Improving medication adherence in older adults prescribed polypharmacy

by

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A thesis submitted to:

Faculty of Medicine, Health and Life Sciences

School of Pharmacy

Queen's University Belfast

for the degree of

Doctor of Philosophy

October 2017

Dedicated to my grandfather, William James (Jim) McBride and late grandmother, Gladys May McBride.

Contents

Acknowledgements

Firstly, I would like to express sincere thanks to my two PhD supervisors, Professor Carmel Hughes and Dr Cristín Ryan for their invaluable guidance and support during the previous three years. Their dedication to pharmacy practice research is inspiring and I am very grateful to have been mentored by them.

The research presented in this thesis would not have been possible without the contribution of all the patients and community pharmacists who generously dedicated their time to participate. I would also like to thank Mrs Claire Leathem and colleagues at the Northern Ireland Clinical Research Network for their assistance with patient recruitment from GP practices. I am grateful for the support and guidance that I received from everyone in the Dunhill-funded polypharmacy project research group (Dr Cathal Cadogan, Professor Jill Francis, Dr Gerry Gormley, Professor Ngaire Kerse and Professor Peter Passmore). A very special thanks to Dr Cadogan for his help throughout the project and to Professor Francis for her kind words of support and guidance with the health psychology aspects of this project. Thanks also to the Pharmaceutical Society of Northern Ireland for providing information and contact addresses for community pharmacies in Northern Ireland.

I am thankful for all of the office staff in the School of Pharmacy who provided assistance throughout this research, with particular thanks to Mr Ross Archibald and Miss Claire Lyttle for their assistance with the postal survey, Ms Lee-Anne Howell and Ms Nicola Magill for their help with general enquires, Mr David McQuade and Mr Gervase McGivern for their help with procurement and Mr Mark McCalmont for help with computer issues. The past three years would not have been the same without the friendship, advice and encouragement from all of my colleagues in the Primary Care Research Group (Anna, Anne, Audrey, Bridgeen, Heather, Karen, Sarah, Máiréad and Maureen) and so I am extremely grateful to them.

Last but not least, I would like to thank my friends and family, with special thanks to my parents (David and Alison), brother (Michael), grandfather (Jim), late grandmother (Gladys), and Rory for all of their love, support and words of encouragement over the years, for without them I would not be where I am today.

Funding

The research presented in this thesis was supported by:

- The Dunhill Medical Trust [grant number: R298/0513]
- The Harold and Marjorie Moss Charitable Trust Fund (PhD Research Award)
- The Department for Employment and Learning

Abbreviations

BCI	Behaviour change intervention
BCT	Behaviour change technique
BCTTv1	Behaviour Change Technique Taxonomy version 1
BP	Blood pressure
CC	Cathal Cadogan
CH	Carmel Hughes
CHF	Congestive heart failure
CKD	Chronic kidney disease
COM-B	Capability, opportunity, motivation-behaviour (model)
COREQ	Consolidated criteria for reporting qualitative research
CP	Community pharmacist
CR	Cristín Ryan
DP	Deborah Patton
PDC	Proportion of Days Covered
DPPR	Daily Polypharmacy Possession Ratio
EPOC	Effective Practice and Organisation of Care Group
EU	European Union
GP	General practitioner
HBM	Health Belief Model
HCP	Healthcare professional
HRQOL	Health-related quality of life
JF	Jill Francis
KW	Kruskal-Wallis (statistical test)
LTC	Long-term condition
MA	Medication adherence
MAS	Medication adherence support
MDS	Monitored Dosage System
MEMS	Medication Events Monitoring System
MESH	Medical Subject Headings
MI	Motivational Interviewing
MMAS	Morisky Medication Adherence Scale
MPR	Medication Possession Ratio
MRC	Medical Research Council

MUR	Medicine Use Review (service)
MWU	Mann-Whitney U (statistical test)
MYM	Managing Your Medicines (service)
N/A	Not applicable
NHS	National Health Service
NI	Northern Ireland
NICE	National Institute for Health and Care Excellence (previously known as National Institute for Health and Clinical Excellence)
NIHR	National Institute for Health Research
NICRN	Northern Ireland Clinical Research Network
ORECNI	Office of Research Ethics Committees for Northern Ireland
PMR	Patient medication record
PSNI	Pharmaceutical Society of Northern Ireland
QUB	Queen's University Belfast
RCT	Randomised controlled trial
SCT	Social Cognitive Theory
SD	Standard deviation
SRM	Self-regulation Model
TCS	Theory Coding Scheme
TDF	Theoretical Domains Framework
TIDieR	Template for Intervention Description and Replication
TPB	Theory of Planned Behaviour
TST	Temporal Self-regulation Theory
TTM	Trans-theoretical Model
UK	United Kingdom
USA	United States of America
VAS	Visual Analogue Scale
WHO	World Health Organisation
WIDER	Workgroup for Intervention Development and Evaluation Research

Abstract

Introduction

Medication adherence is vital to ensuring optimal patient outcomes, particularly amongst older adults prescribed polypharmacy. However, complex interventions aimed at improving adherence have shown only limited effectiveness. To maximise effectiveness, the Medical Research Council (MRC) supports the use of both evidence and theory in developing interventions. Feasibility and pilot testing is then recommended to optimise interventions in advance of definitive trials. The aim of this research was to develop a novel complex intervention (using evidence and theory) to improve adherence in older adults (prescribed polypharmacy) and to test the feasibility of delivering this in community pharmacies.

Methods

The presented research models the MRC complex intervention framework and focuses on development and feasibility testing phases. Firstly, a systematic review was conducted to address an identified evidence gap in relation to theory-based adherence interventions previously delivered to older adults prescribed polypharmacy. Qualitative research was then conducted to explore older patients' adherence behaviour and identify determinants (barriers, facilitators) to target for change. Using the Theoretical Domains Framework (TDF) as a lens, key domains were selected for targeting and mapped to behaviour change techniques (BCTs) using established methods. These BCTs formed the basis of a complex intervention that was delivered to older patients by community pharmacists (CPs) as part of a small-scale feasibility study. In addition to exploring older patients' adherence behaviours, further research focused on CPs' clinical behaviour in relation to providing medication adherence support (MAS). The qualitative TDF-based methods used in the patient study were extended and a mixed methods (qualitative, quantitative) approach was used to identify determinants influencing CPs' behaviour. Key target domains were identified and mapped to BCTs that could be directed at CPs (e.g. in a training package) to improve future implementation of the patient intervention.

Results

The systematic review found that adherence interventions delivered to older patients prescribed polypharmacy were rarely based on theory, supporting the need for further research. The qualitative research conducted with older patients identified eight key domains (e.g. 'Beliefs about consequences', Memory, attention and decision process') that could be targeted and these domains were mapped to 11 BCTs (e.g. 'Prompts/cues', 'Self-monitoring')

which formed the basis of a complex intervention. The feasibility study demonstrated that the intervention was highly acceptable to both patients and CPs but some modifications were suggested. It also highlighted the need for additional research that focuses on CPs' behaviour (i.e. MAS provision). Findings from the mixed methods study on CPs' behaviour led to the identification of seven key domains that could be targeted for change (e.g. 'Skills', 'Motivation and goals'). Eighteen BCTs were then selected for inclusion in a training package (e.g. 'Demonstration of the behaviour') or for delivery alongside the patient intervention in future research (e.g. 'Rewards/incentives') to improve implementation.

Discussion/Conclusion

The MRC framework served as a useful guide for developing a complex intervention to improve adherence in older patients prescribed polypharmacy. This systematic theory-based approach that involved explicitly linking theoretical domains to intervention components (BCTs) will aid future replication and understanding of how the intervention aims to bring about behaviour change. Aside from targeting patients' adherence behaviours, this research emphasised the importance of exploring the behaviours of intervention providers (i.e. CPs) to enhance implementation. Future research will involve pilot testing a refined version of the patient intervention and CP training package to establish if a definitive trial of effectiveness (e.g. randomised controlled trial) is warranted.

Publications

Manuscripts

Patton, D.E.*, Cadogan, C.A.*, Ryan, C.A, Gormley, G.J., Passmore, P., Francis, J.J., Kerse, N., Hughes, C.M., 2017. Improving adherence to multiple medications in older people in primary care: selecting intervention components to address patient-reported barriers and facilitators. *Health Expectations* [Epub ahead of print]; doi: 10.1111/hex.12595 *(*joint first authors).*

Patton, D.E., Hughes, C.M., Cadogan, C.A., Ryan, C.A., 2017. Theory-based interventions to improve medication adherence in older adults prescribed polypharmacy: A systematic review. *Drugs & Aging*; 34:97–113.

Hughes, C. M., Cadogan, C. A., Patton, D., Ryan, C. A., 2016. Pharmaceutical strategies towards optimising polypharmacy in older people. *International Journal of Pharmaceutics;* 512:360-365.

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Patton D., Hughes C., Cadogan C.A., Ryan C., 2016. Theory-based interventions that aim to improve medication adherence in older adults who are prescribed multiple medications: a systematic review. *International Journal of Pharmacy Practice*; 24(S3):22–102. [Conference: Royal Pharmaceutical Society Annual Conference: Poster presentation].

Patton, D., Ryan, C., Cadogan, C.A., Gormley, G.J., Passmore, P., Francis, J., Kerse, N., Hughes, C., 2015. Using the Theoretical Domains Framework (TDF) to explore barriers and facilitators to adherence to polypharmacy in community based older adults. *International Journal of Pharmacy Practice;* 23(S2):11-12. [Conference: Royal Pharmaceutical Society Annual Conference: Oral presentation].

Chapter 1

General introduction

1.1 Medicines use in older adults

1.1.1 The ageing population

With declining birth rates and increasing life expectancy, the global population is undergoing a major demographic shift (United Nations, 2015). Over the coming years the largest rate of growth is expected in older adults, a population group commonly defined as those aged 65 years and over. By 2050, the number of older people worldwide is expected to increase two-fold (United Nations, 2015). In Northern Ireland (NI), the number of older people is predicted to rise from approximately 286,000 to almost half a million, between 2014 and 2039 (Northern Ireland Statistics and Research Agency, 2015) (see Figure 1.1).

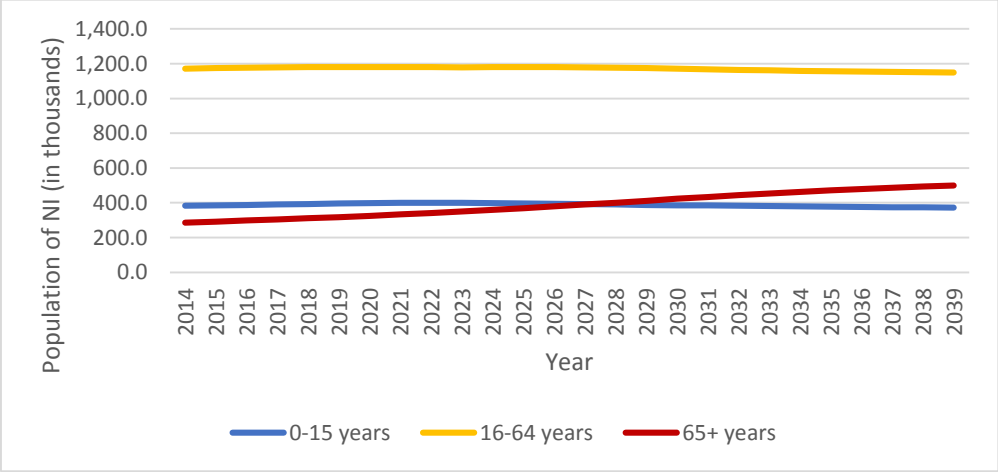


Figure 1.1: Northern Ireland's (NI) projected population figures by age category from 2014 to 2039 (Adapted from: Northern Ireland Statistics and Research Agency, 2015)

1.1.2 Chronic conditions and multimorbidity

With increasing economic pressures, healthcare services worldwide will have to adapt to meet the complex care needs of an ageing population. During the ageing process, the human body undergoes a number of physiological changes, for example, cardiac output is reduced, blood pressure (BP) is raised and lung function is impaired (Dillin et al. 2014). Examples of the most common causes of death in older adults globally include stroke, heart disease and chronic lung disease. These types of conditions are described as chronic or long-term conditions (LTCs) as they last longer than 12 months and cannot be cured, but can often be controlled with medication as part of a management plan (Scottish Government, 2015). A recent United Kingdom (UK) Government report, 'Future of an Ageing population', has emphasised that a shift in focus from acute conditions towards LTCs is a high priority if the National Health Service (NHS) is to remain sustainable with the current economic pressures

(Government Office for Science, 2016). To make optimal use of limited resources, there is a need for better management of LTCs and optimisation of drug treatments.

The term comorbidity describes the presence of other conditions in addition to an index condition, with the latter generally deemed to be of greatest importance (Valderas, 2015). Multimorbidity is a more useful term that is used to describe patients who suffer from two or more LTCs as it does not place greater emphasis on any one condition (Chew-Graham et al. 2016). Although multimorbidity is seen in all age groups it is most prevalent in older adults (Salive, 2013; Tinetti et al. 2012), with approximately 65% of older patients suffering from multimorbidity (Barnett et al. 2012). The treatment of multiple LTCs often follows single disease treatment guidelines, such as those published by the National Institute for Health and Care Excellence (NICE), and commonly leads to the prescribing of several medications. Recent NICE guidance on multimorbidity has recognised the limitations of single disease guidelines as these have generally been developed based on evidence from younger patients suffering from single conditions and taking comparatively fewer medications (National Institute for Health and Care Excellence, 2016). The guidance recommends that healthcare professionals (HCPs) should adopt a tailored approach to caring for multimorbid patients. The risks and benefits of treatments, as well as patient preferences, should be carefully taken into consideration when making decisions about treatment regimens. Nonetheless, the prescribing of multiple medications to treat LTCs in older adults is a very common practice in modern medicine and one that is likely to continue.

1.1.3 Polypharmacy

Where several medicines are concomitantly prescribed, this is often referred to as polypharmacy. Although the concept of polypharmacy was first discussed in the literature over 150 years ago, there is still no standard and agreed definition (Wise, 2013). Common definitions include numerical thresholds such as the consumption of at least four or five regular medications or more (Rollason and Vogt, 2003; Duerden et al. 2013; Patterson et al. 2014). The term polypharmacy has previously carried a negative connation and has been seen as a major evil in geriatric medicine (Aronson, 2004; Cadogan et al. 2016b). However, recent research conducted with large population datasets challenges the viewpoint that polypharmacy is always negative and should be avoided (Appleton et al. 2014; Payne et al. 2014). These cohort studies highlight the important role that polypharmacy can play in treating multimorbid older patients, provided that prescribing is evidence-based and takes into consideration the clinical context and relevant drug interactions. It is therefore increasingly being recognised that polypharmacy can be entirely appropriate in treating older

multimorbid patients and has been described more recently as a 'necessary evil' (Wise, 2013; Duerden et al. 2013). To take into account this changing viewpoint, there has been a suggestion to go beyond simple counts of medicines when defining polypharmacy and introduce the possibility of it being either appropriate ('many' drugs) or inappropriate ('too many' drugs) (Aronson, 2004; Hughes et al. 2016). However, as a new definition is yet to be agreed, the most common definition of 'four or more medications' has been used throughout this thesis to denote polypharmacy (Patterson et al. 2014).

The increasing incidence and prevalence of polypharmacy in recent years, particularly in older adults, has been illustrated by a study that analysed prescribing and dispensing data for over 300,000 patients in Scotland (Guthrie et al. 2015). The authors reported that in 2010, 20.8% of patients (in all age groups) were dispensed five or more medicines, an increase of almost 10% since 1995 (11.4%). They also reported that in 2010, 17.2% of patients aged over 65 years old were dispensed 10 or more medicines compared to just 4.9% in 1995. Similar findings have been reported in other countries such as Sweden, the United States of America (USA) and Italy (Haider et al. 2007; Bourgeois et al. 2010; Franchi et al. 2014). Whilst the consequences of inappropriate polypharmacy are important to consider (e.g. safety, drug interactions, adverse events), the potential benefits to be gained should not be overlooked (Kaur, 2013). Where polypharmacy has been appropriately prescribed using the best available evidence, in order to achieve potential benefits (e.g. improved condition control, increased functional capacity, improved quality of life and longevity), it is important that patients adhere to the prescribed directions (Elliott, 2013).

1.2 Adherence to long-term treatments

1.2.1 Terminology and concepts

Over 2000 years ago, Hippocrates first recognised that patients do not always take medicines as prescribed (Vrijens et al. 2012). In 1985, a high profile US Surgeon-General (C. Everett Koop) famously stated that 'Drugs don't work in patients who don't take them' (Osterberg and Blaschke, 2005). Adherence to medicines has been an area of great interest for practitioners, academics and policy makers around the world for over four decades (Dunbar-Jacob and Mortimer-Stephens, 2001). Adherence is a complex behaviour defined by the World Health Organisation (WHO) as:

> *"The extent to which a person's behaviour-taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider."* (Sabate, 2003)

The term 'adherence' is often used interchangeably with the terms 'compliance' and 'concordance', despite there being some subtle, and indeed notable differences between these terms (Horne et al. 2005; De las Cuevas, 2011). 'Compliance' is an older term that has been defined by Haynes et al. (1979) as 'the extent to which the patient's behaviour matches the prescriber's recommendations'. It has fallen out of favour in recent years as it implies that the patient has a passive role in the decision-making process, whereas adherence involves an agreement between the prescriber and patient about how the medicines should be taken or used (Banning, 2008). 'Concordance', a term that focuses on the relationship between the patient and prescriber as opposed to the medication-taking behaviour itself, is sometimes used incorrectly as a synonym for adherence (Horne et al. 2005).

As 'adherence' is currently the preferred term, it will subsequently be used throughout this thesis to describe the medication-taking (or medication-use) process (Nieuwlaat et al. 2014). Although the term of choice, there has been much debate in the literature as to what exactly 'adherence' encompasses. In an attempt to clarify this, Vrijens et al. (2012) undertook a group consensus exercise with 40 participants including researchers and HCPs from across 13 different countries. They agreed that adherence involves three key stages: 'initiation' (taking the first dose of a medication), 'implementation' (the extent to which dosing corresponds with the prescriber's directions) and 'discontinuation' (where a medication is stopped without instruction from a prescriber). 'Persistence' is used to describe the time between the 'initiation' and 'discontinuation' stages.

Non-adherence has also been separated into primary and secondary non-adherence (Fischer et al. 2011; Tamblyn et al. 2014). Primary non-adherence indicates instances where patients do not obtain the medication from the pharmacy in the first place, whereas secondary non-adherence involves the patient obtaining the medication but not taking it as prescribed. The latter encompasses the three stages outlined by Vrijens et al. (2012) (i.e. initiation, implementation and discontinuation). The focus of the research presented in this thesis is on secondary non-adherence, and in particular the 'implementation' phase.

In 2005, the National Coordinating Centre for the NHS also made the distinction between 'intentional' and 'un-intentional' medication non-adherence—this has proved useful for understanding the complexity of this behaviour. Intentional non-adherence involves a conscious decision-making process where decisions are made based on the individual's beliefs; this decision-making process can be seen as either rational or irrational (Horne et al. 2005). In contrast, un-intentional non-adherence involves an unconscious act that can be affected, for example, by orientation in time, prospective memory and physical difficulties

(e.g. forgetting to take medications, misunderstanding instructions, difficulty swallowing medications) (Lehane and McCarthy, 2007). These types of adherence behaviours can vary both within and between individuals. It is possible that an individual patient can be both intentionally and unintentionally non-adherent, for example, the chance of forgetting a medication (unintentional) is likely to be increased when the patient deems the medication to be of limited importance (intentional) (Clifford et al. 2008).

1.2.2 Measuring medication adherence

There are a variety of ways in which adherence can be measured, although there is no gold standard method of measurement currently available (Williams et al. 2013). Direct measures are seen as evidence that the medication has been consumed by the patient but these methods are very time-consuming and expensive. Some examples of direct measures include: drug (or metabolite) level monitoring, measurement of biological markers which are added to the formulation and directly observing patients. Indirect measures involve some degree of assumption that the patient has consumed the medication, for example: pill counts, measures calculated from prescription dispensing databases (refill measures), electronic monitoring devices and self-report measures (Farmer, 1999; Horne et al. 2005; Garfield et al. 2011). Each method has known limitations, for example, self-report questionnaires are commonly used in randomised controlled trials (RCTs) due to their low cost but they can be affected by social desirability bias (i.e. where false information is provided based on what the individual thinks that others would like to hear) (Horne et al. 2005). The ideal adherence measure should be low cost, practical to use in research/clinical practice, objective, user-friendly and reliable (Lam and Fresco, 2015). As no such adherence measure currently meets all of the desired criteria, combining methods has been suggested as a way of overcoming some of the limitations of individual methods (Sabate, 2003).

