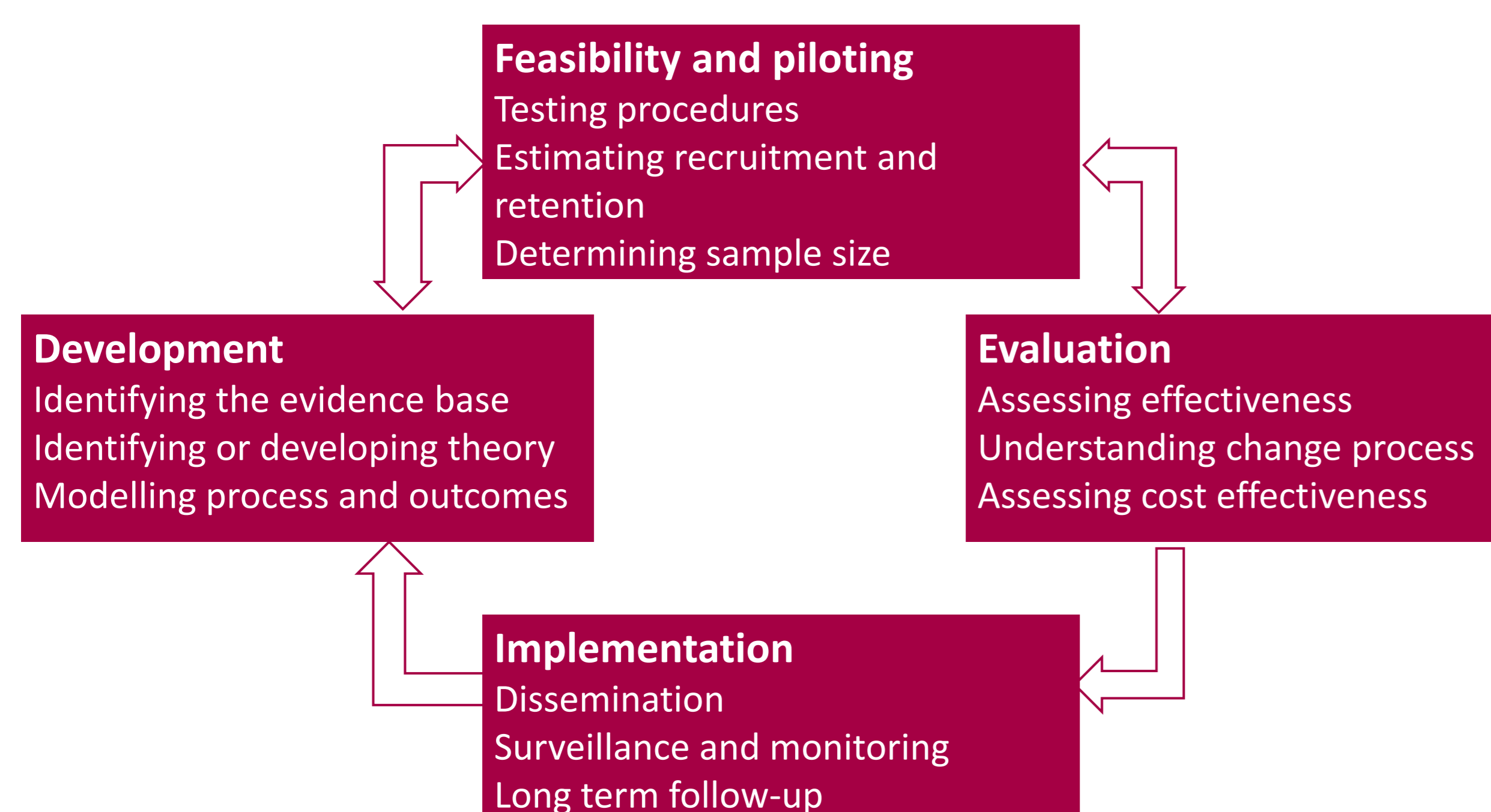
The aim of this study is to conduct a pragmatic cluster randomised controlled trial to evaluate the effectiveness of a multi-faceted intervention in reducing PIP. The intervention incorporates academic detailing, a medicines review, utilising a web-based pharmaceutical treatment algorithm that provides recommended alternative treatment options, and tailored patient information leaflets.

The application of the Medical Research Council (MRC) (4) framework for the design and evaluation of complex interventions to the design of the intervention is presented here.

Methods

The initial phases of the MRC framework were applied to guide the development of the study intervention as shown in Figure 1 below.

