

# The development of a Core Outcome Set for medicines management interventions for people with dementia

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## Introduction

With the number of people with dementia (PWD) continuing to rise, it is critical that interventions to improve medicines management for these patients are developed. As such interventions are developed, it is important that attention is paid to the outcomes used in trials assessing their effectiveness. Often a wide variety of outcomes are measured in trials conducted in the same clinical area. This leads to difficulties in the comparison of different interventions. One method of overcoming this is through the use of a 'Core Outcome Set' (COS), a set of specific outcomes relevant to all trials conducted in a particular clinical area<sup>1</sup>. Guidance has been provided on how to develop a COS and the process is displayed in Figure 1.



Figure 1: The process of developing a COS

In this present study, the scope of the COS encompassed all medicines management interventions for PWD living in their own home or a care home. The aim of this study is to develop a COS for medicines management interventions for PWD living at home or in care homes.

## Results

A total of 1,365 articles were identified from database searches. Of these, only five studies met the criteria for inclusion in the systematic review. The outcomes reported across each of the five RCTs are detailed in Table 1. In total, there were 27 different outcomes identified. Only three outcomes were reported in more than one trial: quality of life (QOL), behavioural and psychological symptoms of dementia (BPSD) and activities of daily living (ADL). Interviews were conducted with 15 community pharmacists and 15 GPs. Interviews with PWD and their carers are ongoing. The outcomes highlighted so far are displayed in Figure 2.

Table 1: Outcomes reported across each of the five RCTs

Outcome	Fossey, 2006	Thyrian, 2012	Smeets, 2013	Jordan, 2015	Lingler, 2016
Neuroleptic use	✓				
Mean dose of neuroleptic	✓				
Agitation	✓				
Quality of life	✓	✓	✓		
Proportion of patients taking other psychotropic drugs	✓				
Falls	✓				
Incidents involving irritable behaviour directed at staff/ other residents	✓				
Caregiver burden		✓			
Behavioural and psychological symptoms of dementia		✓	✓		
Prevention or suspension of a potentially inappropriate medication		✓			
Identification of screening false positives and differentiate different symptoms of dementia		✓			
Medications		✓			
Activities of daily living		✓	✓		
Social support		✓			
Health status		✓			
Utilisation of health care resources		✓			
Appropriateness of psychotropic drug use			✓		
Overall frequency of psychotropic drug use			✓		
Psychotropic drug side effects			✓		
Serious adverse drug reactions			✓		
Number and nature of medication related problems				✓	
Changes in individual problems				✓	
Prescribing				✓	
Disease severity				✓	
Potential costs of the intervention				✓	
Medication management deficiencies					✓
Acceptability of the intervention					✓

## Discussion

The outcomes identified from the systematic review and qualitative interviews will be combined into a Delphi questionnaire distributed to a panel of experts to gain consensus on the final COS. This COS will be used to assess the effectiveness of a medicines management intervention currently being developed in an ongoing project.

## References:

1. Williamson PR, Altman DG, Blazeby JM, Clarke M, Devane D, Gargon E, Tugwell P. Developing core outcome sets for clinical trials: issues to consider. *Trials* 2012; 13: 1-8

## Method

This study involves three phases as described below.

### Phase 1

A systematic search was conducted across a range of databases to identify randomised controlled trials (RCTs) examining medicines management interventions for PWD.

### Phase 2

Qualitative interviews were conducted with community pharmacists, general practitioners (GPs), PWD and their carers.

### Phase 3

Outcomes identified from the first two phases will be condensed into the final COS through a Delphi consensus exercise.

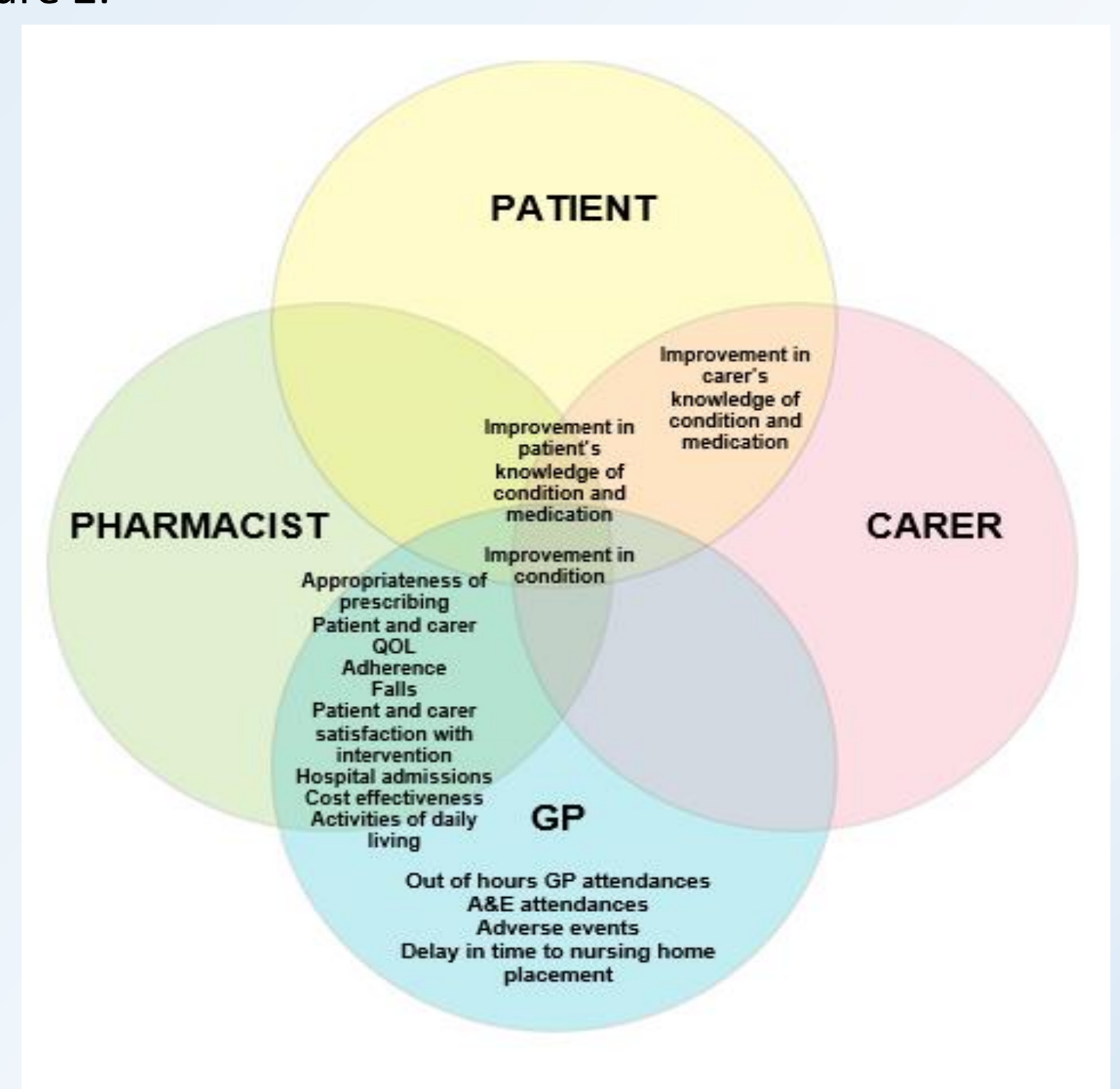


Figure 2: Outcomes highlighted during qualitative interviews with community pharmacists, GPs, PWD and carers