Based on direct or indirect measurements, patients' adherence rates can range from taking 0% to beyond 100% of the prescribed doses, with those taking more than the number of prescribed doses (>100%) considered to be over-adherent. Although there is no consensus on what the optimal level of adherence should be, researchers commonly use an arbitrary cut-off point of consuming less than 80% of the recommended doses to categorise patients as non-adherent. This cut-off point has been supported by research that examined the association between adherence levels (calculated using prescription dispensing data) and hospitalisations (all-cause and disease-specific) for a range of common chronic conditions such as diabetes, hypertension and congestive heart failure (CHF) (Karve et al. 2009). Research conducted by Hansen et al. (2009) also demonstrated that this cut-off point

provides sufficient balance between specificity (i.e. ability to correctly detect non-adherent patients) and sensitivity (i.e. ability to correctly detect adherent patients) for three commonly used adherence measures (self-report, electronic monitoring and prescription dispensing data-based measures). In reality, the optimal level of adherence for each patient is unlikely to be as clear-cut as this. Instead it is likely to differ from patient-to-patient due to heterogeneity in conditions and prescribed medications. However, due to the difficulty associated with determining such optimal levels for each individual patient and limited research in this area, a cut-off point of 80% was deemed sufficient for medications that are used to treat LTCs (Hansen et al. 2009; Karve et al. 2009).

1.2.3 Incidence of medication non-adherence in older adults

Non-adherence exists in all patient groups irrespective of age, education or socioeconomic status. Although age is not a strong predictor of medication adherence, older patients often have more risk factors for non-adherence. Older patients are also more commonly prescribed several medications (i.e. polypharmacy) which is correlated with lower adherence (Kardas et al. 2013). In addition, older multimorbid patients may be prescribed highly complex regimens which can include a mixture of formulations (e.g. tablets, inhalers, patches), multiple daily doses (e.g. three times daily) or special administration instructions (e.g. take half an hour before food). Regimen complexity has been reported to have a negative impact on medication adherence (Barat et al. 2001; Kardas et al. 2013).

On average, half of all patients in developed countries do not take their medications for chronic conditions as prescribed. For older adults, estimates of non-adherence in the literature range from 26% to 60% (van Eijken et al. 2003; McGraw and Drennan, 2004; Jimmy and Jose, 2011; Lee et al. 2013a). Due to the methodological difficulties associated with measuring adherence as discussed in Section 1.2.2, it is likely that the true extent of the problem is underestimated.

1.2.4 Consequences of non-adherence

Despite over 40 years of research into medication adherence, many patients still do not take medications as recommended by the prescriber (Sabate, 2003; Brown and Bussell, 2011). Consequences of non-adherence include poor disease control and reduced quality of life (Sabate, 2003). Non-adherent patients are also more likely to visit their general practitioner (GP) in the primary care setting and accident and emergency departments in the secondary care setting (Malhotra et al. 2001; DiMatteo et al. 2002; Sabate, 2003). In the USA, it has been estimated that between 33% to 69% of hospital admissions and 125,000 deaths per

year are the result of mediation non-adherence (McCarthy, 1998; Osterberg and Blaschke, 2005; Benjamin, 2012).

Increasing healthcare costs and wastage of medications resulting from non-adherence has major financial implications for healthcare systems (Malhotra et al. 2001; DiMatteo et al. 2002; Sabate, 2003). A recent report from the Institute for Healthcare informatics estimated that total avoidable costs from suboptimal medicine use (which included non-adherence, antibiotic misuse, medication errors, untimely medicine use, mismanaged polypharmacy, suboptimal use of generics) globally amounted to an annual total cost of US$475 billion (Aitken and Gorokhovich, 2012). Of this, non-adherence represented the largest avoidable cost at 57% of the total cost (approximately US$270 billion per year). In England, it is estimated that an improvement in adherence across five key chronic diseases (type 2 diabetes, asthma, cardiovascular disease/hypercholesterolemia, hypertension and schizophrenia) could save the NHS £500 million per year (Trueman et al. 2011). The clinical impact and associated cost of non-adherence varies from patient to patient and so these figures only estimate the extent of the problem. Nonetheless, the global scale of non-adherence is considered to be equivalent to a major disease epidemic. The WHO has recognised that addressing the problem of non-adherence could have a much larger impact on treatment effectiveness than any attempts to improve the efficacy of existing drug treatments (Sabate, 2003).

A large amount of research evidence supports the efficacy of medications that are commonly used in the treatment of LTCs. Where medications have been appropriately prescribed as part of a polypharmacy regimen— with benefits outweighing the risks— adherence to the recommended directions is vital to treatment success (Brown and Bussell, 2011). For example, Sokol et al. (2005) demonstrated that higher rates of medication adherence were associated with reduced hospital admissions and decreased total medical costs in patients with a range of chronic conditions including hypertension, diabetes and CHF. Older patients who are appropriately prescribed multiple medications to treat several LTCs therefore have the most to gain from treatments and consequently the implications of non-adherence are greater. For that reason, improving adherence to long-term medicines continues to be a key priority for researchers, clinicians and policy makers across the globe (Sabate, 2003; Horne et al. 2005; Bosworth et al. 2011).

1.2.5 Determinants of non-adherence

A wide range of factors have been identified as potential influences on patients' adherence to long-term medications (Clifford et al. 2008; Demonceau et al. 2013; Allemann et al. 2016) These factors have previously been classified by the WHO into five broad dimensions (see Figure 1.2).

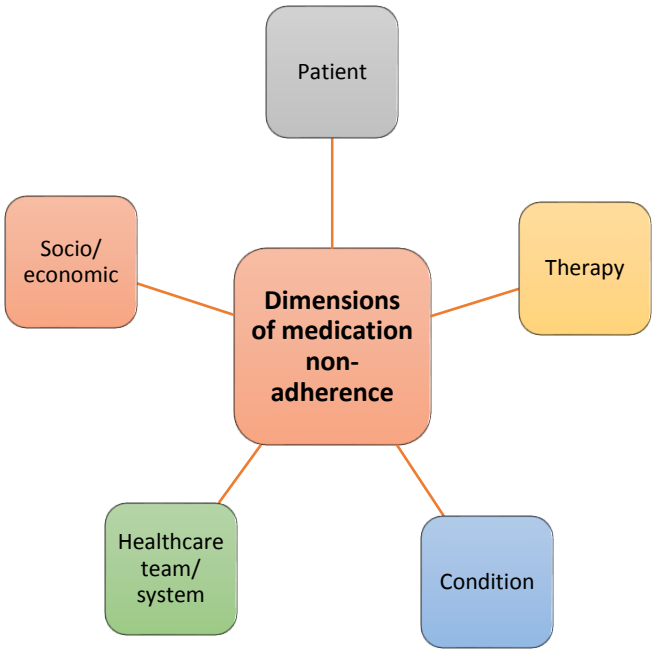


Figure 1.2: The five dimensions of non-adherence (Sabate, 2003)

Patient-related factors include physical and psychological factors. Physical factors include hearing and sight impairment, cognitive impairment, impaired dexterity, reduced mobility and swallowing difficulties. Psychological factors include knowledge about conditions/medications, attitudes towards medications, motivation, confidence, fear of side effects and perceived benefits of treatment. Condition-related factors include severity of symptoms, absence of symptoms, depression and psychiatric conditions. Healthcare team/system-related factors include patient-HCP relationship, HCP communication skills, continuity of care, access to treatments and waiting times. Social/economic-related factors include literacy, social support levels, living conditions, and access to healthcare facilities (Sabate, 2003). Although this framework aids understanding of potential influences on adherence behaviours, the categories are too broad to guide research that seeks to change adherence behaviours (Allemann et al. 2016).

Kardas et al. (2014) identified 771 individual factors (400 determinants) related to adherence to long-term treatments and categorised these into 40 clusters. Although having knowledge

of all potential determinants is important, not all are amenable to change. For example, Allemann et al. (2016) grouped 40 identified patient determinants into modifiable (n=27 e.g. knowledge about therapy, forgetfulness) and unmodifiable determinants (n=13 e.g. chronicity of illness, prior history of medication non-adherence). However, there is also no single determinant that predicts adherence in all patients and the individual factors facing each patient are likely to differ (Marengoni et al. 2016). It is also unclear which modifiable determinants are the most salient in the context of older patients who are prescribed polypharmacy to treat a range of clinical conditions (Vik et al. 2004).

1.3 Introduction to behaviour change and behaviour change interventions

1.3.1 The challenge of behaviour change

Medication adherence, is commonly labelled as a behaviour, a term used to describe how a 'person behaves in response to a particular situation or stimulus' (Oxford English Dictionary, 2016). Changing the behaviour of individuals (or groups of individuals) is an important part of health services research and one that poses a considerable challenge. Take for example, physical inactivity or tobacco smoking; these behaviours have gained significant attention over the past few decades, yet despite many years of research they continue to be difficult to change (Kelly and Barker, 2016). As highlighted by Michie et al. (2014a) 'changing ingrained behaviour patterns can be challenging'. It requires a thorough understanding of an individual's motivations, as well as any influences from others and/or the social environment. Understanding these factors can help to identify how to change and maintain the desired behaviour (Kelly and Barker, 2016).

For a given behaviour to be performed, Michie et al. (2011) have suggested that an individual must: (1) be psychologically and physically capable of performing the desired behaviour; (2) have social and physical opportunities to do so; (3) be motivated to carry out the behaviour. This has been described as the COM-B (capability, opportunity, motivation—behaviour) model (see Figure 1.3). The COM-B model has been derived from a larger, more complex, framework for understanding behaviour change known as the Theoretical Domains Framework (TDF); the latter will be discussed in more detail in Section 1.5.3 (Michie et al. 2015).

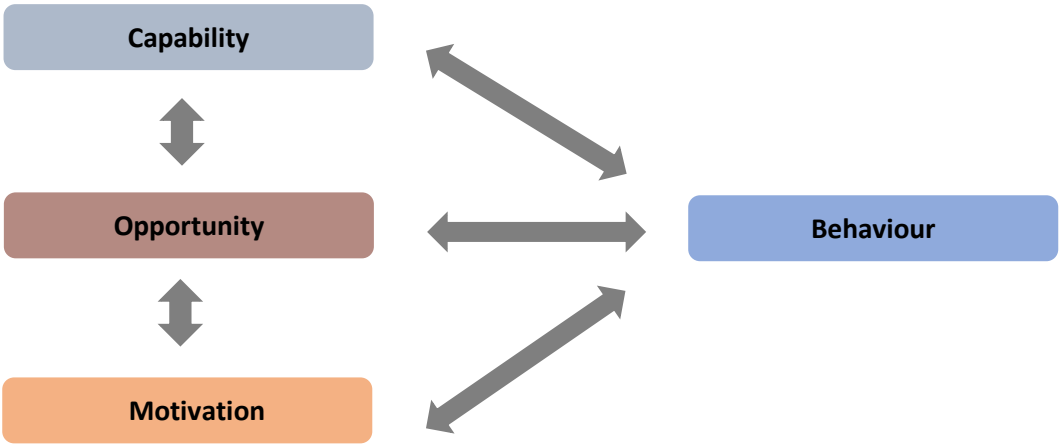


Figure 1.3: COM-B model [adapted from Michie et al. (2011)]

In the context of medication adherence, the main behaviour is of those required to take or use the medications (i.e. patients), however, the behaviours required of others who engage with patients in the clinical context (e.g. HCPs) should also be considered. The behaviour of HCPs in the context of providing adherence support to patients is discussed in more detail in Section 1.4.3.

1.3.2 Behaviour change interventions (BCIs)

One way of changing an individual's (or groups of individuals') behaviour (e.g. patients, HCPs) is through the delivery of an intervention. An intervention can be described as a single action or set of actions delivered to the target recipient(s) at a specific time and place (Conn et al. 2016a). When the intervention aims to change a specific behaviour and includes multiple components, it is described as a behaviour change intervention (BCI). BCIs are defined by NICE as 'sets of techniques, used together, which aim to change the health behaviours of individuals, communities or whole populations' (National Institute for Health and Clinical Excellence, 2007).

1.4 Interventions to improve medication adherence in older adults

1.4.1 Single verses multi-component adherence interventions

A plethora of adherence interventions have been tested over the last four decades to change patients' adherence behaviours, with the earliest interventions first reported in the early 70's (Cole et al. 1971; Epstein et al. 1973; Conn and Ruppar, 2017). These have ranged from

individual component interventions such as simple reminders through to multi-component intervention packages. Interventions have been educational-based (e.g. improving patients' knowledge of medications and conditions), cognitive/behavioural-based (e.g. daily reminders, modifications to packaging, counselling) or a mixture of both (Nieuwlaat et al. 2014). The majority of adherence interventions have been directed at patients' adherence behaviours, as opposed to HCPs' behaviours, although the latter should not be overlooked (see Section 1.4.3).

Where 'multiple interacting components' are delivered as part of an intervention package, these interventions can be described as BCIs or complex interventions (Craig et al. 2008). Aside from the number of intervention components, complexity can also arise from the number and difficulty of behaviours required either by intervention recipients or providers and the amount of individualisation or tailoring of intervention content to individual circumstances that is permitted. Thus, due to the complexity of the behaviour itself, adherence interventions are rarely ever truly simple in nature.

A range of single component interventions (e.g. regimen simplification, provision of pill reminder boxes) have been tested in an attempt to improve medication adherence but these have shown mixed effects (Nieuwlaat et al. 2014). Based on the knowledge that medication adherence is a complex behaviour with a range of potential determinants, it seems highly unlikely that a single component intervention will be the answer for all non-adherent patients. This view is supported by a Cochrane review that assessed the effectiveness of 182 RCTs in terms of improving both medicine adherence and clinical outcomes in all age groups (Nieuwlaat et al. 2014). The review authors concluded that out of the 17 studies with the lowest risk of bias, only five showed improvements in both adherence and clinical outcomes. Those demonstrating effectiveness were complex in nature but improvements were generally limited. The interventions delivered were heterogeneous in design, ranging from daily support through to educational and behavioural-based interventions. Although the authors highlighted some concerns around the use of complex interventions (such as difficulty in identifying the most effective components and difficulty with replication due to poor reporting), they indicated that it is rational to adopt them for targeting a complex behaviour such as medication adherence.

1.4.2 Adherence interventions targeting older adults

A small number of systematic reviews have focused more specifically on adherence interventions that target older adults, patients with multimorbidity and/or patients

prescribed multiple medications (van Eijken et al. 2003; Banning, 2008; George et al. 2008; Ruppar et al. 2008; Williams et al. 2008). A systematic review conducted by George et al. (2008) identified only a limited number of interventions (n=8) that targeted older patients who were prescribed polypharmacy. Out of the eight interventions identified, only four showed improvements in adherence. Strategies included Monitored Dosage Systems (MDS; plastic containers with slots for each day and time of the week), group education, individual medication lists and medication reviews but there was no common effective component identified.

Williams et al. (2008) conducted a systematic review of adherence interventions targeting multimorbid patients, with five out of the eight studies they identified targeted at older adults aged 70 years or older. They found that adherence was commonly addressed as part of larger interventions to manage polypharmacy and reduce healthcare costs, with pharmacists as the most prominent intervention provider. The authors indicated that the current evidence base for such interventions was weak and interventions often lacked a psycho-social focus (i.e. they did not focus on the influence of the social environment on adherence behaviours).

More recently, a systematic review conducted by Marcum et al. (2017) explored interventions that aimed to improve medication adherence and health outcomes (e.g. mortality, morbidity, healthcare costs) in older adults. This review reported mixed findings, with only five out of the 12 identified studies showing improvements in both adherence and health outcomes; two combined educational and behavioural strategies and three were pharmacist-led counselling interventions. The authors indicated that interventions delivered by pharmacists produced promising findings but that such interventions need to be more carefully designed and evaluated in future research.

Adherence interventions have commonly focused on improving older patients' knowledge of medications/medical conditions through education (Nieuwlaat et al. 2014; Conn and Ruppar, 2017). Although knowledge is an important pre-requisite and necessary for adherence, it has been recognised that education alone is insufficient for changing adherence behaviours, particularly with regards to unintentional non-adherence such as forgetfulness (Conn et al. 2009; Conn et al. 2016b; Kahwati et al. 2016). A review by Schlenk et al. (2008) found that educational-based interventions were not consistent in improving older patients' medication adherence. Instead they found tailored interventions with ongoing contact with HCPs (e.g. pharmacists, health mentors) were more effective than brief interactions or mailed education, but further research in this area is required.

1.4.3 Healthcare professionals' role in improving medication adherence

As alluded to previously, whilst most interventions have focused on patients' behaviour, research has recognised that adherence is not solely the result of an individual's actions but can be influenced by both the healthcare setting and HCPs' behaviours. For example, actions undertaken by HCPs and their relationships with patients have been reported as determinants of adherence (Kardas et al. 2013; Conn et al. 2015; Allemann et al. 2016). Consequently, the role that HCPs can play in tackling non-adherence is of growing interest in the field of adherence research (Huston, 2015).

The WHO report on medication adherence recognised that HCPs have an important role to play in identifying non-adherence and in the delivery of interventions to improve it (Sabate, 2003). The report also indicated that HCPs require access to training on how to manage non-adherence and healthcare systems need to be designed in such a way to facilitate this. Guidance produced by NICE in 2009 on medicines adherence (CG76) has also discussed HCPs' clinical role in both assessing adherence (e.g. asking about adherence when prescribing,dispensing or reviewing medicines) and delivering interventions to improve it (e.g. information provision, practical changes, encouragement/support) (National Institute for Health and Clinical Excellence, 2009). Despite this guidance, recent research has shown that HCPs do not frequently ask patients about their medication adherence behaviours and they are unable to accurately predict non-adherence in their patients (Zeller et al. 2008; Conn et al. 2015).

A survey, conducted in Switzerland and nine other European Union (EU) countries (e.g. England, France, The Netherlands), explored the role of primary care and community-based HCPs' (doctors, nurses and pharmacists) in managing medication adherence. This cross-sectional study found that only half of all HCPs routinely questioned patients about missed doses (Clyne et al. 2016). Out of the three groups of HCPs who were surveyed, pharmacists intervened the least. However, pharmacists from England, the Netherlands and Portugal reported slightly more frequent assessment of non-adherence and information provision than pharmacists in other countries. Pharmacists in England and the Netherlands also reported more frequent recommendation of practical strategies to improve adherence in comparison with pharmacists from other countries. In the primary care setting, community pharmacists (CPs) are seen as the most accessible HCP who have frequent contact with patients (e.g. every time medication is dispensed) (Kocurek, 2009). Therefore, CPs are being presented with an opportunity to support patients with medication adherence and help them obtain maximum benefit from treatments.

A small number of qualitative studies have recently been conducted to explore CPs' perceived barriers to providing medication adherence support (MAS) in the USA (Bacci et al. 2014), Scotland (Lowrie et al. 2014) and Switzerland (Marquis et al. 2014). Initial findings indicate that time pressures, lack of remuneration, CPs' confidence and concerns around discussing multiple medical conditions may be contributory factors that influence CPs' behaviour (i.e. the provision of MAS). However, it appears that barriers to providing MAS may vary both within and between countries. For example, a lack of confidence was identified as a barrier in qualitative interviews with CPs in Switzerland (Marquis et al. 2014), whereas, a Scottish study (Lowrie et al. 2014) showed that CPs appeared to be confident, although the latter study focused solely on the provision of adherence support to heart failure patients. With contrasting findings in the current (somewhat limited) evidence base, there is a need for additional research into the most influential barriers and facilitators to the provision of MAS by CPs (Huston, 2015). Due to the influence of HCPs on patients' adherence behaviours, it may be necessary to target HCPs' behaviour directly (e.g. through a training package, changes to policy) to have an impact on patients' behaviour.

