The development of a Core Outcome Set (COS) for use in interventions aimed at improving appropriate polypharmacy in older people in primary care

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Introduction

- The prescribing of multiple medicines, or polypharmacy (≥4 regular medicines), is increasingly common in clinical practice, particularly in older people (age ≥65 years)[1]
- Polypharmacy in older people is linked to hospital admissions, adverse drug events and mortality[2], however, evidence suggests that polypharmacy may be entirely appropriate and necessary, particularly when prescribing for older people who have more than one medical condition[3]
- Intervention studies have aimed to address the use of polypharmacy in older people, yet randomised controlled trials (RCTs) often differ in the outcomes reported, which has resulted in an inability to synthesise results[4]
- The COMET (Core Outcome Measures in Effectiveness Trials) initiative has suggested that one method of addressing this problem is through the development of a core outcome set (COS)[5]
- A COS is an agreed and standardised set of outcomes or outcome domains which should be measured and reported, as a minimum, in all trials in a specific clinical area[5]

Aim

The aim of this study is to develop a COS that can be applied to trials investigating the effectiveness of interventions targeting polypharmacy in older people

Methods

This study follows the standard methodology for COS development, set out by the COMET initiative, which involves establishing the scope of the COS, identifying the existing knowledge, stakeholder involvement, screening and a consensus exercise[5] (Figure 1)

Scope: This COS is intended to identify key outcomes for inclusion in clinical trials measuring the effectiveness of interventions aiming to improve appropriate polypharmacy for older people in primary care

A Cochrane Systematic Review (update) of trials investigating the effectiveness of interventions targeting polypharmacy in older people, has been conducted to determine which outcomes are currently being included in published trial reports

Extraction of outcomes from **previously collected qualitative data** (involving general practitioners, pharmacists and patients)[5] has been completed to identify the potential outcomes which were important to the three stakeholder groups

Outcome inventory: Key outcomes were extracted from the systematic review and the qualitative data collated into the COS long-list (i.e. all potential outcomes that will be considered for inclusion in the consensus exercise) and organised into key domains (i.e. a broad class of outcomes)

Initial screening of outcomes by the Project Steering Group has been conducted to refine the long-list of outcomes before the main consensus exercise [to identify any process measures (i.e. outcomes relating to the implementation of the intervention), duplicate outcomes and outcomes that are outside the scope of the COS]

Consensus Exercise: The consensus exercise will encompass three rounds (as recommended by the COMET initiative) of Delphi questionnaires [using a web-based survey tool (Survey-Gizmo®)]

Phase 1: Identifying potential outcomes		
Establish the scope of the COS	Update systematic review and extract information on key outcomes	Extract outcomes from previously conducted qualitative work with stakeholders

Phase 2: Determining core outcomes	
Outcome inventory and initial screening	Consensus Exercise Delphi surveys (3 rounds)

Figure 1: Study Flowchart

Results

Cochrane Systematic Review (update): 10 eligible trials were included in the current review update (in addition to 12 trials identified from the 2014 update[4])

52 outcomes were measured in the trials. Removal of 20 duplicate outcomes resulted in 32 unique outcomes

Previously collected qualitative data: 22 outcomes were extracted from the transcripts

Outcome Inventory: This resulted in a total of 54 outcomes and after considering the definitions, 29 unique outcomes were synthesised into 8 'outcome domains' which were used as the basis of the Delphi questionnaire structure