Figure 1: MRC Framework – key elements of the development and evaluation process



Development

In the development stage, an understanding of the subject was gained through:

1. Conducting a literature review
2. Modelling processes and outcomes by combining the literature with information gained from experts in the area using -
 - a. A consensus based methodology to determine which PIPs to focus on in the study. A list of published PIP criteria, with the prevalence in Ireland, was compiled and viewed independently by a panel consisting of 3 GPs, 2 pharmacists and a clinical pharmacologist with an interest in prescribing in the elderly. PIPs with full agreement from the panel were included. Appropriate alternatives for each included PIP were decided in the same manner.
 - b. Simulated patient cases to test the concept and content of the intervention. 8 GPs involved in a CME discussion group conducted a medicines review following the intervention format on 23 patient cases. They evaluated the actions they would take and commented on the validity/relevance of the included PIPs and recommended alternatives by filling in evaluation forms and participating in a focus group.

Feasibility and Piloting

5 GPs piloted the intervention in practice with 1-3 of their patients. They obtained consent from the patients and conducted a medicines review using the intervention tool. GPs filled in outcome forms and participated in short (5-10 minutes) qualitative, semi-structured interview. These were transcribed and a thematic analysis conducted.

Results

Development

32 individual PIP criteria were included in this study and pharmacological and non-pharmacological alternatives for each were compiled. From the case studies and focus group it emerged that the information needed to be more structured, with more emphasis on non-pharmacological alternatives. These comments were taken into consideration and a treatment algorithm was compiled for each indicator included. The algorithms were compiled into a hardcopy booklet and a web-based platform for GPs to access the information was developed, as shown in Figure 2.

Figure 2: OPTI-SCRIPT web based platform

OPTIScript		
Patient ID: 15	Patient ID: 18	Patient ID: 23
Proton Pump Inhibitors (PPIs) Done	Long Acting Benzodiazepines Done	Long Acting Benzodiazepines To Do
Full Therapeutic Dose > 8 weeks	long acting, long term (>1 month)	long acting, long term (>1 month)
PIP Outcome Form Done	PIP Outcome Form Done	PIP Outcome Form To Do
Please fill this in for each PIP!	Please fill this in for each PIP!	Please fill this in for each PIP!
Non-steroidal anti-inflammatory drugs (NSAIDs) Done		Non-steroidal anti-inflammatory drugs (NSAIDs) To Do
Warfarin, SSRI, ACE inhibitor, Diuretic, Congestive Heart Failure, Peptic Ulcer Disease, Long-term use for mild osteoarthritis		Warfarin, SSRI, ACE inhibitor, Diuretic, Congestive Heart Failure, Peptic Ulcer Disease, Long-term use for mild osteoarthritis
PIP Outcome Form Done		PIP Outcome Form To Do
Please fill this in for each PIP!		Please fill this in for each PIP!

Pilot

In total 8 medicines reviews were conducted and a total of 10 individual PIPs were addressed. 9 out of the 10 PIPs were addressed in the form of either a dose reduction or a discontinuation of a targeted medication. In 1 case, the PIP was unaltered due to patient preference. The outcomes from the medicines review are shown in Table 1.

Table 1: Pilot study – outcomes of medicines review

Patient	PIP	Outcome of review
P1	PPI TCA & CCB	Dose reduction TCA discontinued
P2	PPI Therapeutic duplication - ACEI & ARB	Dose reduction ARB discontinued
P3	Long term long acting benzodiazepine	Dose reduction
P4	PPI	Dose reduction
P5	Bladder antimuscarinics and constipation	Left unaltered
P6	NSAID & diuretic	NSAID discontinued
P7	NSAID & ACEI	NSAID discontinued
P8	Long term steroid for maintenance therapy in COPD/Asthma	Switched from steroid to other treatment

Abbreviations – ACEI - angiotensin-converting-enzyme inhibitor, ARB - Angiotensin II receptor blockers, CCB – Calcium Channel Blocker, COPD - chronic obstructive pulmonary disease, NSAID - Nonsteroidal anti-inflammatory drugs, PPI Proton Pump Inhibitor, TCA – Tricyclic Anti-depressant

Pilot - Qualitative findings

The qualitative evaluation of the pilot study indicated that, overall GPs and patients were very positive about their experience of the review process and were receptive to the intervention. Potential barriers were also identified as indicated in Table 2:

Table 2: Pilot study – Qualitative findings

Theme	Supporting Quotation
Satisfaction	<p>“Certainly the guy who was the most complicated was very grateful. It was actually lovely doing it with him, coz he thought he was getting a special service” I2</p> <p>“she was delighted, I stopped some of her other medications because she was in front of me and I had a bit of time to do it.” I4</p>
Barriers	<p>“I mean it is time consuming which will be the biggest challenge” I2</p> <p>“When I said initially we wanted her to come off it, she said, o no, I’ve been on that for ages, and I don’t want to come off it.” I3</p>

Preliminary conclusions

The intervention has been developed using the best available evidence and the pilot study has ensured applicability to clinical practice in primary care.

References:

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