A recent systematic review by Conn et al. (2015) explored HCP-targeted interventions that ultimately aimed to improve patients' medication adherence. This review identified 218 interventions which, overall, produced a small overall effect size (Cohen's d) of 0.233 in comparison with usual/standard care (effect sizes ranged from 0.088 to 0.301 for individual interventions, where 0.2 indicates a small effect size, 0.5 a moderate effect size and 0.8 a large effect size). Interventions that contained multiple components (i.e. complex interventions) directed at HCPs were more effective but there was a lack of evidence to support any particular strategy. Interventions ranged from educating HCPs on adherence and skills training (e.g. communication skills, barrier identification skills, Motivational Interviewing skills) through to reminder systems to prompt HCPs to ask patients about adherence. It is unclear how such multi-component interventions (e.g. training packages) directed at HCPs have been developed and their anticipated mechanisms of actions. Thus, there is a need for more research in this area.

1.4.4 Pitfalls with adherence intervention research

Although there has been a substantial amount of work in the field of adherence research, it is clear that no individual intervention component or package of components has led to substantial improvements in medication adherence in older patients (Brown and Bussell, 2011). Those interventions that have led to improvements in adherence have shown only modest improvements. For example, meta-analyses have shown improvements in adherence

measures in the range of 4-11% (Peterson et al. 2003; Kripalani et al. 2007; Bosworth et al. 2011).

There are a number of major issues with previous adherence research. Firstly, adherence interventions have commonly targeted individual (or groups of) medications for a single clinical condition, yet over two-thirds of older patients are multimorbid and require treatment with several medications (Barnett et al. 2012). Boyd and Fortin (2011) have emphasised the importance of taking '…care of people with multimorbidity, not the individual conditions that add up to multimorbidity'. As stated in the latest Cochrane review on medication adherence interventions, the clinical condition is not deemed to be a major determinant of behaviour (Nieuwlaat et al. 2014). Therefore to be relevant for future clinical practice, adherence research needs to shift its focus away from single conditions. Instead, interventions need to be designed to account for the presence of multiple medications and clinical conditions, which will likely vary from patient-to-patient (Salisbury, 2012). There is a need for more research that explores the effectiveness of novel complex interventions that can be tailored to each older patient's individual medications/conditions and readily integrated into clinical practice. Previous interventions have also failed to focus on the patient perspective to medication-taking and are described as being only 'loosely patient-centric' (Bosworth et al. 2011).

Another issue is that adherence is often addressed as part of a complex disease management programme instead of being the sole focus of interventions (Nieuwlaat et al. 2014). Details of exactly what has been delivered as part of complex intervention packages and their proposed mechanism of action for changing patients' adherence behaviours are often unclear, missing or not fully described in published reports. Researchers need to carefully report the components of complex interventions to allow for replication or adaption by others.

1.5 Developing and evaluating complex behaviour change interventions

1.5.1 Challenges associated with complex interventions

As discussed in Section 1.4, complex interventions are often employed in an attempt to improve medication adherence and these are usually directed at patients (although they can also be directed at HCPs). However, challenges have been identified around the design, standardisation and delivery of such interventions (Craig et al. 2008). Research into methods

used in clinical trials suggests that there is often a lack of initial preparatory work, which may impact on the outcomes and overall success of complex interventions (Eldridge et al. 2004).

What appears to be lacking from the current evidence base is clear justified reasons for selecting particular intervention components and a detailing understanding and report of their proposed mechanism of action for eliciting behaviour change (e.g. a change in patients' adherence behaviours) (Nieuwlaat et al. 2014). Conventionally, components of complex interventions have been selected based on what researchers think might be effective, rather than on established theory and patient views. A better understanding of how adherence interventions work through the use of theory could help to advance this field of research (Michie et al. 2015).

1.5.2 The potential role of theory in adherence research

A theory has been defined as:

> *"(…) a systematic way of understanding events or situations. It is a set of concepts, definitions, and propositions that explain or predict these events or situations by illustrating the relationship between variables."* (Glanz and Rimer, 2005, p.4)

Theories (also termed models) consist of building blocks called 'theoretical constructs' which are labels given to complex sets of observations of human behaviour (Binning, 2016). Theories can stem from a range of disciplines including psychology, sociology, anthropology and economics. Psychological theories are the most common type of theory used in the field of health behaviour change and are therefore the focus of this research (Michie et al. 2014a). These can facilitate researchers' understanding of health behaviours by: (1) explaining and predicting the behaviour (when, how and why it occurs); (2) helping to identify key influences on behaviour that could be targeted to bring about behaviour change. Incorporating theory into the design of adherence interventions could prove to be effective but further research is required.

A range of psychological theories have been used to explain and predict health behaviours. Social Cognitive Theory (SCT), the Health Belief Model (HBM) and the Theory of Planned Behaviour (TPB) are examples of commonly used theories; these are briefly explained below in Table 1.1 as illustrative examples (Munro et al. 2007; Holmes et al. 2014).

Table 1.1: Examples of psychological theories including brief descriptions and illustrative diagrams

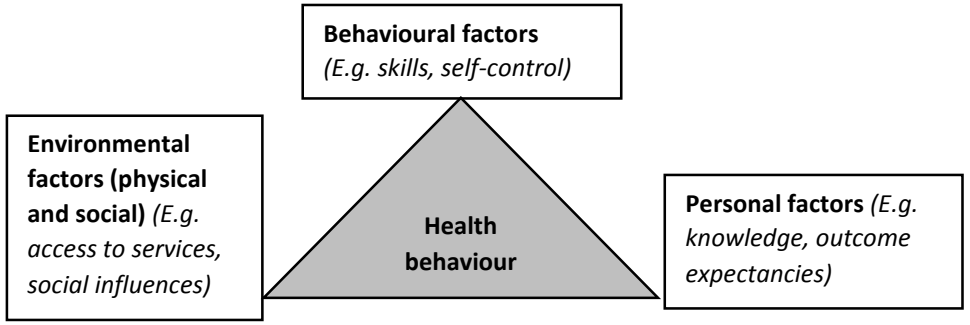
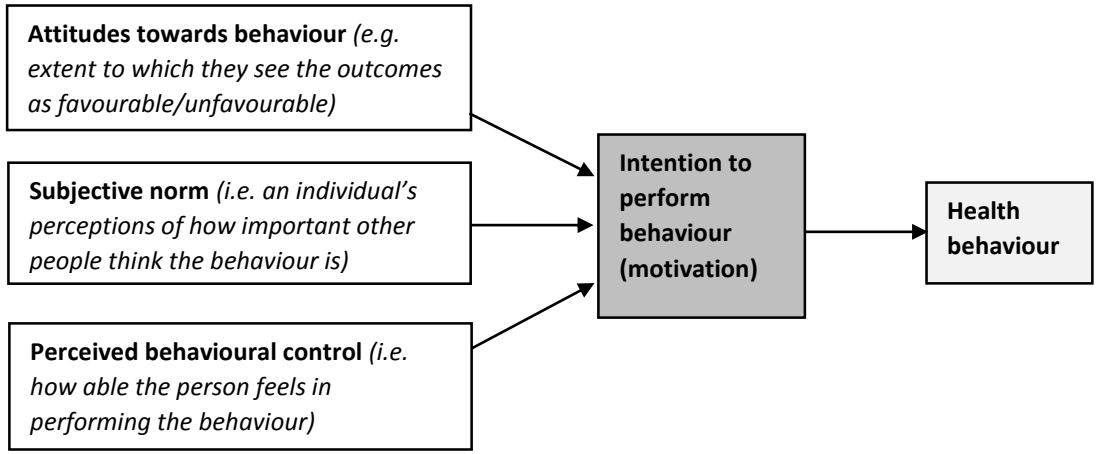
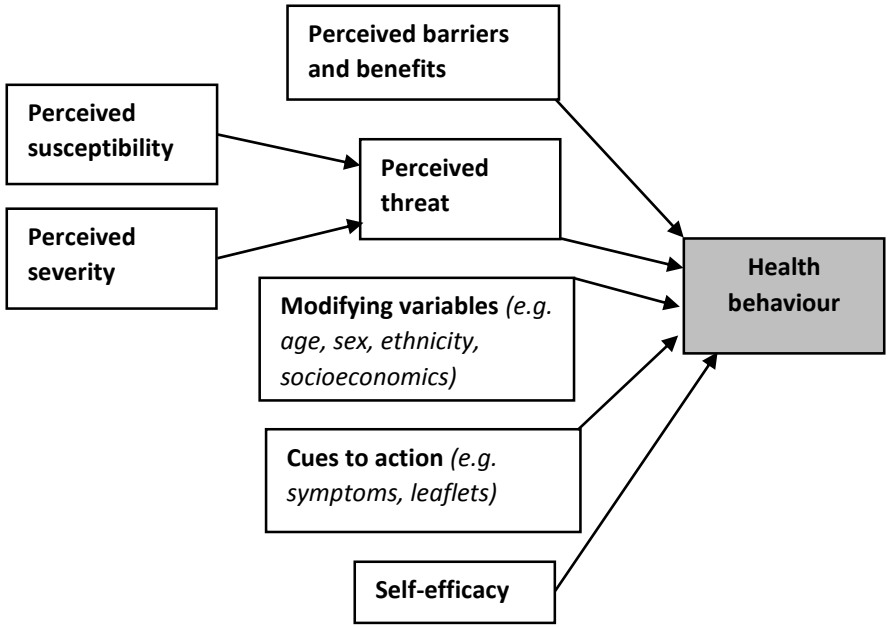
Theory	Brief description	Illustrative diagram
Social cognitive theory (SCT) (Bandura, 1986)	SCT focuses on how individuals learn from past experiences and the actions of others, as well as the impact from the environment. Three key factors (environment, personal, behavioural) continuously influence each other and impact on the health behaviour.	
Theory of planned behaviour (TPB) (Ajzen, 1985; Ajzen, 1991)	TPB explains that a combination of beliefs (attitudes towards the behaviour, subjective norm, perceived behavioural control) predict an individual's intention (motivation) to perform a health behaviour.	

Table 1.1 (cont'd): Examples of psychological theories including brief descriptions and illustrative diagrams

Theory	Brief description	Illustrative diagram
Health belief model (HBM) (Rosenstock, 1974; Glanz et al. 2008)	A health behaviour can be predicted by core theoretical constructs including perceived susceptibility and severity of the illness and perceived barriers and benefits. Behaviour can also be influenced by internal or external cues to action and a person's self-efficacy (i.e. an individual's belief in their ability to carry out the desired behaviour).	

Although a wide range of psychological theories have been used to help explain and predict patients' non-adherence behaviours, it seems that only a limited number of interventions to improve adherence have been explicitly based on theory (Nieuwlaat et al. 2014). Consequently, there is a need to explore exactly how researchers have used psychological theory to develop complex interventions to improve medication adherence in older adults who are prescribed polypharmacy.

Although theory cannot guarantee intervention effectiveness, there are a range of reasons why it is thought that its use could advance scientific research. Theory can provide intervention developers with a lens through which to view the behaviour of interest and identify exactly what factors need to be targeted for change. It can also be used to explore the intervention's underlying mechanisms of action and contribute to the knowledge base on how interventions work (Rothman, 2004; Michie et al. 2014a). It can be difficult to identify the most effective individual active components within complex interventions (Campbell et al. 2000). Psychological theories offer a potential way of addressing this complexity. As a result, theory can increase research efficiency by ensuring researchers undertake a systematic and methodological approach to generating new knowledge (Michie et al. 2014a).

Recommendations to have a coherent theoretical underpinning for complex interventions (including guidance from the UK Medical Research Council; see Section 1.5.4) have led to researchers selecting commonly cited theories (e.g. HBM, SCT) to develop BCIs without fully exploring the target behaviour in their target audience (Moore and Evans, 2016). Moore and Evans (2016) argue that this approach acts as a distraction from identifying the true mechanism of action through which behaviour change could be achieved. Citing such theories without exploring their true fit to the target audience is also unlikely to lead to improved intervention effects. It is therefore important to explore the behaviour in detail when establishing the theoretical basis of a complex intervention.

Holmes et al. (2014) conducted a review that looked at the ability of psychological theories to predict medication adherence in adults (>18 years). The majority of studies were cross-sectional in nature (49 out of 67) and the most common condition under investigation was HIV (n=22). The authors concluded that individual theories or models only explained a small amount of the variability in adherence across adult patients. This may be because individual theories do not cover all of the possible influences on a person's behaviour, for example, SCT does not take into account the role that habits have to play in adherence (Bandura, 1998).

Benefits of using theory are likely to be limited if researchers limit their selection to individual theories rather than taking into consideration a broad range of theories (Munro et al. 2007; Holmes et al. 2014; Michie et al. 2014a). Psychological theories, often with overlapping constructs, are abundant in the literature; this makes it difficult to select the most appropriate one to inform intervention development (Michie et al. 2014a).

1.5.3 The Theoretical Domains Framework (TDF)

To overcome problems associated with theory selection, a group of psychologists and health service researchers designed the Theoretical Domains Framework (TDF) of behaviour change. The original 12 domain framework (TDF1), developed in 2005, incorporates theoretical constructs from 33 psychological theories of behaviour change (Michie et al. 2005). Definitions of each domain in TDF1 and descriptions in the context of medication adherence are presented in Table 1.2. Theoretical constructs assigned to each theoretical domain are also provided. The TDF can be used by intervention developers to inform the design of complex interventions and incorporate a theoretical underpinning in their development (Michie et al. 2014a).

Table 1.2: Domains in TDF1 (Michie et al. 2005), definitions, descriptions of the domain in the context of medication adherence behaviour and theoretical constructs assigned to each domain [adapted from Francis et al. (2014)]

Domain in TDF1	Definition of domain (Michie et al. 2005)	Description of domain in the context of medication adherence behaviour	Theoretical constructs represented within each domain (Michie et al. 2005)
Knowledge	'An awareness of the existence of something'	Knowledge related to medications, regimens and clinical conditions	Knowledge (including knowledge of condition/scientific rationale); Procedural knowledge; Schemas+ mindsets+ illness representations
Skills	'An ability or proficiency acquired through practice'	Abilities (i.e. physical skills) required to take several medications as prescribed	Skills; competence/ability/skill assessment; Practice/skills development; Interpersonal skills; Coping strategies
Social/ professional role and identity	'A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting'	Whether patients see the behaviour as their own responsibility or as someone else's	Identity; Professional identity/boundaries/role; group/social identify; Social/group norms
Beliefs about capabilities[1]	'Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use'	How confident the patient feels about being able to adhere to a multiple medication regimen (i.e. ease or difficulty of the behaviour)	Self-efficacy; Control—of behaviour and material and social environment; Perceived competence; Self-confidence/professional confidence; Empowerment; Self-esteem; Perceived behavioural control; Optimism/pessimism
Beliefs about consequences[2]	'Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation'	Perceptions about the outcomes of taking (or not taking) several medications as prescribed (benefits and unwanted side effects)	Outcome expectancies; Anticipated regret; Appraisal/evaluation/review; Consequents; Attitudes; Contingencies; Reinforcement/punishment/consequences; Incentives/rewards; Beliefs; Unrealistic optimism; Salient events/sensitisation/critical incidents; Characteristics of outcome expectancies–physical, social, emotional; Sanctions/rewards, proximal/distal; Valued/not valued, probable/improbable, salient/not salient, perceived risk/threat
Motivation and goals (intentions)[3]	'Mental representations of outcomes or end states that an individual wants to achieve and their intentions to perform the target behaviour'	Strength of intention to adhere to the medication regimen Priorities, perceived importance and commitment to taking several medications as prescribed	Intention; Stability of intention/certainty of intention; Goals (autonomous, controlled); Goal target/setting; Goal priority; Intrinsic motivation; Commitment; Distal and proximal goals; Transtheoretical model and stages of change

Table 1.2 (cont'd): Domains in TDF1 (Michie et al. 2005), definitions, descriptions of the domain in the context of medication adherence behaviour and theoretical constructs assigned to each domain [adapted from Francis et al. (2014)]]

Domain in TDF1	Definition of domain (Michie et al. 2005)	Description of domain in the context of medication adherence behaviour	Theoretical constructs represented within each domain (Michie et al. 2005)
Memory, attention and decision processes	'The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives'	Memory—whether adherence to polypharmacy is problematic because patients simply forget Decision-making – whether patients choose to take certain medicines over others; whether they decide to have occasional breaks from taking medications;	Memory; Attention; Attention control; Decision-making
Environmental context and resources	'Any circumstances of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour'	Physical factors (e.g. difficulty swallowing large tablets) Financial and healthcare system factors (e.g. difficulty accessing a repeat prescription service) Circumstances (e.g. location, time) under which the behaviour is occurring (e.g. whether adherence is more difficult when the patient is away from home)	Resources/material resources (availability and management); Environmental stressors; Person X environment interaction; Knowledge of the task environment
Social influences	'Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours'	External pressure/influence from others (e.g. HCPs, carers, family, other patients) Whether patients take several medications as prescribed simply because they are told to	Social support; Organisational development; Leadership; Team working; Group conformity; Organisational climate/culture; Social pressure; Power/hierarchy; Professional boundaries/roles; Management commitment; Supervision; Inter-group conflict; Champions; Social comparisons; Identity; Group/social identity; Organisational commitment/alienation; Feedback; Conflict—competing demands, conflicting roles; Change management; Crew resource management; Negotiation; Social support: personal/professional/organisational, intra/interpersonal, society/community; Social/group norms: subjective, descriptive, injunctive norms; Learning and modelling

Table 1.2 (cont'd): Domains in TDF1 (Michie et al. 2005), definitions, descriptions of the domain in the context of medication adherence behaviour and theoretical constructs assigned to each domain [adapted from Francis et al. (2014)]

Domain in TDF1	Definition of domain (Michie et al. 2005)	Description of domain in the context of medication adherence behaviour	Theoretical constructs represented within each domain (Michie et al. 2005)
Emotion	'A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event'	Affect (positive or negative) Feelings towards taking (or not taking) several medications as prescribed	Affect; Stress; Anticipated regret; Fear; Burn out; Cognitive overload/tiredness; Threat positive/negative affect; Anxiety/depression
Behavioural regulation	'Anything aimed at managing or changing objectively observed or measured actions'	Whether patients have ways of monitoring their medication adherence/non-adherence and outcomes Whether patients have difficulty translating intentions to take several medications as prescribed into action	Goal/target setting; Action planning; Self-monitoring; Goal priority; Generating alternatives; Feedback; Moderators of intention-behaviour gap; Project management; Barriers and facilitators
Nature of the behaviours[4]	'Essential characteristics of the behaviour'	Past experiences of adherence/non-adherence to polypharmacy Whether medication adherence is a routine/automatic behaviour for the patient	Routine/automatic/habit; Breaking habit; Direct experience/past behaviour; Representation of tasks; Stages of change model.

[1] *Split into two domains in TDF2 (14 domains): 'Optimism' and one retaining the original name;* [2]*Split into two domains in TDF2 (14 domains): 'Reinforcement' and one retaining the original name;* [3]*Split into two domains in TDF2 (14 domains): 'Intentions' and 'Goals';* [4] *Removed in TDF2 (14 domains)*

This framework has recently been updated to a 14 domain version (TDF2) (Cane et al. 2012), however, both versions of the TDF are useful frameworks for developing complex interventions such as BCIs (Huijg et al. 2014b; Atkins et al. 2017).

As discussed previously in Section 1.3.1, three key factors need to be taken into consideration in the context of behaviour change: capability, opportunity and motivation; these form the COM-B model (Michie et al. 2011). Jackson et al. (2014) have recommended the use of the COM-B model in exploring medication adherence as it offers 'a more complex explanation of adherence than existing models'. The TDF1 is a more comprehensive framework that can be mapped onto the COM-B model. The links between the TDF1 and the COM-B model are shown below in Figure 1.4. The COM-B was developed to simplify the framework for use by a wider audience, such as policy makers. As the TDF is more detailed than the COM-B model, it is more useful in the context of research (Michie et al. 2014b).