Initial screening of outcomes and further discussion within the Project Steering Group resulted in a final list of 30 outcomes which will be included in the Delphi questionnaire
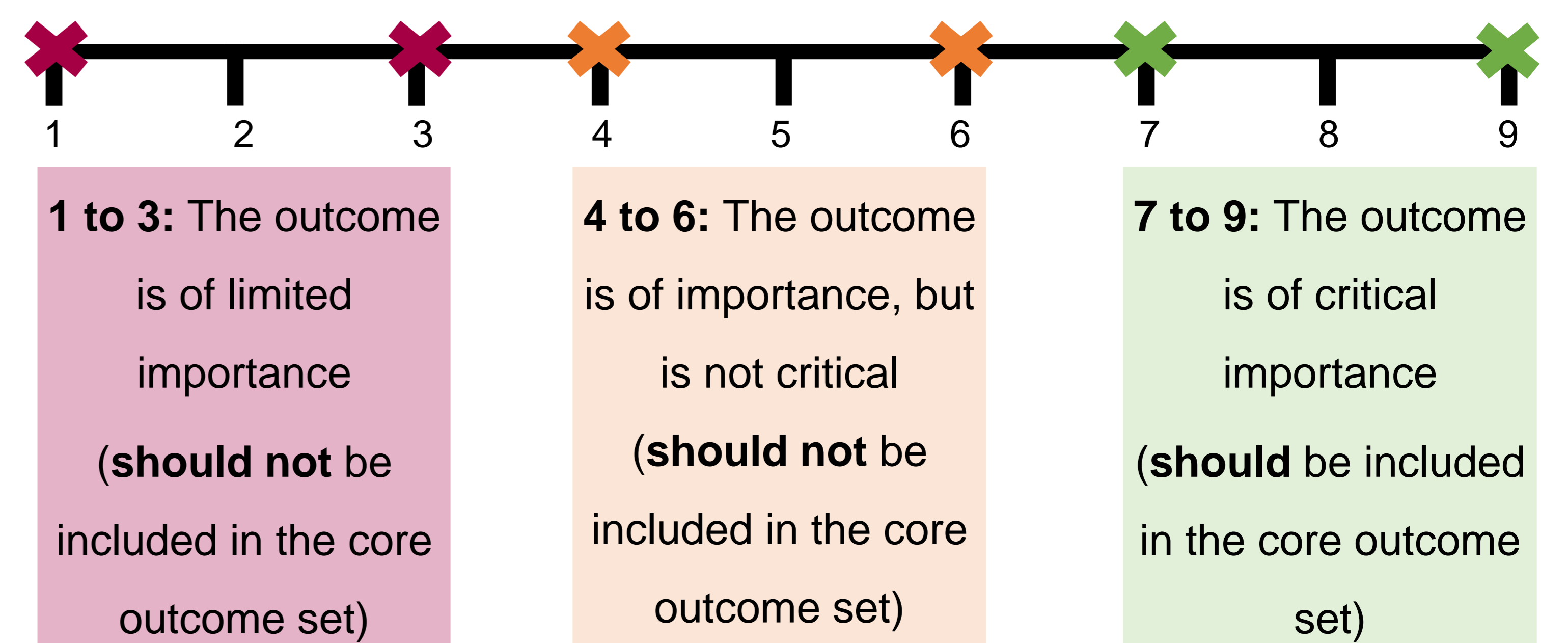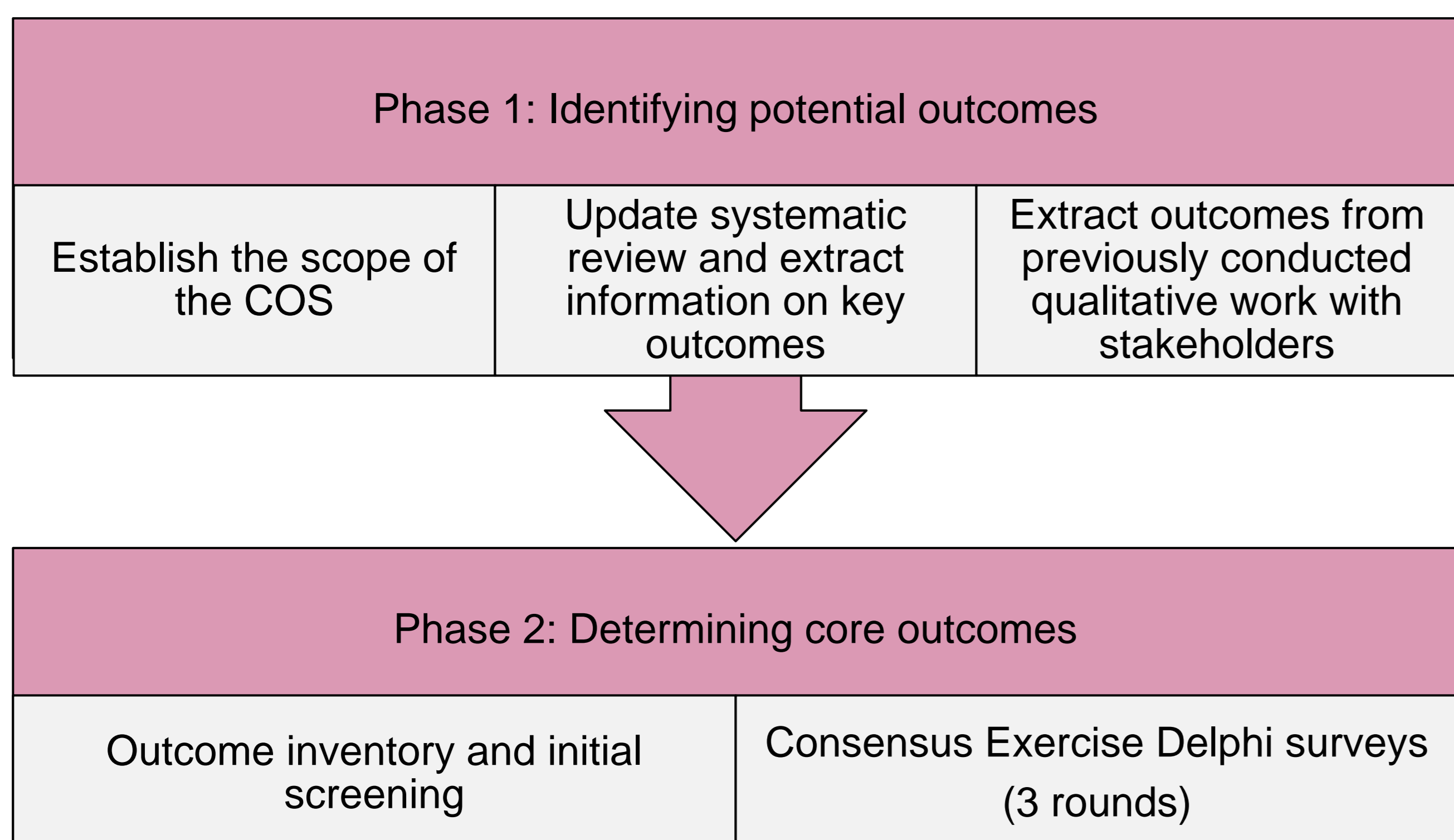
Outcome domains	Number of outcomes
Medication-related outcomes	8
Health care utilisation	7
Patient-related outcomes	6
Satisfaction	4
Adverse effects or harms	2
Clinical outcomes	1
Knowledge	1
Resource use	1

Future Work

Consensus Exercise: Three sequential questionnaires will be completed by a panel of researchers, academics, healthcare professionals and older people (the Delphi panel)

A total target of 160 participants will be recruited:
40 public participants (Northern Ireland) and 120 experts (World-wide)

Delphi Questionnaire: Participants will be presented with list of outcomes and asked to rate their importance to older people prescribed many medicines (polypharmacy) using the scale below:

1 2 3 4 5 6 7 8 9

1 to 3: The outcome is of limited importance (**should not** be included in the core outcome set)

4 to 6: The outcome is of importance, but is not critical (**should not** be included in the core outcome set)

7 to 9: The outcome is of critical importance (**should** be included in the core outcome set)

Outcomes will be included in the final COS based on the following criteria:

Consensus classification	Definition
Consensus in	≥70% scoring 7 – 9 AND ≤15% scoring 1 - 3
Consensus out	≥70% scoring 1 – 3 AND ≤15% scoring 7 - 9
No consensus	Anything else

References

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