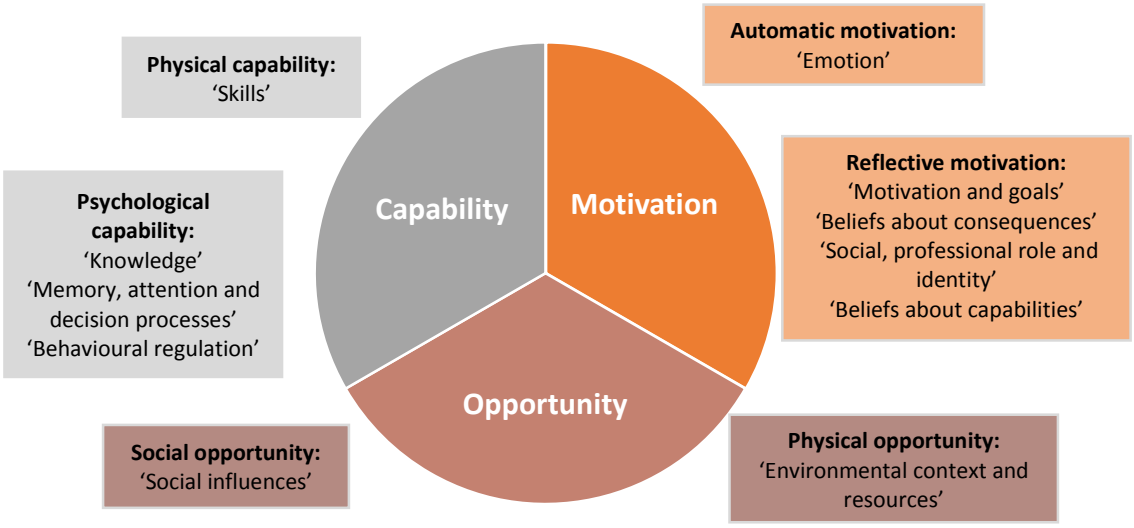


Figure 1.4: Links between the COM-B model (central pie chart) and the TDF1 (outer boxes)

NB: *The domain 'Nature of the behaviours' is considered to be slightly different to the other 11 domains in the TDF1 as it is not deemed a source of the behaviour (i.e. independent variable); instead it is described as a dependent variable (Cane et al. 2012; Michie et al. 2014b).*

In order to bring about behaviour change it is important to fully understand the target behaviour in the target audience. The TDF can be used as a 'theoretical lens' to identify key determinants of target behaviours (Stewart and Klein, 2016; Atkins et al. 2017). These key determinants are seen as barriers and/or facilitators, where a barrier is anything that prevents the behaviour being carried out and a facilitator helps in carrying out the behaviour. Identification of key determinants (i.e. barriers, facilitators) can be achieved by undertaking

a behavioural analysis via qualitative and/or quantitative methods. Key theoretical domains can then be selected for targeting and linked to the most appropriate intervention components (Michie et al. 2008; Michie et al. 2013; Cane et al. 2015). In the field of behaviour change, the components of complex BCIs are termed behaviour change techniques (BCTs). BCTs are defined as….

> *"…the smallest components of behaviour change interventions that on their own in favourable circumstances can bring about change."* (Michie et al. 2014b)

BCTs can be described as 'theory-based' as they originate from social science and behavioural theories (Kok et al. 2016). A change in key determinants (barriers, facilitators) through targeting key domains (from the TDF) with appropriate BCTs will, in theory, lead to behaviour change (Michie et al. 2014a).

To date, TDF-based intervention development studies have primarily focused on HCPs' clinical behaviours, particularly in relation to the implementation of evidence-based guidelines (Francis et al. 2012). More recently, the TDF has been used to explore patients' behaviours. For example, Cahir et al. (2015), McCullough et al. (2015) and Easthall et al. (2014) have used the TDF to explore medication adherence, albeit in different patient populations (in patients with breast cancer, bronchiectasis and cardiovascular disease, respectively). However, no studies have explored older patients' adherence to multiple medications (i.e. polypharmacy) using the TDF as a 'theoretical lens'.

1.5.4 Guidance from the Medical Research Council

The Medical Research Council (MRC) has produced guidelines for those undertaking complex intervention studies to help overcome the difficulties associated with their design and testing (Craig et al. 2008). The most recent MRC framework was published in 2008 and advises that intervention development should consist of a number of non-linear stages including: development; feasibility and piloting; evaluation and implementation (Figure 1.5).

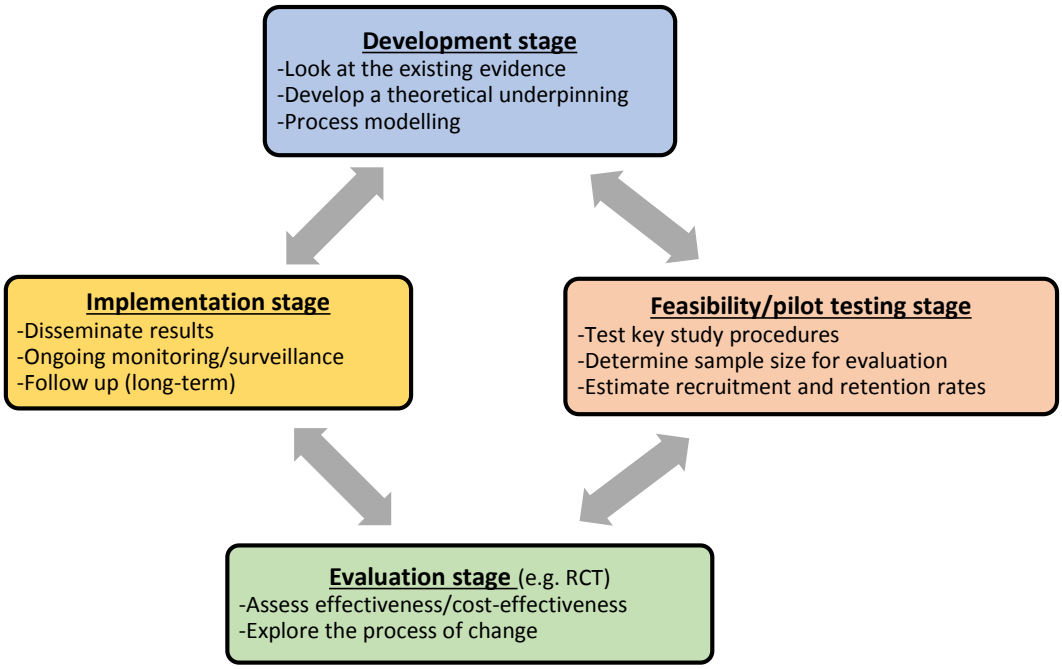


Figure 1.5. The key stages involved in 'developing and evaluating complex interventions' (Adapted from: Medical Research Council, 2008)

The MRC recommends that the initial development stage should include establishing the intervention's evidence and theoretical base and triangulating these findings to develop an intervention. Previous complex interventions have been developed using the acronym as 'ISLAGIATT': 'It Seemed Like A Good Idea At The Time' (acronym created by Martin Eccles; Emeritus Professor of Clinical Effectiveness, and implementation researcher) rather than using a systematic development approach (Michie et al. 2014a). Using the MRC approach to development, may involve conducting a systematic review (evidence base), in addition to conducting primary research such as interviews or focus groups (qualitative methodology) or questionnaire studies (quantitative methodology) to explore the behaviour in detail and develop the interventions' theoretical base.

By developing an understanding of the behaviour that needs changed through the use of theory (or a theoretical framework such as TDF), the most appropriate intervention components (i.e. BCTs) can be chosen to facilitate the behaviour change process (Glanz and Rimer, 2005; Michie and Prestwich, 2010). It is also thought that interventions based on theory are more likely to be effective than those with unknown mechanisms of actions (Holmes et al. 2014).

Following the systematic development of an intervention, the MRC recommends that such interventions should undergo feasibility and pilot testing. The terms feasibility and piloting are commonly used interchangeably in the literature, but some authorities claim that there

are subtle difference between the two (Arain et al. 2010). The National Institute for Health Research (NIHR) describes feasibility studies as research studies that are conducted in advance of a main trial to answer the key question 'Can this study be done?' (definitions of 'Feasibility studies' and 'Pilot studies' can be found at http://www.nets.nihr.ac.uk/glossary). Based on the NIHR's definition, the aim of a feasibility study can also be to address key study parameters required to inform future evaluations such as the willingness of HCPs to recruit patients and willingness of patients to be recruited, time needed to collect data etc. Eldridge et al. (2016) have provided the following definition for feasibility and pilot studies:

> *"A feasibility study asks whether something can be done, should we proceed with it, and if so, how. A pilot study asks the same questions but also has a specific design feature: in a pilot study, a future study, or part of a future study, is conducted on a smaller scale."*

The definition of a feasibility study proposed by the NIHR was adopted for the research presented in this thesis due to it being the most up-to-date definition available at the time that the research was conducted. Irrespective of the definition used, it is clear that feasibility studies do not aim to evaluate the effect of the intervention on any outcomes of interest; rather they can be used to assess whether outcomes (e.g. medication adherence outcomes, clinical outcomes) can be feasibly measured as part of a study in the selected setting.

It is important to note that the stages in the MRC framework are non-linear and researchers can move back and forth between stages until the intervention is optimised. In addition, researchers may want to consider implementation issues early on in the process. As discussed previously in Sections 1.3 and 1.4.3, researchers may wish to consider the behaviour of those who will be responsible for implementing the intervention in practice (such as HCPs) and the context in which it will be delivered.

1.6 Overview of research presented in this thesis

1.6.1 Overall research aim

The overall aim of the research outlined in this thesis was to design a complex theory-based intervention to improve medication adherence in older patients who are prescribed polypharmacy. It was intended at the outset of the project that the developed intervention would be delivered by CPs in the community pharmacy setting. CPs were selected as they are readily accessible to patients (Kocurek, 2009) and recent reviews have supported their involvement in interventions to improve the use of medicines by patients (Nieuwlaat et al.

2014; Ryan et al. 2014). Although the main focus of this research was on improving older patients' adherence behaviour, the behaviour of CPs in terms of providing MAS was also considered important to explore and potentially target as CPs will ultimately be responsible for implementing the intervention into practice, if it is shown to be effective.

The key objectives of this research project were to:

- Identify theory-based adherence interventions, delivered to older adults prescribed polypharmacy, in the literature and explore which theories were selected, how they were used and their potential impact on effectiveness
- Develop the theory base of a novel patient-targeted intervention to improve adherence to polypharmacy in older adults and select intervention components (i.e. BCTs) to target key behavioural determinants
- Combine selected intervention components into an intervention package for older patients prescribed polypharmacy and test the feasibility of delivering this in the community pharmacy setting
- Select components that could be delivered as part of a theory-based training package for CPs and strategies that could be used to facilitate the future implementation of the patient-targeted intervention in clinical practice

1.6.2 Overview of thesis chapters

To address the key research objectives stated above, the project was divided into four phases. The findings from each phase are outlined in Chapters 2-5 of this thesis:

Chapter 2: A systematic review of theory-based adherence interventions delivered to older adults prescribed polypharmacy

Chapter 3: Selection of components for a theory-based intervention to improve medication adherence in older adults prescribed polypharmacy

Chapter 4: Design and feasibility testing of a theory-based intervention to improve medication adherence in older adults prescribed polypharmacy

Chapter 5: Selection of components for a theory-based community pharmacist training package and strategies to improve the provision of medication adherence support: a mixed methods approach

Chapter 2

A systematic review of theory-based adherence interventions delivered to older adults prescribed polypharmacy

2.1 Introduction

This chapter focuses on a systematic review, conducted in line with the development stage of the UK MRC framework for complex interventions (Medical Research Council, 2008). The study reported here sought to address gaps in the current evidence base and inform the development of a novel complex intervention to improve medication adherence in older adults prescribed polypharmacy.

2.1.1 Overview of the current evidence base

As discussed in Chapter 1, a wide range of systematic reviews (and meta-analyses) have explored the effectiveness of medication adherence interventions across different clinical conditions, settings and population groups (Nieuwlaat et al. 2014; Conn et al. 2016b). A number of these reviews have focused specifically on older patients, multi-morbid patients or those prescribed multiple medications (George et al. 2008; Schlenk et al. 2008; Williams et al. 2008; Conn et al. 2009; Marcum et al. 2017). A common finding across previous reviews is the lack of strong evidence to support individual, or specific combinations of, intervention components. Where effectiveness has been demonstrated, improvements in adherence, clinical and humanistic outcomes (e.g. health-related quality of life; HRQOL) have been modest at best. It is evident that there is substantial room for improvement (Nieuwlaat et al. 2014).

It has been recognised that a 'one-size-fits-all' or 'simple' intervention approach is unlikely to improve medication adherence in all patients, and so the development of a complex intervention (with multiple interacting components) to address this problem is justified (Brown and Bussell, 2011; Nieuwlaat et al. 2014). However, as highlighted in Chapter 1, there are a number of challenges surrounding the development and evaluation of complex interventions. For example, the current gold standard evaluation approach (i.e. a definitive RCT) does not allow researchers to distinguish between active and inactive intervention components (Medical Research Council, 2008). Failure to understand exactly how individual intervention components exert their effect is a potential limiting factor in the advancement of this field of research.

2.1.2 Theory and complex interventions

An emerging concept in the development of complex interventions is the use of psychological theory to improve understanding of the behaviour change process (Medical Research Council, 2008). Psychological theories can help researchers identify: (1) '*What*' exactly needs

to change (i.e. which aspects of the behaviour should be targeted); (2) '*How*' to bring about behaviour change (i.e. which intervention components should be delivered in a complex intervention); (3) '*Why*' a particular effect is observed (i.e. the intervention's underlying mechanism of action) (Michie and Prestwich, 2010). For example, a theory-based process evaluation study, conducted alongside a RCT, could help researchers disentangle the causal chains that link the delivery of a complex intervention with study outcomes, as shown in Figure 2.1 (Mukhtar et al. 2014).

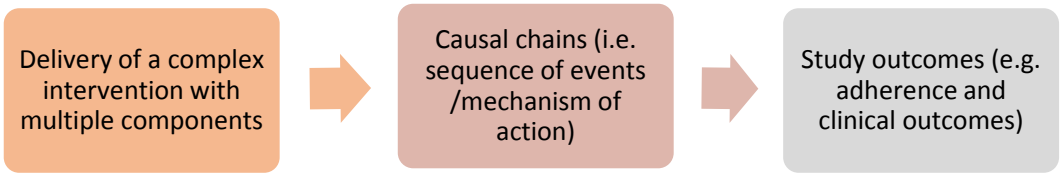


Figure 2.1: Diagrammatic representation of the linkage between complex intervention delivery and study outcomes

This type of process evaluation could involve the measurement of relevant theoretical constructs (e.g. 'motivation') pre- and post-intervention delivery (Michie and Prestwich, 2010). It is proposed that the systematic use of theory could contribute to the development of more effective interventions and also lead to the accumulation of evidence on what works, what does not work and the underlying reasons why (Medical Research Council, 2008).

2.1.3 Theory use in previous adherence intervention research

Little is currently known about how researchers have previously used psychological theory in the development of medication adherence interventions. The authors of the latest Cochrane review on medication adherence interventions noted whether an intervention appeared to be based on theory, but they did not explore this in detail (Nieuwlaat et al. 2014). Another recent meta-analysis of adherence interventions (delivered to adults aged over 18 years) examined the use of theory by identifying those that cited theory or a particular intervention approach commonly linked to theory (e.g. Motivational Interviewing; MI) (Conn et al. 2016a). This review identified 146 interventions that produced a modest overall effect size of 0.294. The authors indicated that this modest effect may have been influenced by poor theory selection, application/operationalisation, but they did not undertake a detailed examination of this.

Although the UK MRC's framework advocates the use of an underpinning theory for complex interventions, the guidance does not provide explicit details of exactly how theory should be utilised (Medical Research Council, 2008). Experts in the field of behaviour change and health

psychology have recognised that the specific way in which theory is used can affect the outcome of the intervention. It is therefore important to examine the exact nature of theory application (Michie and Prestwich, 2010). A Theory Coding Scheme (TCS) has been developed by Michie and Prestwich (2010) to assist researchers in systematically identifying and reliably describing an intervention's theoretical base. This research tool aims to encourage transparency and consistency in reporting, as well as a clearer understanding of what the term 'theory-based' means when used to describe BCIs. It has been successfully utilised in a number of systematic reviews on behaviour change, for example, in exploring theory use in internet-based health interventions (Webb et al. 2010; Prestwich et al. 2014; Ayling et al. 2015; Farmer et al. 2015). However, to date, no review has specifically investigated theory use in the design of adherence interventions, delivered to older adults prescribed polypharmacy, using the TCS. This chapter provides an overview of the methodology and findings from a systematic review that aimed to address this gap in the literature and inform the development of a novel complex intervention.

2.2 Aims and objectives

The overall aim of this systematic review was to determine the effectiveness of theory-based interventions in improving medication adherence and clinical/humanistic outcomes in older adults prescribed polypharmacy and explore exactly how psychological theory informed intervention design. The objectives were to:

- Identify studies which explicitly referenced, applied or tested a psychological theory in the development of adherence interventions delivered to populations of older adults (aged 65 years or older) who were prescribed polypharmacy (four or more medications)
- Determine the specific theories that underpinned these interventions
- Examine how theory informed intervention development
- Determine how the intervention was implemented (e.g. setting, provider)
- Identify how the authors defined the extent of adherence (or non-adherence) and the method(s) used to measure it
- Establish the effectiveness of theory-based interventions in improving medication adherence and clinical/humanistic outcomes in older adults prescribed polypharmacy.

2.3 Research design and methodology

2.3.1 Protocol

This systematic review followed a protocol developed using methods established by the Cochrane Collaboration (The Cochrane Collaboration, 2011). The review findings have been reported in line with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement (Moher et al. 2009) (see completed PRISMA checklist in Appendix 2.1).

2.3.2 Eligibility criteria

Types of studies

All types of RCTs, including cluster trials, were considered for inclusion. Ideally, systematic reviews should include the highest level of primary evidence available (i.e. RCTs), but in cases where limited evidence is anticipated or the concepts and recommendations are relatively novel, the next best level of evidence should be considered to help answer the research question (Sackett et al. 1996; Burns et al. 2011). Based on the findings from the latest Cochrane review on adherence interventions and limited number of theory-based interventions identified, the decision was made to include quasi-experimental studies, providing they had a comparative control group (Nieuwlaat et al. 2014). Table 2.1 details the types of quasi-experimental studies that were considered to be eligible for the review, on the condition that they met the criteria specified in the Cochrane Effective Practice and Organisation of Care (EPOC) Group's Data Collection Checklist (Bero et al. 2007).

Table 2.1: Eligible quasi-experimental studies and criteria for inclusion (Bero et al. 2007)

Study design	Criteria for inclusion
Non-randomised controlled clinical trials	The study had a comparative control group
Interrupted time series studies	The study had a comparative control group and at least three time points preceded and three time points followed the intervention date
Controlled before-and-after studies	Second sites were used as controls and were comparable in baseline characteristics. The exact times at which the intervention occurred were clearly stated

Pilot RCTs were also considered for inclusion in this review as studies in the preliminary stages of development and testing could use theory in intervention design (Medical Research Council, 2008). This decision was made on the basis that preliminary findings from small-scale pilot studies may provide useful insights that could inform the development of future adherence interventions, in the absence of larger definitive trials.

Types of interventions

Interventions delivered in all healthcare settings (e.g. primary care, secondary care) were considered for inclusion. Any type of intervention that had an underpinning psychological theory, theories or theoretical framework was considered for inclusion. Theories were included if they met the definition proposed by Glanz and Rimer (2005, p.4):

> *"…a set of concepts, definitions, and propositions that explain or predict… events or situations by illustrating the relationship between variables."*

Studies were excluded if they did not explicitly state that an established theory (or theoretical framework) underpinned the selected intervention or intervention components.

Types of participants

Studies were only included if the population had a mean (or median) age of 65 years or older, and were prescribed a mean (or median) of four or more medications (the definition of polypharmacy stated previously in Chapter 1). Studies focusing on patients with opioid, alcohol or tobacco addictions were excluded from this review as these problems are considerably more severe and differ in nature compared to chronic disease management (Sansone and Sansone, 2008; Nieuwlaat et al. 2014).

Types of outcome measures

To be eligible, studies had to include at least one medication adherence outcome (either direct or indirect measures) and one clinical or humanistic outcome (e.g. HRQOL).

2.3.3 Search strategy

Studies published in the English language, from inception of the database to the search date (March 2015), were considered for inclusion. Eight databases (Medline, EMBASE, PsycINFO, Scopus, CINAHL, Web of Science, International Pharmaceutical Abstracts and Cochrane Library) were searched using both free text terms and Medical Subject Headings (MeSH) that were devised in accordance with a subject librarian. Search terms focused around four key areas: 'medication adherence', 'polypharmacy', 'theory' and 'older adults'. The MEDLINE search string is provided in Appendix 2.2. The search terms were adapted according to each database, and where applicable, variations and truncations were applied.

Hand-searching was carried out using the reference lists of relevant papers identified through the electronic search above. A search of the Science Citation Index (in Web of Science) was also used to identify potentially relevant articles that cited studies that met the inclusion criteria. The 'grey literature' (e.g. Government reports and theses) were searched to identify

any other relevant studies. All other sources that were hand-searched are detailed in Appendix 2.3.

2.3.4 Study selection

After removal of duplicates, study titles and abstracts were screened independently by two reviewers (DP, CR) to identify studies suitable for inclusion. Following this, full-text articles were retrieved and assessed for eligibility. Disagreements were resolved through discussion and by consultation with a third reviewer (CC).

2.3.5 Data extraction

A data extraction form (Appendix 2.4) was developed and piloted using one of the agreed studies for inclusion. Refinements were made before using the data extraction form to extract data from the remaining studies. Any disagreement, for any component of data analysis, was resolved through third part discussion (CC).

The reviewers (DP, CR) conducted independent risk of bias assessments on all included studies using tools developed by the Cochrane Collaboration ('Risk of bias' tool for randomised studies and 'Suggested risk of bias criteria for EPOC reviews' for non-randomised studies). Studies were assigned an overall rating of low, high or unclear risk (Bero et al. 2007; The Cochrane Collaboration, 2011).

2.3.6 Data analysis

It was anticipated *a priori* that a meta-analysis would not be feasible due to the wide variety of outcomes measures and intervention designs that are commonly reported in adherence interventions (Nieuwlaat et al. 2014). Therefore, an in-depth narrative analysis was selected to present the review findings in this instance.

The extent of theory use in each included study was evaluated using pre-defined categories from the TCS (Michie and Prestwich, 2010). This coding scheme consists of 19 items, each of which falls into at least one of six categories. Categories 1-3 encompass the extent to which the intervention has been based on theory ('Is theory mentioned?'; 'Are relevant theoretical constructs targeted by the intervention?'; 'Is theory used to select intervention recipients or tailor interventions?'). Categories 4-6 relate to theory testing and refinement ('Are the relevant theoretical constructs measured?'; 'Is theory tested?'; 'Is theory refined?'). The items in each category in the TCS are detailed in Table 2.2.

Table 2.2: Categories of the Theory Coding Scheme (TCS) (Michie and Prestwich, 2010)

TCS Category	Relevant items of TCS	Description
Category 1: Is theory mentioned?	'Theory/model of behaviour mentioned' (TCS item 1)	'Models/theories that specify relations among variables, in order to explain or predict behaviour are mentioned, even if the intervention is not based on this theory.'[1]
	'Targeted construct mentioned as predictor of behaviour' (TCS item 2)	'Evidence that the psychological construct relates to (correlates/predicts/causes) behaviour should be presented within the introduction or method.'[1]
	'Intervention based on a single theory' (TCS item 3)	'The intervention is based on a single theory (rather than a combination of theories or predictors).'[1]
Category 2: Are relevant theoretical constructs targeted by the intervention?	'Targeted construct mentioned as predictor of behaviour' (TCS item 2)	See above under Category 1.
	'Theory/predictors[2] used to select/develop intervention techniques' (TCS item 5)	'The intervention is explicitly based on a theory or predictor[3] or combination of theories or predictors.'[1]
	Intervention techniques(s) linked to theory-relevant construct(s)	
	• 'All intervention techniques are explicitly linked to at least one theory-relevant construct/predictor' (TCS item 7)	'Each intervention technique is explicitly linked to at least one theory-relevant construct/predictor.'[1]
	• 'At least one, but not all, of the intervention techniques are explicitly linked to at least one theory-relevant construct/predictor' (TCS item 8)	'At least one, but not all, of the intervention techniques are explicitly linked to at least one theory-relevant construct/predictor.'[1]
	• 'Group of techniques are linked to a group of constructs/predictors' (TCS item 9)	'A cluster of techniques is linked to a cluster of constructs/predictors.' [1]
	Theory-relevant construct(s) linked to intervention techniques(s)	
	• 'All theory-relevant constructs/predictors are explicitly linked to at least one intervention technique' (TCS item 10)	'Every theoretical construct within a stated theory, or every stated predictor (see item 5), is linked to at least one intervention technique.'[1]
	• 'At least one, but not all, of the theory relevant constructs/predictors are explicitly linked to at least one intervention technique' (TCS item 11)	'At least one, but not all, of the theoretical constructs within a stated theory or at least one, but not all, of the stated predictors (see item 5) are linked to at least one intervention technique.'[1]
Category 3: Is theory used to select intervention recipients or tailor interventions?	'Theory/predictors used to select recipients for the intervention' (TCS item 4)	'Participants were screened/selected based on achieving a particular score/level on a theory-relevant construct/predictor.'[1]
	'Theory/predictors used to tailor intervention techniques to recipients' (TCS item 6)	'The intervention differs for different sub-groups that vary on a psychological construct (e.g. stage of change) or predictor at baseline.'[1]

Table 2.2 (cont'd): Categories of the Theory Coding Scheme (TCS) (Michie and Prestwich, 2010)

TCS Category	Relevant items of TCS	Description
Category 4: Are the relevant theoretical constructs measured?	'Theory-relevant constructs/predictors are measured' (TCS item 12)	'At least one construct of theory (or predictor) mentioned in relation to the intervention is measured post-intervention; At least one construct of theory (or predictor) mentioned in relation to the intervention is measured pre- and post-intervention.'[1]
	'Quality of measures' (TCS item 13)	'All of the measures of theory relevant constructs/predictors had some evidence for their reliability; At least one, but not all, of the measures of theory relevant constructs/predictors had some evidence for their reliability; All of the measures of theory relevant constructs/predictors have been previously validated; At least one, but not all, of the measures of theory relevant constructs/predictors have been previously validated; The behavior measure had some evidence for its reliability; The behavior measure has been previously validated.'[1]
Category 5: Is theory tested?	'Theory relevant constructs/predictors are measured' (TCS item 12)	See above under Categeory 4.
	'Quality of measures' (TCS item 13)	See above under Category 4.
	'Randomization of participants to condition' (TCS item 14)	'Do the authors claim randomization? Is a method of random allocation to condition described (e.g., random number generator)? Was the success of randomization tested? Was the randomization successful (or baseline differences between intervention and control group statistically controlled)?'[1]
	'Changes in measured theory-relevant constructs/predictors' (TCS item 15)	'The intervention leads to significant change in at least one theory-relevant construct/predictor (vs. control group) in favour of the intervention.'[1]
	'Mediational analysis of construct(s)/predictors' (TCS item 16)	Do any constructs mediate the effect of the intervention on the behaviour?[3]
	'Results discussed in relation to theory' (TCS item 17)	'Results are discussed in terms of the theoretical basis of the intervention.'[1]
	Appropriate support for theory (TCS item 18)	'Support for the theory is based on appropriate mediation OR refutation of the theory is based on obtaining appropriate null effects (i.e. changing behaviour without changing the theory relevant constructs)'[1]
Category 6: Is theory refined?	'Results used to refine theory' (TCS item 19)	'The authors attempt to refine the theory upon which the intervention was based by either: a) adding or removing constructs to the theory, or b) specifying that the interrelationships between the theoretical constructs should be changed and spelling out which relationships should be changed.'[1]

Key: TCS= Theory Coding Scheme

[1] Explanation taken from the original TCS paper by Michie and Prestwich (2010); [2] A predictor is defined as 'a construct that is not explicitly linked to a theory by the authors, but is targeted for intervention (as a means to change behavior) because it predicts behavior.' Evidence that a predictor causes (or correlates with) the behaviour should be presented by the authors;
[3] Explanation adapted from the original TCS paper by Michie and Prestwich (2010)

2.4 Results

The electronic searches identified 4,366 citations and hand-searching identified a further 33 citations (total n = 3588 following duplicate removal). Following title and abstract screening, 76 full-text articles were retrieved and reviewed for eligibility of inclusion. Five studies met the inclusion criteria: one RCT (Solomon et al. 2012) and four pilot RCTs (Barnason et al. 2010; Ruppar 2010b; Williams et al. 2012; O'Carroll et al. 2013). A PRISMA flow diagram of the screening process is presented in Figure 2.2.

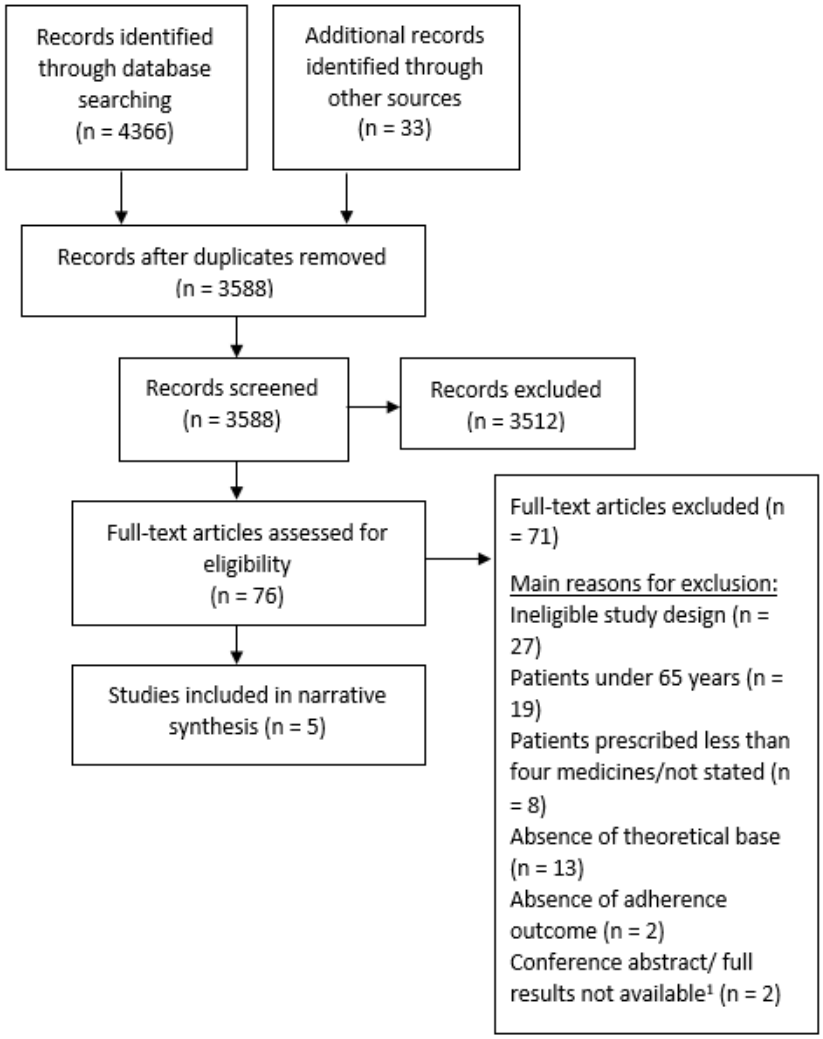


Figure 2.2: PRISMA flow diagram of the literature searching process

[1]*Authors were contacted in both instances with no response*

As expected, the included studies were heterogeneous in terms of outcome measures, targeted clinical conditions and psychological theories underpinning intervention design. In addition, four out of the five included studies were pilot RCTs with small sample sizes. Therefore, a descriptive overview of the included studies is presented in the next section along with a narrative summary outlining how each study reported the use of theory during

intervention development. Outcome data have been summarised to give an indication of preliminary findings (Lancaster, 2015).

2.4.1 Description of included studies

A total of 2,294 participants were recruited across all five studies (range: 15- 2097). The mean age of participants ranged from 67-78 years and the mean number of regularly prescribed medications ranged from 5.5-11.25 medications. Four studies targeted individual clinical conditions [hypertension (Ruppar, 2010a), osteoporosis (Solomon et al. 2012), heart failure (Barnason et al. 2010), stroke (O'Carroll et al. 2013)] and one study focused on co-existing conditions [diabetes and chronic kidney disease (CKD) (Williams et al. 2012)]. Although the study populations were all prescribed a mean of four or more medications, only two studies measured adherence to all prescribed medications (Barnason et al. 2010; Williams et al. 2012); the other three studies measured adherence to a group of medications used to treat the particular condition that was the intervention target (Ruppar, 2010a; Solomon et al. 2012; O'Carroll et al. 2013). Four studies used a cut-off point to classify patients as adherent, using self-report scores, pill counts or electronic monitoring (Barnason et al. 2010; Ruppar, 2010a; Williams et al. 2012; O'Carroll et al. 2013). Two studies specifically recruited patients who were classified as non-adherent using electronic monitoring (Ruppar, 2010a) and a self-reported measure (O'Carroll et al. 2013).

All of the interventions were complex in nature (i.e. multiple interacting components) and included a range of educational and behavioural techniques, such as self-monitoring, prompts, feedback and MI. Intervention participants received between 1-8 sessions, ranging from 2-89 minutes in duration. Participants were followed up for various time periods, from 3-12 months. Adherence measures varied across studies, with three studies relying on a single measure (Barnason et al. 2010; Ruppar, 2010a; Solomon et al. 2012). Measures included self-report, Medication Possession Ratios (MPR) calculated using pharmacy dispensing records, pill counts, and electronic monitoring using Medication Event Monitoring Systems (MEMS). The clinical outcomes measured depended on the clinical condition targeted, for example, a change in BP for patients with hypertension and self-reported falls and fractures for patients with osteoporosis. Only two studies measured generic humanistic outcomes (e.g. HRQOL) (Barnason et al. 2010; Solomon et al. 2012). A summary of the characteristics of included studies is provided in Table 2.3.

Table 2.3: Descriptive summary of included studies

First author (year published, country of origin)	Study type (N= total participants recruited) [conditions targeted]	Participant characteristics 1. Mean age (SD): years 2. Mean number of medications (SD) 3. % of males	Intervention Provider	Brief description of interventions	Cut-off point for classifying patients as adherent	Adherence outcome(s)	Clinical outcomes(s)
Barnason (2010, USA)	Pilot RCT (N=40) [Heart failure]	1. 76.9 (± 6.5) 2. 11.3 (±3.8) 3. 65%	Nurse	**Hospital transition intervention** Telephone counselling and three education modules delivered over two sessions. **Standard care/education only (control)** Standard discharge education program.	≥88%	**Effect shown (statistically significant)** Self-reported adherence, measured via BMQ, was higher in the intervention group than control group [F(1,35)= 13.4, p< 0.001][1] (Svarstad et al. 1999)	**Effect shown (statistically significant)** HRQOL measured via KCCQ (Green et al. 2000). The intervention group had significantly fewer heart failure-related symptoms that impaired HRQOL [F(1,35)= 9.1, p<0.05][1] and fewer social limitations [F(1,35)= 8.6, p<0.05][1] when compared to control.
O'Carroll (2012, UK)	Pilot RCT (N= 62) [Stroke]	1. Not stated for total sample. Intervention mean: 68.4 (±11.3); Control mean: 70.7 (±10.5) 2. 5.5 (±2.3) 3. 69%	Trained research fellow	**Behavioural intervention** Two brief sessions consisting of: (1) Modification of incorrect illness/medication beliefs; (2) Action planning. **Control** Same number of visits as intervention group but sessions focused on non-medication related conversation (e.g. impact of diagnosis)	Participants were deemed non-adherent if they scored less than maximum on a self-report questionnaire (MARS; maximum score =25) (Thompson et al. 2000).	**Effect shown (statistically significant)** Electronic monitoring: Intervention group had higher adherence on all three MEMS outcome measures[2] than control group, but only significant for % doses taken on schedule (mean difference 9.8% CI (0.2, 16.2) p=0.048).[1] Self-report: Adherence, measured by MARS, improved in both groups at follow-up but a significantly greater improvement was observed in the intervention group (mean difference, 0.61; 95% CI (0.1, 1.2); p=0.0027).[1]	**No effect shown** BP: both groups showed a reduction in systolic and diastolic BP but there was no significant difference between groups.[1]

Table 2.3 (cont'd): Descriptive summary of included studies

First author (year published, country of origin)	Study type (N= total participants recruited) [conditions targeted]	Participant characteristics 1. Mean age (SD): years 2. Mean number of medications (SD) 3. % of males	Intervention Provider	Brief description of interventions	Cut-off point for classifying patients as adherent	Adherence outcome(s)	Clinical outcomes(s)
Ruppar (2010, USA)	Pilot RCT (N=15) [Hypertension]	1. 72.5 (± 8.5) 2. 5.8 (±SD not stated) 3. 27%	Advanced practice nurse	**Behavioural/ education intervention** Face-to-face intervention delivering: feedback, skills training, education and habit adjustment. Delivered biweekly over 8 weeks. **Usual care (control)** Varied according to usual HCP. Also received educational materials.	>85%	**Effect shown (statistically significant)** Electronic monitoring: Timing adherence (measured via MEMS). Treatment group adherence was higher than the control group at the end of the intervention (week 8) (Median MA: 96.45% vs. 16.4%[3], U=5.00, P=0.013).[1] Intervention group had a median improvement of +15.4%, control had a change of -5.6% (U=2.00, P=0.003).[1]	**Effect shown (statistically significant)** Systolic BP: slightly improved in intervention group. Statistically significant when compared with control group at week 12 (intervention group median= 130mmHg; control group median= 152mmHg, U=4.50, P=0.008)[1] but not at week 20. No significant impact on diastolic BP.
Solomon (2012, USA)	RCT (N=2097) [Osteoporosis]	1. 78.0 (SD not stated) 2. 10.4 (SD not stated) 3. 6%	Health educator	**Motivational Interviewing (MI)** Counselling telephone sessions on specific education topics and attitudes/barriers to adherence (average: 8 sessions). Also received educational mailings. **Education only (control)** Seven educational mailings on various topics (e.g. falls).	Not stated	**No effect shown** Pharmacy dispensing records (used to calculate MPR): No statistically significant differences in intervention versus control groups. Intervention group median MPR= 49% (IQR 7-86%); Control group median MPR= 41% (IQR 1-88%) (P=0.074).[4]	**No effect shown** Self-reported fractures: No statistically significant differences noted (intervention group= 11%, control group= 11%). Self-reported falls: No statistically significant difference in groups found (intervention group=38%; control group= 36%). General health: No difference between groups in either poor or fair general health categories (intervention group=40%; control group= 41%).

Table 2.3 (cont'd): Descriptive summary of included studies

First author (year published, country of origin)	Study type (N= total participants recruited) [conditions targeted]	Participant characteristics 1. Mean age (SD): years 2. Mean number of medications (SD) 3. % of males	Intervention Provider	Brief description of interventions	Cut-off point for classifying patients as adherent	Adherence outcome(s)	Clinical outcomes(s)
Williams (2012, Australia)	Pilot RCT (N=80) [diabetes with CKD]	1. 67.0 (± 9.6) 2. Not stated for total sample Intervention mean: 7.6 (± 2.6); Control mean: 7.2 (± 3.3) 3. 56.3%	Research nurse	**Multi-factorial intervention** Self-monitoring, medication review, psychosocial DVD and fortnightly MI-based telephone calls for 12 weeks. **Standard care (control)** Dependent on individual circumstances. BP control was a key component.	≥ 80%	**No effect shown** Pill count: No statistically significant differences reported. Mean adherence: control= 66.0% (SD: 22%) intervention= 58.4% (SD: 24.3%) Self-report (Morisky's 4 item questionnaire) (Morisky et al. 1986): No difference between intervention and control groups. 65.3% had no change in adherence in terms of forgetting to take the medication.	**Effect shown (not statistically significant)** BP: Mean Systolic BP reduction was greater in intervention group but not statistically significant. Intervention= -6.9 (95% CI -13.8, 0.02); Control= -3.0 (95% CI -8.4, 2.4) (P=0.371); Average Diastolic BP reduction: Intervention= -2.3 (95% CI -5.2, 0.7); Control= -3.1 (95% CI -5.9, -0.3) (P=0.681)

KEY: BMQ= Brief Medication Questionnaire; BP= Blood pressure; CI= Confidence Interval; CKD= Chronic kidney disease; F(1,35)= F statistic from ANCOVA (analysis of covariance) test (degrees of freedom); HCP: Healthcare professional; HRQOL= Health-related quality of life; IQR= Interquartile range; KCCQ= Kansas City Cardiomyopathy Questionnaire; MA=Medication adherence; MARS= Medication Adherence Reporting Scale; MEMS= Medication Event Monitoring System; MI= Motivational Interviewing; MPR= Medication Possession Ratio; P= p value (probability associated with selected test statistic); RCT= Randomised controlled trial; SD= Standard deviation; U= U statistic from Mann-Whitney U test

[1] Significance level p< .05; [2] Percentage of doses taken, percentage of days that the correct dosage was taken, percentage of doses taken on time; [3] Non-significant baseline differences noted; [4] Significance level not stated

2.4.2 Theoretical underpinning of included studies

All of the included studies were originally based on a single theory, although O'Carroll et al. (2013) also made reference to a separate related theory in a linked publication regarding a process evaluation; this is discussed below in more detail (O'Carroll et al. 2010; O'Carroll et al. 2014). The majority of included studies (n=4) in this review were small-scale pilot studies and only one study reported testing the underpinning theory (O'Carroll et al. 2013). None of the authors reported theory refinement based on the study results. Consequently, the decision was made to focus solely on Categories 1-3 of the TCS for the purposes of this in-depth narrative review, as these categories explore how the researchers have directly used theory in developing their interventions. TCS categories 4-6 focus more on theory testing and refinement, which are processes often carried out by researchers during the later stages of intervention testing (i.e. evaluations). An overall judgement of 'Yes', 'No' or 'Partially' has been made for TCS Categories 1-3 based on whether the study met all, none or some of the relevant TCS items (see Table 2.2 in Section 2.3.6 for descriptions of items). A summary of the overall judgement for TCS Categories 1-3 is presented below in Table 2.4.

Table 2.4: Summary of overall judgement for TCS Categories 1-3 for each included study

Study	Category 1	Category 2	Category 3
Barnason et al. (2010)	Yes	Yes	Partially
O'Carroll et al. (2013)	Yes	Yes	No
Ruppar (2010a)	Yes	Partially	No
Solomon et al. (2012)	Partially	No	No
Williams et al. (2012)	Yes	Partially	No

Further explanations for judgements on whether relevant TCS items in each category were met or not met are presented in Table 2.5 (Category 1), Table 2.6 (Category 2), and Table 2.7 (Category 3).

Table 2.5: Explanations for judgements of TCS items in Category 1 (Is theory mentioned?)

Study	**Overall judgement for category**[1]	**TCS item 1:** Theory/model of behaviour mentioned	**TCS item 2:** Targeted construct mentioned as predictor of behaviour	**TCS item 3:** Intervention based on a single theory
Barnason et al. (2010)	Yes	Based on Bandura's Social cognition theory (SCT)	Targeted constructs of SCT (e.g. self-regulation) were mentioned as predictors of adherence	Based on Bandura's SCT
O'Carroll et al. (2013)	Yes	Based on Leventhal's Self-regulation Model (SRM)[2]	Targeted construct of SRM ('illness perceptions') was mentioned as a predictor of adherence	Based on Leventhal's SRM[2]
Ruppar (2010a)	Yes	Based on Leventhal's SRM[2]	Targeted construct ('illness perceptions') was mentioned as a predictor of adherence behaviour	Based on Leventhal's SRM
Solomon et al. (2012)	Partially	Based on Prochaska's Transtheoretical Model of behaviour change (TTM)	**Not met:** The authors did not explicitly indicate that the constructs of TTM (e.g. stage of change, process of change, self-efficacy) were predictors of adherence	Based on Prochaska's TTM
Williams et al. (2012)	Yes	Based on Health Belief Model (HBM) (Modified)	Targeted constructs of the modified HBM were mentioned as predictors of adherence (e.g. self-efficacy)	Based on HBM (Modified)

[1]Judgement of 'Yes' if study met TCS items 1 and 2 and 3 in Category 1. Judgement of 'Partially' if study met any of the TCS items in Category 1. Judgement of 'No' if study did not meet any TCS items in Category 1; [2]The authors also made reference to Hall and Fong's Temporal Self-regulation Theory (TST) but the intervention was originally based on one theory

Table 2.6: Explanations for judgements of TCS items in Category 2 (Are relevant theoretical constructs targeted by the intervention?)

Study	**Overall judgement for category**[1]	**TCS item 2:** Targeted construct mentioned as predictor of behaviour	**TCS item 5:** Theory/predictors used to select/develop intervention techniques	**TCS items 7 or 8 or 9:** Intervention techniques(s) linked to theory-relevant construct(s)	**TCS items 10 or 11:** Theory-relevant construct(s) linked to intervention techniques(s)
Barnason et al. (2010)	Yes	Targeted constructs of SCT (e.g. self-regulation) were mentioned as predictors of adherence	Theory was used to select intervention techniques (e.g. self-monitoring selected based on self-regulation construct of SCT)	All intervention techniques were linked to theoretical constructs or predictors (e.g. verbal persuasion technique linked to self-efficacy)	Targeted constructs were linked explicitly to at least one intervention technique
O'Carroll et al. (2013)	Yes	Targeted construct of SRM ('illness perceptions') was mentioned as a predictor of adherence	Theory was used to select intervention techniques (e.g. health consequences was selected based on theory)	All intervention techniques were linked to theoretical constructs/predictors (e.g. health consequences was linked to illness perceptions)	Targeted constructs/predictors were linked explicitly to at least one intervention technique
Ruppar (2010a)	Partially	Targeted construct ('illness perceptions') was mentioned as a predictor of adherence behaviour	**Not met:** Theory was not used to select all intervention techniques (e.g. prompts)	At least one, but not all intervention techniques were explicitly linked to theoretical constructs (e.g. habit modification not linked)	Key theoretical constructs (e.g. identity) were linked to intervention techniques
Solomon et al. (2012)	No	**Not met:** The authors did not explicitly indicate that the constructs of TTM (e.g. stage of change, process of change, self-efficacy) were predictors of adherence	**Not met:** Theory did not appear to guide the selection of MI techniques. MI techniques appear to have been selected based on similar interventions and then linked back to theory	**Not met:** MI techniques were not directly linked back to constructs within the model	**Not met:** Key constructs of TTM were not explicitly linked to MI techniques
Williams et al. (2012)	Partially	Targeted constructs of the modified HBM were mentioned as predictors of adherence (e.g. self-efficacy)	**Not met:** Theory was not used to select all intervention techniques (e.g. self-monitoring)	At least one, but not all intervention techniques were explicitly linked to theoretical constructs (e.g. goal setting wasn't linked to constructs)	**Not met:** Theoretical constructs were not explicitly linked to intervention techniques

[1] *Judgement of 'Yes' if study met TCS items 2 and 5 and 7, 8 or 9 and 10 or 11 in Category 2. Judgement of 'Partially' if study met any of the TCS items in Category 2. Judgement of 'No' if study did not meet any TCS items in Category 2.*

Table 2.7: Explanations for judgements of TCS items in Category 3 (Is theory used to select intervention recipients or tailor interventions?)

Study	**Overall judgement for category**[1]	**TCS item 4:** Theory/predictors used to select recipients for the intervention	**TCS item 6:** Theory/predictors used to tailor intervention techniques to recipients
Barnason et al. (2010)	Partially	**Not met:** Intervention recipients were not selected using theory (e.g. based on 'self-efficacy' levels)	**Met:** Predictors (e.g. motivation) were examined via questionnaires and used to tailor the intervention to individual patients
O'Carroll et al. (2013)	No	**Not met:** Intervention recipients were selected based on a self-report questionnaire score but not specifically using theory (e.g. based on 'illness perceptions')	**Not met:** Intervention was not tailored based on theory
Ruppar (2010a)	No	**Not met:** Intervention recipients were not selected using theory (e.g. based on their 'illness perceptions')	**Not met:** Habit modification was tailored but this was not linked to theory
Solomon et al. (2012)	No	**Not met:** Intervention recipients were not selected using theory (e.g. based on their 'stage of change')	**Not met:** The authors did report that MI is based on an 'individual's readiness for change' but they did not link this to their own intervention
Williams et al. (2012)	No	**Not met:** Intervention recipients were not selected using theory (e.g. based on their level of 'self-efficacy')	**Not met:** MI was tailored but this was not linked to theory. Other intervention techniques were not tailored

[1] Judgement of 'Yes' if study met TCS items 4 and 6 in Category 3. Judgement of 'Partially' if study met any of the TCS items in Category 3. Judgement of 'No' if study did not met any TCS items in Category 3.

Bandura's Social Cognition Theory (SCT)

Barnason et al. (2010) based their counselling and education intervention on SCT (TCS Category 1: Yes) (Bandura, 1986). The intervention was delivered to patients with heart failure on transition from secondary to primary care. SCT helps to understand human thought and behaviour and includes a core reciprocal model whereby personal, behavioural and environmental factors influence each other. The authors indicated that personal factors (e.g. motivation) and environmental factors (e.g. assistance from others) impacted on adherence behaviour. Key constructs in this model are 'self-efficacy' and 'self-regulation' and these were linked to intervention techniques, such as verbal persuasion and self-monitoring, respectively (TCS Category 2: Yes). Techniques were also linked to a Medication Adherence Conceptual Framework which was used alongside the theoretical basis to guide intervention design. This conceptual framework, developed through a literature review, links closely with SCT and focuses on 'the relationship between environmental factors, patient characteristics, and medication adherence as a process that ultimately affects patient outcomes' in older adults with HF (Murray et al. 2004).

SCT was not used to select patients for inclusion in the trial but it was used to tailor the intervention based on an initial assessment of personal factors (e.g. participants with low motivation were given tailored information on the benefits of adherence) (TCS Category 3: Partially). This intervention was tested in a randomised pilot study and led to statistically significant differences in both self-reported adherence and HRQOL (see Table 2.3).

Leventhal's Self-regulation Model (SRM)

Leventhal's SRM was cited as the basis for intervention development in two of the included studies (Ruppar, 2010a; O'Carroll et al. 2013). Firstly, SRM was cited by Ruppar (2010a) as the basis of an intervention that aimed to improve adherence to medicines prescribed for hypertension (TCS Category 1: Yes) (Leventhal et al. 1984). SRM consists of three constructs: (1) 'illness perceptions' (i.e. the beliefs a person holds about their illness); (2) 'coping responses'/action planning; (3) 'appraisal'/monitoring of responses. The key construct in this model, 'illness perceptions', consists of both cognitive perceptions (e.g. identity/illness label and symptoms, cause, time-line, consequences and curability/controllability) and emotional perceptions (e.g. anxiety, depression, fear).

In Ruppar's study, SRM was discussed in terms of how it related to hypertension as these patients are commonly asymptomatic. This is in contrast to other conditions, where symptoms act as feedback that medication doses have been missed (e.g. Parkinson's

disease). The author proposed that a lack of feedback from 'perceived symptoms' (i.e. the identity dimension' of the 'illness perceptions' construct) was a possible predictor of non-adherence. To account for the lack of symptom feedback, Ruppar's intervention was based on feedback gained from BP monitoring and medication-taking behaviour. Education on health consequences of poorly controlled hypertension was also linked to the 'illness perceptions' construct (i.e. 'consequences' dimension). However, other techniques, such as habit analysis and prompts, were not explicitly linked to theory/predictors (TCS Category 2: Partially).

Ruppar (2010a) discussed the difficulty encountered when attempting to link the study outcomes back to the theoretical basis and suggested that researchers should measure changes in relevant theoretical constructs (e.g. changes in 'illness perceptions') to allow them to relate theory to outcomes (e.g. changes in adherence). Participants were not selected based on theory, nor was theory used to tailor the intervention (TCS Category 3: No). This randomised pilot study reported a statistically significant difference in medication adherence between intervention and control groups at the end of the intervention period (week 8). A significant decrease in systolic BP was noted at week 12 for the intervention group but this increased slightly again at week 20 (see Table 2.3).

O'Carroll et al. (2013) also cited Leventhal's SRM as the underpinning theory for an intervention that aimed to improve adherence in stroke survivors, a group of patients who are commonly prescribed multiple medications (TCS Category 1: Yes). The authors indicated that the two main intervention components [(1) modification of incorrect medication/illness beliefs and (2) implementation planning i.e. action plans of when and where to take medications], would target intentional non-adherence and unintentional non-adherence, respectively. The first intervention component was linked to the 'illness perceptions' construct of SRM. The second component was linked to a predictor of medication adherence that had been demonstrated in previous research (i.e. forgetfulness due to cognitive impairment) (O'Carroll et al. 2010).

In a process evaluation paper, O'carroll et al. (2014) also made reference to a newer self-regulation theory posed by Hall and Fong (Temporal Self-regulation Theory; TST) (Hall and Fong, 2007). TST incorporates a theoretical construct termed 'behavioural pre-potency' ['…reflecting frequency of past performance and/or the presence of cues to action in the environment' (Hall and Fong, 2007)] which the authors also linked to the implementation planning component of this intervention (TCS Category 2: Yes). Theory was not used to select intervention recipients, nor used to tailor this intervention (TCS Category 3: No). This study

led to improvements in objectively measured adherence via MEMs but this finding was only statistically significant for the percentage of doses taken on schedule. Both groups reported higher self-reported adherence at follow-up and this was significantly greater in the intervention group. There were no statistically significant differences in changes to diastolic or systolic BP between groups (see Table 2.3).

Transtheoretical model of behaviour change (TTM)

Solomon et al. (2012) used MI as the basis of their telephone intervention to improve adherence to medications prescribed for osteoporosis. The TTM (also known as the Stages of Change Model) was cited as the underpinning theory for MI (Prochaska and DiClemente, 1982). TTM consists of multiple constructs: 'stages of change'; 'process of change'; 'self-efficacy'; 'temptation' and 'decisional balance'. The 'stages of change' construct consists of five sequential stages: pre-contemplation, contemplation, preparation, action and maintenance (Michie et al. 2014). It appears that the authors selected MI based on success in previous adherence studies and then linked the approach to the TTM (TCS Category 1: Partially) (Heather et al. 1996; Miller, 1996; Prochaska and DiClemente, 1982).

Solomon et al. (2012) discussed MI in general, indicating that it makes use of active listening and relationship-building to allow participants to evaluate risks and treatment options, but they did not make explicit links between their intervention and relevant theoretical constructs in TTM (TCS Category 2: No). The authors did not appear to use theory to select participants or report whether the intervention was tailored based on theory (TCS Category 3: No). Statistically significant improvements in medication adherence, changes in self-reported falls, fractures or general health were not demonstrated in this RCT (see Table 2.3).

Health Belief Model (HBM)

A modified version of the HBM was cited by Williams et al. (2012) as the basis for a multi-component behavioural and educational intervention, delivered to patients with co-existing diabetes and CKD (TCS Category 1: Yes). The original HBM consists of four key constructs: 'perceived barriers'; 'perceived benefits'; 'perceived severity' and 'perceived susceptibility' (Rosenstock, 1974; Glanz et al. 2008) . This model suggests that an individual's thoughts and actions are mainly rational and the behaviour will be carried out if the perceived threat (severity and susceptibility) is high and perceived benefits outweigh barriers. The modified version incorporates the additional construct 'self-efficacy' (Rosenstock et al. 1988).

In the intervention developed by Williams et al. (2012), a psychosocial DVD (i.e. focusing on the interactions between thoughts, feelings and the social environment) was proposed to

exert its effect by 'motivating people to take their medications, appealing to knowledge, thoughts and feelings'. It included information on the consequences of hypertension and benefits of medications, as well as examples of patients sharing their experiences of taking multiple medications and tips to help patients take medications as prescribed. The authors indicated that individuals who were confident in self-managing their health would be more adherent. Confidence (i.e. 'self-efficacy') was linked to aspects of the DVD but other techniques that formed part of this complex intervention, such as MI, self-monitoring and goal-setting, were not clearly linked to theory (TCS Category 2: Partially). Theory was not used to select participants or tailor the intervention in any way (TCS Category 3: No). This pilot study reported no statistically significant improvements in adherence or BP control (see Table 2.3). However, the authors noted that a larger study might demonstrate significant differences.

2.4.3 Risk of bias of included studies

The risk of bias summary, displayed in Figure 2.3, gives an overview of the quality of included studies. An overall assessment of low risk of bias was judged for four studies (Ruppar, 2010a; Solomon et al. 2012; Williams et al. 2012; O'Carroll et al. 2013) and an unclear risk for the fifth (Barnason et al. 2010).

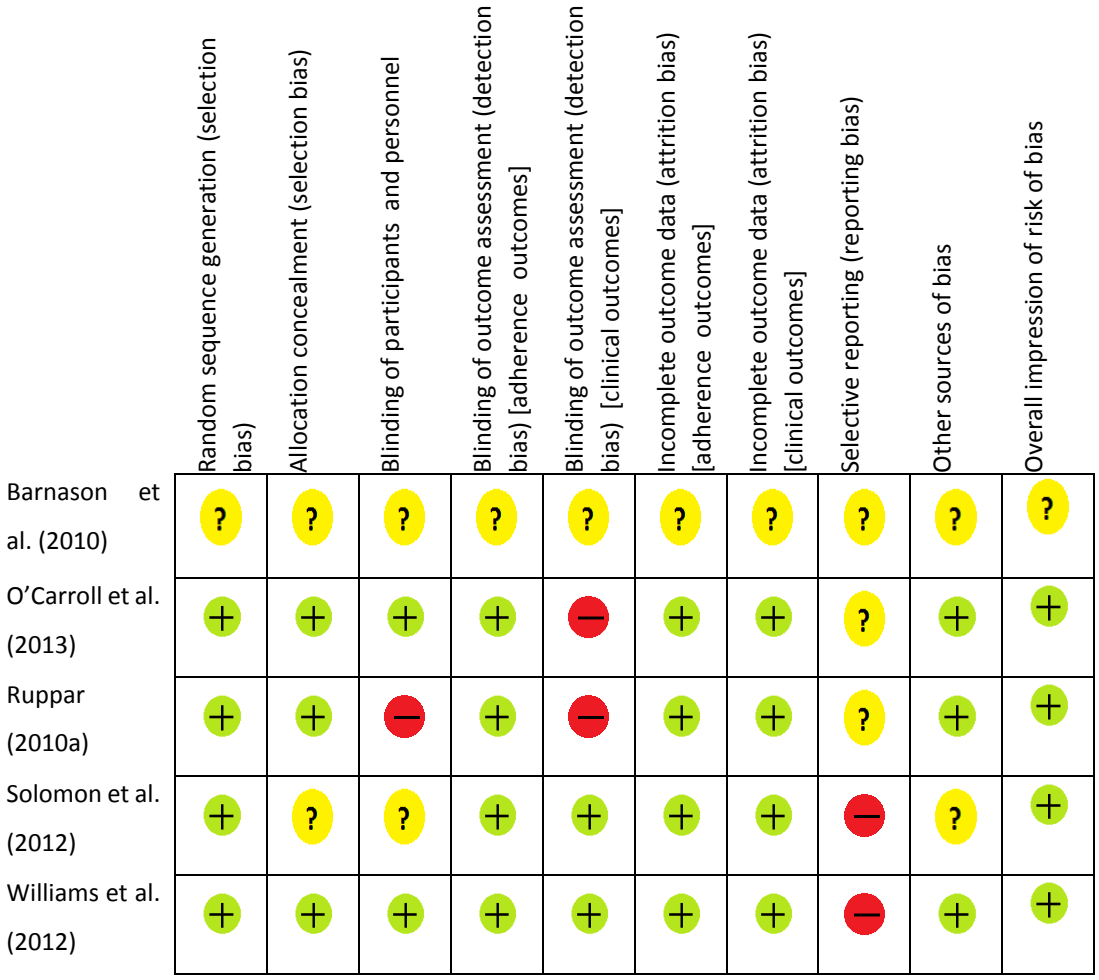


Figure 2.3: Risk of bias summary for the five included studies

Key: − = High risk + = Low risk ? = Unclear risk

[1]Other potential sources of bias included bias relating specifically to adherence studies, for example, self-report bias.

2.5 Discussion

This systematic review adds to the existing evidence base by providing an in-depth examination of theory-based adherence interventions delivered to older adults prescribed polypharmacy. It differs from other reviews in the literature as it has examined, in detail, the extent to which psychological theory was used in intervention development (van Dulmen et al. 2007; Conn et al. 2009; Holmes et al. 2014; Nieuwlaat et al. 2014; Conn et al. 2016a). This review also explored the methods used to measure adherence and the types of clinical outcomes investigated as these are important to consider when developing an intervention for older patients prescribed polypharmacy with a range of potential clinical conditions.

2.5.1 Adherence and clinical/humanistic outcomes

Both adherence and clinical/humanistic outcomes were considered to be important as an improvement in adherence alone does not prove that this has led to positive clinical/humanistic outcomes for patients. Conversely, solely demonstrating an improvement in clinical/humanistic outcomes cannot guarantee that this has been the direct result of improved medication adherence (Nieuwlaat et al. 2014). The type of adherence measures varied across studies and only two studies followed recommendations to employ multiple measures (O'Carroll et al. 2013; Williams et al. 2012). Self-report, which potentially overestimates adherence, was the only measure used by Barnason et al. (2010). This introduced potential bias, particularly as it was unclear whether this pilot study was effectively blinded. Electronic monitoring via MEMS, was used in two studies and provided a more objective adherence measure (Ruppar, 2010a; O'Carroll et al. 2013). However, this form of assessment is costly and has the potential to act as an intervention component in both intervention and control groups, because it prompts monitoring of the behaviour.

Pill counts were employed alongside self-report by Williams et al. (2012) but the authors indicated that this approach 'was confounded by the participants' multiple medications' as patients had difficulty recalling prescription start dates. Solomon et al. (2012) used pharmacy dispensing data to calculate MPRs ('Number of days' supply obtained during observation period' divided by 'number of days in observation period'), however this was only calculated for participants' osteoporosis medication. Calculating an average MPR for multiple medications confers several potential challenges, for example, this could potentially under or over-estimate adherence (Arnet et al. 2014). Another similar measure that is widely used in adherence research is the Proportion of Days Covered (PDC) (Nau, 2006). This has been adapted for calculating adherence to multiple related medications, by identifying the proportion of days that have been covered by all regular long-term medications (Choudhry et al. 2009; Basak et al. 2014). At present, there is no consensus or guidance on how best to measure adherence to multiple medications using pharmacy dispensing data. Validated measures that are currently available (e.g. MPR, PDC) require further testing with multiple medications to determine their suitability. To allow adherence research to advance, it is essential that robust methods of measuring adherence to polypharmacy are developed, tested and consensus reached.

Only two studies considered the impact of polypharmacy on medication adherence and discussed the associated challenges (Williams et al. 20012; O'Carroll et al. 2013). For patients prescribed polypharmacy, reasons for non-adherence can vary both across and within

individuals, depending on the prescribed regimens, clinical conditions and their associated beliefs. Nonetheless, as highlighted by Nieulwaat et al. (2014), the 'clinical condition is not a major determinant of medication adherence' and the types of adherence problems reported across conditions are generally comparable. This has important implications for adherence research and psychological theory has a potentially important role to play in allowing complex interventions to be tailored to the individual needs of older patients, prescribed polypharmacy to treat a range of clinical conditions.

The methods employed for measuring adherence can impact on study outcomes, as can the types of participants selected for inclusion (Conn et al. 2016b). Studies that include participants who are classified as highly adherent, may find it difficult to demonstrate a significant effect as there is limited scope for improvement, a phenomenon referred to as the 'ceiling effect' (Ruppar, 2010a). To avoid this, future interventions need to specifically target patients who are non-adherent at baseline, as these patients are likely to benefit most. Exact cut-off points were used for classifying patients as adherent or non-adherent in four of the studies, but only two studies reported using this classification to recruit non-adherent patients (Ruppar, 2010a; O'Carroll et al. 2013).

In adherence research, it is important that clinical outcomes are carefully selected based on the target population. The variety of clinical outcomes measured by included studies reflects the range of clinical conditions targeted. Although general humanistic outcomes (e.g. HRQOL) were measured in two studies, no studies measured healthcare utilisation (e.g. GP visits, hospitalisations) or mortality rates. This is likely due to study design, most of which were pilot studies (n=4) of short duration and lacked sufficient power to demonstrate a significant effect. For future adherence studies that include multi-morbid patients, generic humanistic outcomes such as HRQOL or healthcare utilisation measures, may be more appropriate as opposed to condition-specific outcomes (Nieuwlaat et al. 2014).

2.5.2 Intervention effectiveness

Pilot studies, which the MRC recommends should be part of the preliminary evaluation of complex interventions, are described as 'a version of the main study that is run in miniature to test whether the components of the main study can all work together' (Arain et al. 2010). Although not powered to test for significance, all four pilot studies identified in this review used some form of hypothesis testing, with three describing the positive effects shown as significant (Barnason et al. 2010; Ruppar, 2010a; O'Carroll et al. 2013). Results from pilot studies are not always reported and many fail to advance to definitive trials. On the one hand,

it is possible that a significant effect may be missed in an underpowered pilot study, but conversely, there is also the chance of observing the opposite effect in a larger definitive trial (Thabane et al. 2010). Consequently, the results of pilot studies should be interpreted with caution. This limitation was recognised by Williams et al. (2012) whose pilot study failed to show significant effects. The authors indicated that the intervention appeared to be acceptable and feasible and that statistically significant differences may be seen in a larger trial. Although conclusions on the overall effectiveness of theory-based studies cannot be drawn from this review, the findings from the included pilot studies are a stepping stone in the advancement of the application of theory in designing adherence interventions (Arain et al. 2010; Lancaster, 2015).

2.5.3 Theoretical basis

Overall, very few studies cited theory as a basis for their intervention and only one reported theory testing based on study outcomes (O'Carroll et al. 2013). An in-depth analysis, using Categories 1-3 of the TCS, indicated that the selection of intervention components was not always guided by theory, or was not reported as such. Both studies that included MI did not outline exactly how the key constructs of the cited theory explicitly linked to MI techniques (Miller, 1996; Miller and Rollnick, 2012). MI was not originally developed from a single theory, and although some researchers have attempted to link it to various theories (e.g. TTM, SCT), the mechanisms through which it facilitates behaviour change remain unclear (Burke et al. 2003). Solomon et al. (2012) described MI as a method that was 'built upon Prochaska's trantheoretical model of behaviour change' but did not make explicit links between theoretical constructs and their own adherence intervention. This lack of theoretical understanding may be reflected in the design of this MI-based intervention and the subsequent outcome.

The other four studies employed a more theory-driven approach whereby theory guided the selection of intervention techniques (Barnason et al. 2010; Ruppar, 2010a; Williams et al. 2012; O'Carroll et al. 2013). However, in two of these studies all techniques were not linked to theory (Ruppar 2010a; Williams et al. 2012). It is evident from the analysis that theory could be utilised further, either in recruiting participants or in tailoring the intervention to their needs based on theoretical constructs. For example, Barnason et al. (2010) measured relevant theoretical constructs/predictors (e.g. motivation) and used these to tailor the intervention to participants; this approach may have influenced the positive effect seen.

As discussed previously, an in-depth analysis of TCS Categories 4-6 was not undertaken in this review due to the pilot nature of the majority of studies (n=4) and the lack of theory testing and refinement. However, O'Carroll et al. (2014) have provided a useful example of how theory can be utilised to explore the intervention's mechanism of action via the measurement of theoretical constructs in a theory-based process evaluation.

All five interventions targeted the same behaviour (adherence) but were based on a range of different psychological theories. As discussed previously in Chapter 1, with such a wide range of theories available in the literature, selecting just one to guide intervention development can be a difficult task. As a result, theory selection is commonly based on experience, personal preference or what is 'in fashion' (Michie et al. 2014a). When selecting theory it is important to provide a clear rationale, however, none of the study authors clearly outlined their choice. It is, however, possible that the authors gave theory selection due consideration but did not report this. Selecting the most appropriate theory can also be challenging in instances where individual theories do not cover all potential influences on the target behaviour. For example, the role that habits play in medication-taking are often overlooked. Failure to consider all potentially relevant psychological processes, such as non-reflective processes, can place limitations on the types of techniques developed. A comprehensive theoretical framework such as the TDF (discussed in Chapter 1) has the potential to overcome these limitations.

This systematic review presents preliminary findings from pilot work and demonstrates that even when cited, theory appears to be under-utilised when designing interventions. Further research needs to be conducted in order to draw definitive conclusions regarding the effectiveness of theory-based interventions that aim to improve adherence in older adults prescribed polypharmacy. Other reviews of theory-based interventions targeting health-related behaviours (e.g. physical activity, diabetes self-management) have shown some marginally positive effects, but in common with this review, they identified an overall under-utilisation of theory (Lopez et al. 2011; Ayling et al. 2015; Gourlan et al. 2015). A recent review that looked specifically at text messaging and medication-use monitoring interventions to promote adherence in Type 2 diabetics (in all age groups), showed that only four out of eleven trials stated an underlying theory (Farmer et al. 2015). The review authors also used the TCS but they did not go beyond identifying the number of studies that met each TCS item and the specific theory that each intervention was based on. In contrast, the current review provides an additional in-depth narrative discussion of each intervention which will inform the development of future theory-based adherence interventions.

As Michie et al. (2014a) highlight, using an explicit theory does not guarantee the intervention will be effective. It has been proposed that in order for theory to influence intervention effectiveness, it must form a key component of rigorous and systematic intervention development (Michie and Prestwich, 2010; Ayling et al. 2015). It is important to note that the use of theory in intervention design is based primarily on principle and therefore more empirical research is required to determine whether appropriate use of theory does, in fact, lead to more effective interventions (Colquhoun et al. 2013). A review by George et al. (2008) has presented findings from non-theory based adherence interventions (n=8) delivered to older adults prescribed polypharmacy. Effective interventions in this review (n=4) were resource-intensive and had no common components. Without a theoretical understanding of the interventions' mechanism of action, it is impossible to decipher the essential ingredients that led to behaviour change. Even if theory-based interventions fail to produce a positive effect, they can still be used to develop an understanding of what does and does not work and, more importantly, provide better insights into the underlying reasons for the observed outcomes. Where no effect is observed, theory could help researchers avoid re-testing ineffective approaches and strengthen any weak links in the proposed causal chain. A theory-based approach therefore has the potential to advance the field of adherence research (Michie et al. 2014a).

The TCS was used in this systematic review to guide a detailed and systematic evaluation of how theory was reportedly used during intervention development. Another useful application of this tool is as a guide for researchers who are developing theory-based adherence interventions and reporting their findings in publications. Its use in this manner would be in line with WIDER (Workgroup for Intervention Development and Evaluation Research) guideline recommendations which advocate that researchers include detailed descriptions of the underpinning design and proposed mechanism of change, including any psychological theory (Albrecht et al. 2013).

2.5.4 Limitations

This review was limited to studies published in the English language and delivered to older adults that were prescribed a mean of four or more medications. Given the paucity of adherence research that targets older adults, studies were deemed eligible if the sample population had a mean/median age of 65 years or older. As study inclusion/exclusion age was not part of the eligibility criteria for this review, studies may have included a small proportion of patients who were younger than 65 years old. However, as noted in Section 2.3.6, the pooling of outcome data in a meta-analysis was not undertaken and so this was

not considered to have any significant implications on the findings of the review. Although extensive electronic and hand-searching strategies were conducted for this review, studies which met the inclusion criteria but were not adequately indexed in the literature may have been missed. The TCS which was used to guide the narrative summary relies solely on details reported by authors in published articles. Studies that made use of theory but failed to report this in published reports may also have been overlooked.

2.6 Conclusion

There is a lack of robust evidence on theory-based adherence interventions delivered to older adults who are prescribed polypharmacy and, therefore, no overall conclusion on intervention effectiveness can be drawn at this stage. Four key findings from this review are pertinent to the development of future interventions in this area: (1) the importance of having theory as core component of the design process as opposed to a loosely applied framework to allow the intervention's underlying mechanism of action to be understood and tested; (2) the potential usefulness of theory in tailoring the components of complex interventions to individual patients' needs; (3) the need to identify and target non-adherent patients as these patients are most likely to benefit; (4) the importance of carefully selecting adherence and clinical outcomes that are relevant to patients with multi-morbidities and prescribed polypharmacy.

The findings from this review support the need for the development of the intervention outlined in this thesis. At present there is insufficient evidence to support the use of any individual theory in developing an intervention to improve medication adherence in older adults prescribed polypharmacy. Therefore, to ensure all relevant psychological processes are considered, the use of a comprehensive theoretical framework, such as the TDF, to guide intervention development is justified. Chapter 3 outlines how the TDF has been used to develop the theoretical basis of a novel complex intervention that aims to improve medication adherence in older adults (prescribed polypharmacy).

Chapter 3

Selection of components for a theory-based intervention to improve medication adherence in older adults prescribed polypharmacy

3.1 Introduction

The MRC framework for 'developing and evaluating complex interventions' recommends that they should be developed based on relevant theory such as psychological theory (Medical Research Council, 2008). As highlighted in Chapter 2 of this thesis, there are a lack of adherence interventions targeting older adults (prescribed polypharmacy) with a robust theoretical underpinning. The objective of the study outlined in this chapter was therefore to develop the theoretical basis and components of a novel intervention to improve adherence to polypharmacy in older adults in the primary care setting, using the TDF as the underpinning theoretical model of behavioural determinants (Michie et al. 2005).

3.1.1 Theoretical Domains Framework (TDF)

As discussed in the preceding chapters (Chapters 1 and 2), the TDF is a comprehensive theoretical framework that incorporates a wide range of theoretical constructs (Allemann et al. 2016). There are currently two versions in existence: TDF1 (original 12 domain version developed in 2005) and TDF2 (updated 14 domain version developed in 2012) (Michie et al. 2005; Cane et al. 2012). Both versions of the TDF can act as a 'theoretical lens' through which determinants (i.e. barriers and facilitators) of the behaviour can be identified for targeting with an intervention (Michie et al. 2014a). Previous studies employing the TDF as an underpinning theoretical model have utilised a range of research designs to explore behavioural determinants. This has included qualitative designs (e.g. interviews, focus groups), quantitative designs (e.g. cross-sectional surveys) and systematic reviews of the literature (Francis et al. 2012). The most commonly selected approach to date has been qualitative research designs (Atkins et al. 2017). For example, Duncan et al. (2012) used qualitative interviews to explore prescribing errors made by trainee doctors, whereas Bussières et al. (2012) used qualitative focus groups to identify barriers and facilitators to implementing guideline recommendations for patients with spinal disorders.

To date, TDF-based studies have mostly targeted HCPs' clinical behaviours, particularly in relation to the implementation of evidence-based guidelines (Dyson et al. 2011; French et al. 2013). More recently, the TDF has been used to explore patients' behaviours such as dietary intake (Edwards et al. 2010; Guillaumie et al. 2010). Cahir et al. (2015), McCullough et al. (2015) and Easthall et al. (2014) have used the TDF to explore medication adherence, albeit in different patient populations (breast cancer, bronchiectasis and cardiovascular disease patients, respectively).

3.1.2 Selection of key theoretical domains to target for behaviour change

Methods for selecting key TDF domains to target with an intervention have varied according to the selected research methodology (e.g. interviews, focus groups etc.). The first consideration in selecting key domains to target is the relevance/importance of each domain in relation to the behaviour of interest. Previous researchers have employed pre-defined decision criteria (e.g. frequency counts in interviews) and group consensus techniques to assess domain relevance (Francis et al. 2009; Bussières et al. 2012; Cadogan et al. 2015). For example, in a TDF-based interview study that explored clinicians' blood transfusion behaviours, a domain was considered to be '…relevant if frequently mentioned responses indicated that it might affect performance of the clinical behaviour' (Francis et al. 2009). Domains that are considered relevant/important in the context of the behaviour of interest are then assessed to determine whether they contain barriers and facilitators that could feasibly be targeted for change with an intervention. Factors that need to be taken into consideration are the available project resources and any contextual factors such as limitations of the proposed research setting (Cadogan et al. 2015).

3.1.3 Mapping key domains to behaviour change techniques (BCTs)

Selected key TDF domains can then be mapped to BCTs using established methods reported in the literature (Michie et al. 2008; Cane et al. 2015). As discussed in Chapter 1, BCTs are the active ingredients of behaviour change interventions that aim to bring about change (Michie et al. 2013). Michie et al. (2008) have produced a mapping matrix which indicates links between 35 BCTs and theoretical domains in TDF1 (see Appendix 3.1). The 35 BCTs in this preliminary work were identified from two systematic reviews and links were agreed by four experts in behaviour change. Cane et al. (2015) have updated this TDF to BCT linking process by mapping BCTs in BCT Taxonomy version 1 (BCTTv1) to domains in TDF2 (see Appendix 3.2) (Michie et al. 2013). BCTTv1 consists of 93 BCTs, along with definitions and illustrative examples. It is important to note that a number of the BCTs from the preliminary 35 BCTs identified by Michie et al. (2008) have overlapping characteristics with BCTs in BCTTv1. For example, 'Information regarding behaviour, outcome' overlaps with 'Information about health consequences' and can therefore be considered equivalent.

BCTs selected using this mapping approach can then form the 'active ingredients' of a theory-based intervention, whereby they are used to bring about the required changes in the target behaviour (Michie et al. 2009). For example, Cadogan et al. (2015) employed both mapping resources mentioned above in identifying BCTs to include in an intervention to improve the

appropriate prescribing of polypharmacy by GPs. Eight key TDF domains (e.g. 'Skills') were identified to target for behaviour change and these mapped these across to four BCTs (e.g. 'Modelling/demonstration of behaviour by others'). This offers a robust and systematic approach to developing theory-based behaviour change interventions and understanding of the proposed theoretical mechanism of action (Francis et al*.* 2012).

The research presented in this chapter focuses on the identification of determinants (i.e. barriers and facilitators) of adherence to multiple medications (i.e. polypharmacy) in older adults using the TDF as the underpinning theoretical model. It also outlines the process of mapping from key TDF domains to BCTs for inclusion as components in a community pharmacist-led adherence intervention. As mentioned in Chapter 1, CPs were selected as the intervention provider from the outset of the project due to their accessibility in the primary care setting and evidence from two recent Cochrane reviews that supported pharmacists' involvement in adherence interventions (Nieuwlaat et al*.* 2014; Ryan et al*.* 2014).

3.2 Aims and objectives

The overall aim of the current study was to develop the theoretical basis and components of an intervention to improve adherence to polypharmacy in older adults using the TDF as the underpinning theoretical framework of behavioural determinants. The objectives were to:

- Identify determinants (barriers and/or facilitators) of adherence to polypharmacy from the viewpoint of older adults using the TDF as a 'theoretical lens' (Stage 1)
- Select key TDF domains to target in an intervention to bring about change in the target behaviour (adherence to polypharmacy) (Stage 2)
- Map key TDF domains to appropriate BCTs for inclusion in an intervention that could feasibly be delivered by community pharmacists (Stage 3)

3.3 Research design and methodology

3.3.1. Rationale for choice of research design

As discussed in Section 3.1 there are a range of research designs available to explore the target behaviour using the TDF. The choice of research design (e.g. quantitative, qualitative) and methodology (e.g. cross-sectional survey, interviews) in any project is influenced by a range of factors including the research objectives and nature of the research question, the target audience, project resources and timelines (Bryman, 2013). Qualitative approaches, which focus on words and language, allow researchers to gain in-depth information on the

behaviour of interest and explore '*why?*', *'what?*' and '*how?*' type research questions. In comparison, quantitative approaches focus more on numbers in an attempt to quantify the behaviour and answer research questions such as *'how many?'* or *'how much?'* (Pope and Mays, 2006). A number of studies have previously explored medication adherence in older adults using both qualitative and quantitative research designs (Tordoff et al*.* 2010a; Tordoff et al*.* 2010b; Ben-Natan and Noselozich, 2011; Henriques et al*.* 2012; Lee et al*.* 2013b). However, no studies have explored, in detail, the barriers and facilitators that influence adherence to polypharmacy in older adults using the TDF as a 'theoretical lens'.

For the study outlined in the current chapter, a qualitative approach was selected to facilitate a detailed examination and theoretical understanding of the target behaviour (adherence to polypharmacy). An overview of qualitative research design is provided in the following section.

3.3.2. Overview of qualitative research design

Data collection methods

A range of research methods are available for studies that adopt a qualitative research design, including interviews, focus groups and participant observation (Bryman, 2013). There are three types of interviews available: structured, semi-structured, and unstructured interviews. In a structured interview, there is little flexibility and questions are posed in the same order and phrased in the same way for all participants. Semi-structured interviews have more flexibility and additional questions can be posed based on the respondent's answers, but the researcher generally follows a pre-prepared topic guide (i.e. a list of questions) to ensure consistency. With unstructured interviews, although the researcher will have an idea of the main themes for the interview (e.g. a list of topics), the participant is encouraged to talk freely about the topic under study (Edwards and Holland, 2013).

Focus groups are group-based interviews (with approximately 4-10 participants per group) that are facilitated by a moderator. The ideal number of participants per group is 6-8 participants and the suggested maximum number of participants is 10. Beyond this size, the group becomes too difficult to manage and some participants may not get the opportunity to contribute (Krueger and Casey, 2009). A semi-structured topic guide is developed to guide the group discussion but conversation is not restricted to set questions (Bryman, 2012). Focus groups encourage group interaction and help to explore decision-making processes and uncover how participants think and feel (Barbour, 2008).

Participant observation involves the immersion of the researcher in a social setting in which they observe behaviours, listen to conversations and ask questions (Bryman, 2013). This research method is more applicable for research into group-based behaviours (e.g. school classroom activities, community pharmacy teams) and so will not be discussed in great detail in the following sections. The key considerations, in terms of advantages and disadvantages of interviews, focus groups and participant observation are presented below in Table 3.1.

Table 3.1. Advantages and disadvantages of qualitative data collection methods (Pope and Mays, 2006; Krueger and Casey, 2009; Bryman, 2013)

	Pros	**Cons**
Interviews	• Ability to collect in-depth information • Can probe/clarify meaning • Can be tailored to individuals	• Time-consuming • Smaller sample sizes (than focus groups) • Can be expensive (e.g. if travelling to conduct interviews, payment for participation) • Potential for response bias (interviewer effect)
Focus groups	• Ability to collect in-depth information • Can probe/clarify meaning • Efficient approach for collecting information from a larger number of participants than interviews • Group setting can stimulate others and help generate new ideas • Participants from mixed backgrounds can encourage alternative ways of thinking	• Time-consuming • Can be expensive (e.g. payment for participation) • Confidentiality concerns • Dominant group members may affect input from other participants • Some participants may be more comfortable on a one-to-one basis • Potential for response bias (interviewer effect)
Participant observation	• More natural setting • Observer can be passive (observation only) or active (involvement in activities, asking questions etc.)	• Observation skills required • More applicable to group-based behaviours • Time consuming • 'Hawthorne effect' (i.e. changes in behaviour that arise from being observed) • Active involvement may reduce objectivity of researcher

Sampling and sample size

Another key consideration when conducting qualitative research is the approach by which individuals are selected to participate in the study (i.e. the sampling strategy) (Pope and Mays, 2006). Sampling strategies are commonly categorised into random/probability or non-random/non-probability approaches. Quantitative research, which seeks to produce

statistically representative findings, often employs random sampling strategies, whereas for qualitative research, non-random sampling strategies are generally sufficient for answering the research question (Bryman, 2013). There is no general rule for selecting the sampling approach, however, sampling decisions should be systematically determined at the outset of a research study and reported in subsequent publications (Holloway and Wheeler, 2013).

Two common types of non-random sampling are convenience sampling and purposive sampling. With convenience sampling, participants are selected because they are readily available to the researcher (Bryman, 2013). In comparison, purposive sampling is a strategic approach commonly employed by qualitative researchers to identify 'information-rich' individuals using pre-defined eligibility criteria (Patton, 2015). Maximum variation sampling is a sub-set of purposive sampling whereby researchers seek heterogeneity in a sample and aim to identify a diverse range of participants (e.g. participants from different settings). Another subset of purposive sampling is snowball sampling i.e. '…the researcher makes initial contact with a small group of people… and then uses these to establish contacts with others' (Bryman, 2013).

In relation to the size of the sample in qualitative research, there are no set rules and an upper limit is generally not imposed at the outset of the study (Pope and Mays, 2006). Instead, sample size is determined by the quality of information obtained from participants. The point at which no new relevant themes are emerging from participants is referred to as 'data saturation' and data collection will cease once this stage has been reached (Fusch and Ness, 2015). Guest et al. (2006) have indicated that sample sizes as small as 6 may be sufficient for obtaining data saturation in qualitative interviews. Sample sizes between n=12 and n=58 have been reported in TDF-based interview studies in the literature (Pitt et al. 2008; Helms et al. 2011; Francis et al. 2012). In comparison with interview studies, fewer TDF-based studies have employed focus groups as part of their methodology (Francis et al. 2012). Krueger and Casey (2009) have recommended that three or four focus groups should be conducted as a minimum. Dyson et al. (2011) conducted three focus groups as part of a mixed methods TDF-based study (n=21 participants) and Bussières et al. (2012) held six focus groups (n=21 participants) with TDF as the underpinning theoretical framework.

Topic guides and questions

To ensure that there is a degree of consistency across qualitative interviews and focus groups, a topic guide is often prepared prior to commencing data collection (Tracy, 2012). Topic guides can be structured, semi-structured or unstructured, with the latter two being

more common in qualitative research (Bryman, 2013). Standard topic guides consist of opening questions, main questions and closing questions. Opening questions are introductory in nature, easy to answer and help to establish rapport between the interviewer and interviewee. These introductory questions are followed by the main questions which explore the topic of interest in detail. For TDF-based interviews or focus groups, the main questions explore each of the theoretical domains in the framework (e.g. 'Skills', 'Knowledge'). Both open-style questions (e.g. 'What do you think of X?') and closed-style questions (e.g. yes or no responses) can be included, but open-style questions are generally preferred to allow rich, in-depth information to be obtained (Tracy, 2012; Bryman, 2013). Probing questions can be included to encourage elaboration of views or opinions, reassure participants that the researcher is actively listening, clarify ambitious responses and to avoid misinterpreting the meaning. Closing questions usually allow participants to add in anything else they feel is relevant to the topic but has not already been covered (Bryman, 2013).

Data collection and management

Data can be managed by audio-recording, video-recording and/or by taking notes during or following sessions. Where possible, recordings are preferred as these help to ensure that key information is not overlooked. Audio-recordings are often selected for qualitative research as they are seen as less intrusive for participants than video-recordings. It is recommended that researchers test their recording devices in advance of sessions and are prepared (e.g. back-up device, note taking) for equipment malfunctions. Audio-recordings are then transcribed verbatim and identifiable information (e.g. names, locations) removed for confidentiality purposes. Software programs (e.g. NVivo®) can assist in organising large volumes of qualitative data, however, they do not replace the need for the researcher to interpret the data (Bryman, 2013).

Data analysis

There are a wide range of approaches available for analysing and interpreting qualitative data. Four approaches that have been widely used in the field of health research are grounded theory, thematic analysis, content analysis and the framework method (Bryman, 2013; Green and Thorogood, 2014). Although there are a number of differences in these approaches, what they all share in common is a process known as data coding (i.e. the assignment of descriptive labels to short phrases or words) (Saldana, 2009).

Grounded theory, first introduced by Glaser and Strauss (1967) focuses on developing theory using an inductive bottom-up style approach. A key strength of this approach is its cyclical

nature which includes data collection, analysis, provisional coding, further data collection and so forth. This process continues until no new theoretical constructs are emerging from the data (i.e. theoretical data saturation is reached). Another important feature of grounded theory is a concept called 'constant comparison' whereby codes are compared and contrasted across cases (e.g. individual interviews). Grounded theory, when carried out correctly, is a lengthy process and one that is often not feasible in healthcare research due to time constraints. It is also a method that is often confused with thematic analysis and content analysis (Green and Thorogood, 2014).

Thematic analysis is the most commonly cited method in qualitative healthcare research (Green and Thorogood, 2014). However, it has been described as a 'poorly branded' method that is broadly defined as 'a method for identifying, analysing and reporting patterns (themes) within data' (Braun and Clarke, 2006). As a result, the boundaries between thematic analysis and content analysis are often blurred. Arguably, thematic analysis differs from other approaches (such as content analysis and grounded theory) in that it does not outline a distinct set of activities to be undertaken by researchers (Bryman, 2013).

In contrast to thematic analysis, content analysis has been well-defined as:

> *"…a systematic coding and categorizing approach used for exploring large amounts of textual information unobtrusively to determine trends and patterns of words used, their frequency, their relationships, and the structures and discourses of communication."* (Vaismoradi et al. 2013)

In more recent years it has been recognised that there are two distinct forms of content analysis; quantitative and qualitative. Quantitative content analysis has received criticism in its attempts to reduce text into small 'quantifiable units' (i.e. frequency counts) (Cho and Lee, 2014). Pyett (2003) argues that strict reliance on 'counting responses [misses] the point of qualitative research' as frequency does not always equate to importance. Consequently, qualitative content analysis has emerged as a more holistic approach to exploring insights and meanings from the data without the need for strict frequency counts (Kracauer, 1952; Schreier, 2014). Qualitative content analysis can be either inductive (codes/categories are derived solely from the data) or deductive (codes/categories are predefined from previous research or theories) (Cho and Lee, 2014).

The framework method is another approach that was first introduced by the National Centre for Social Research in the 1980s as a structured method for organising data (Ritchie and Lewis, 2003; Gale et al. 2013; Green and Thorogood, 2014). The framework method outlines

distinct steps to undertake to analyse data including 'familiarisation' (repeated listening to audio-recordings, re-reading transcripts), 'indexing' (application of codes to the entire data set) and 'charting'. 'Charting' is a unique feature of the framework method that includes the production of a summary matrix (e.g. a Microsoft Excel spreadsheet) whereby rows represent cases (e.g. individual participants in interviews) and columns represent codes. This is a useful method to employ if a pre-defined theory or framework (e.g. TDF) is guiding data analysis. Using the framework method allows researchers to organise, compare/contrast and reduce large volumes of data. Other methods can be used alongside the framework method such as quantitative content analysis (i.e. rigid frequency counting techniques) or qualitative content analysis (i.e. less-rigid but with pre-defined analytical rules). Irrespective of the selected data analysis approach for qualitative research, it is important that the steps undertaken are reported transparently in publications to maintain scientific rigour.

Rigour in qualitative research

Rigour and trustworthiness of qualitative research is of upmost importance given the criticism that it commonly receives in comparison with quantitative research (Pope and Mays, 2006). Quantitative research strives for internal validity (i.e. confidence placed in the cause-effect relationship), external validity (i.e. generalisability beyond the study settings) and reliability (i.e. repeatability of study findings) (Bryman, 2013; Heale and Twycross, 2015). In comparison, qualitative research strives for credibility, transferability, and dependability, respectively (Shenton, 2004). Credibility (also referred to as the truth value) relates to the extent to which the results are believable from the point of view of the research participants. Credibility can be improved by having findings validated by participants where possible and through transparent reporting. Transferability (also referred to as applicability) is a concept whereby study findings can be transferred from one context, setting or group to another if there is a good fit (Guba, 1981). Transferability can be facilitated by providing accurate descriptions of the sampling strategy, data analysis procedures and any assumptions made. This will allow researchers to interpret whether the findings are transferable to their own proposed setting.

Dependability (also referred to as consistency or neutrality) is equivalent to reliability in quantitative research, a concept whereby the same results would be obtained if the study were to be repeated. This concept focuses on the trustworthiness of the methods used and can be influenced by the researchers own perspectives. Dependability can be improved in qualitative research by having multiple independent data coders and a clear audit trail of all decisions made, for example using computer-assisted packages such as NVivo® (Shenton,

2004; Elo et al. 2014). Reflexivity is an important part of ensuring dependability in qualitative research as it involves the researcher reflecting on their own personal assumptions and preconceptions and how this could impact on the findings (Bryman, 2013). Reflexivity is also about transparency and self-awareness, which can be facilitated by the use of reporting checklists such as the 'Consolidated criteria for reporting qualitative studies' (COREQ) checklist (Tong et al. 2007).

3.3.3 Rationale for the use of focus groups

The study outlined in this chapter formed part of a larger polypharmacy research project which explored the prescribing and dispensing of appropriate polypharmacy to older adults (Cadogan et al. 2015). The polypharmacy project involved the conduct of qualitative interviews with both GPs and pharmacists and also sought to gain older adults' perceptions of the roles of HCPs in providing services to them (i.e. prescribing and dispensing of polypharmacy). Focus groups, which were selected to explore older patients' views on HCPs' roles as part of this larger polypharmacy project, were also used to explore barriers and facilitators to adherence using the TDF. This latter phase of the larger polypharmacy project formed part of the study outlined in the current chapter.

Focus groups were selected for this study for three main reasons. Firstly, focus groups are a more efficient method for collecting data from a larger number of individuals than interviews. Secondly, group interaction in this setting can help stimulate ideas and remind participants of similar situations they have encountered with regards to medication-taking. Thirdly, as argued by Krueger and Casey (2009) people are more likely to disclose information with others that they perceive to be similar to them. Therefore, focus groups comprised of patients of a similar age (who were all prescribed several medications) were selected over one-to-one interviews with a researcher.

3.3.4 Sampling and recruitment strategy

General practices that had participated in a previous linked study (described in Section 3.3.3) were approached and asked if they would facilitate patient recruitment for the focus groups. This included general practices from across the five Health and Social Care Trusts in NI (two per Trust area). A purposive sampling strategy was adopted for this study to identify 'information-rich' participants. Pre-defined eligibility criteria were: patients aged 65 years or older, living in their own homes, prescribed four or more medicines (the definition of polypharmacy adopted for this study) and not cognitively impaired. Patient recruitment within each practice was overseen by primary care research nurses from the Northern Ireland

Clinical Research Network (NICRN). NICRN nurses screened practice records and identified patients who met the eligibility criteria. Judgements of cognitive impairment were made by NICRN nurses based on patients' medical notes and confirmed by their GP. Written invitation letters from the practices were issued to patients who met the inclusion criteria. A reply slip and pre-paid return envelope was included with the invitation letter (Appendix 3.3). Patients interested in taking part in the study were instructed to return the reply slip to a member of the research team (CC), who then made follow-up contact with patients. Each patient was provided a study information sheet (Appendix 3.4). Participants were offered an honorarium of £50 for taking part in the study.

One focus group was scheduled per practice (7 practices in total) after an adequate number of patients (five patients minimum; 10 patients maximum) confirmed that they could attend. Written informed consent was obtained from all participants before each focus group was convened (Appendix 3.5). Ethical approval was granted by the Office of Research Ethics Committees for Northern Ireland (ORECNI) (Research Ethics Committee reference: 13/NI/0114) (Appendix 3.6).

3.3.5 Topic guide development

A semi-structured topic guide (Appendix 3.7) was developed by the research team which included a health psychologist (JF) with expert knowledge of the TDF (Francis et al. 2012). In developing the topic guide, the research team made the decision to use the original 12-domain version of the framework (TDF1) rather than the more recent 14-domain version (TDF2) (Michie et al. 2005; Cane et al. 2012). This decision was based on the research team's discussion of the importance of the 'Nature of the behaviours' domain in the context of older adults' adherence behaviour, as previous research has described this behaviour as 'routine' (Tordoff et al. 2010a). As the 'Nature of the behaviours' domain was thus deemed likely to be important to the target behaviour (i.e. adherence to polypharmacy), and is absent from TDF2, TDF1 was selected as the underpinning theoretical model for the current study.

Key interview questions (Appendix 3.7) were developed based on each of the 12 theoretical domains in TDF1 (Michie et al. 2005). Example questions are provided below:

- How important is it to you to take all of your different medicines as the GP has instructed/directed/prescribed? [Motivation and goals domain]
- What do you think the disadvantages are to taking all your medicines as prescribed? [Beliefs about consequences domain]

Prompts were also included to elicit further information from participants where necessary. The topic guide was piloted before use by a group of Pharmacy PhD students and Post-doctoral Research Fellows who acted as participants aged over 65 taking four or more medicines. Refinements were made to the topic guide with ambiguous questions being re-phrased and more examples of prompts included.

3.3.6 Conduct of focus groups

Focus groups were convened by two members of the research team who acted as moderator (CC: BSc, PhD, Post-Doctoral Research Fellow at time of study, qualified pharmacist) and note-taker (DP: MPharm, MPSNI, PhD Research Student/practising community pharmacist), respectively. Both researchers had undergone training (CC, DP) and/or had experience (CC) in qualitative research methods prior to conducting the focus groups. Participants were contacted via telephone to arrange a suitable time and location for each focus group. Participants were not informed of the researchers' backgrounds but were made aware that the study was being conducted by the School of Pharmacy at Queen's University Belfast (QUB). Focus groups were held between October 2014 and January 2015, either at the patients' general practice or another convenient location (e.g. local community centre). Refreshments were provided and an oral summary of the key questions and answers provided by participants was given by the note taker (DP) at the end of each focus group. With participants' consent, each focus group was digitally recorded, transcribed verbatim and checked for accuracy. Patient identifiers were removed and an anonymous code was assigned to each participant (e.g. FG01PT01). The code denoted the specific focus group (i.e. FG01, FG02, etc.) and the individual participant (i.e. PT01, PT02, etc.). Following transcription, data were transferred to NVivo QSR 10. All recordings, consent forms etc. were stored either in a locked fire-resistant filing cabinet or on a password protected laptop, to which only the research team had access. The qualitative aspect of this study has been reported in accordance with the 32 item COREQ checklist (see completed checklist in Appendix 3.8), which seeks to ensure the comprehensive and explicit reporting of qualitative research such as focus group studies.

3.3.7 Data analysis

Data analysis consisted of three stages: (1) Identification of determinants of adherence; (2) Identification of key TDF domains; (3) Mapping of key TDF domains to BCTs. Figure 3.1 provides an overview of these three stages with further details provided in the subsequent text.

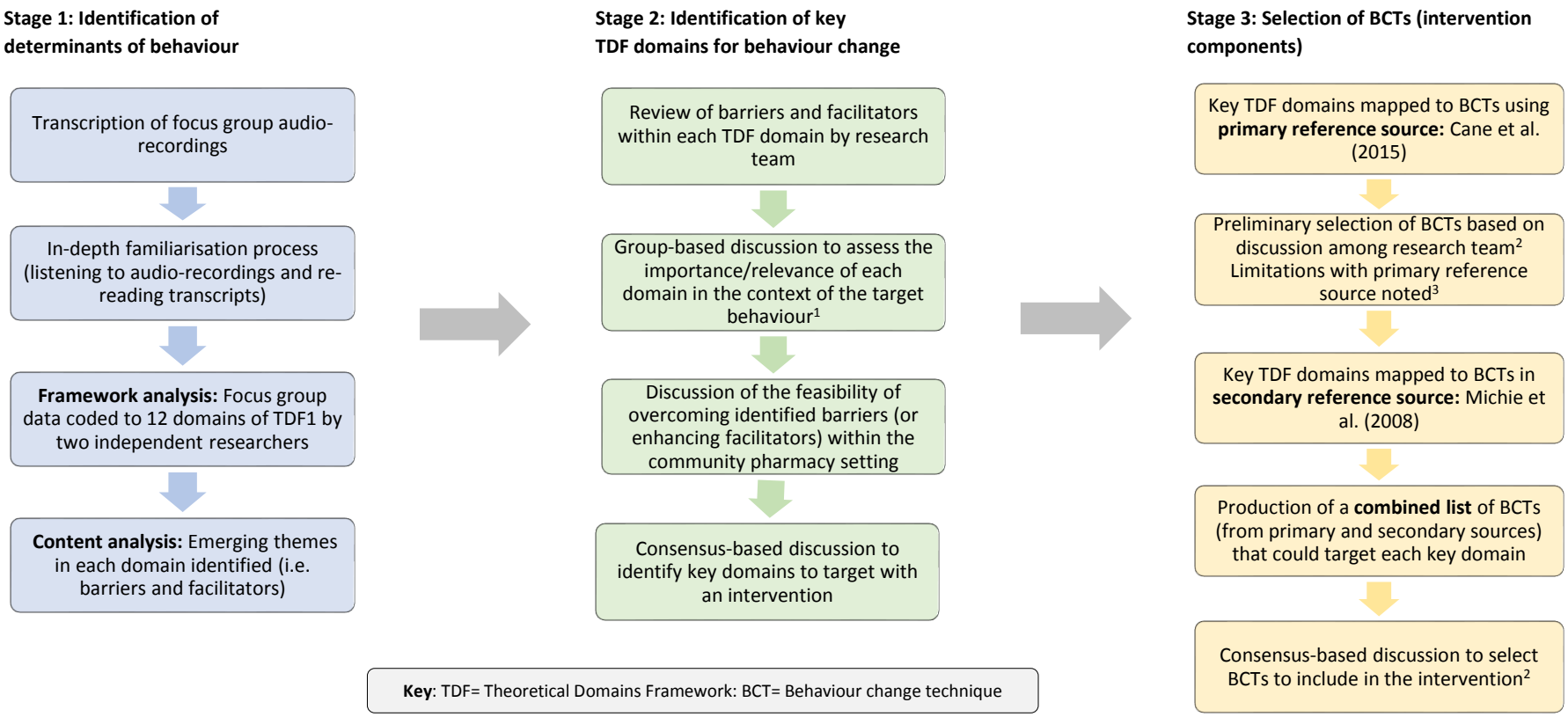


Figure 3.1 An overview of the three stages involved in data analysis

[1]A domain was considered to be important/relevant if it met the criterion 'evidence of verbal agreement or strong beliefs expressed by an individual'; [2]Selection was based on expected feasibility of BCT delivery in the proposed setting and applicability to target group; [3]No BCTs were mapped to 'Memory, attention and decision processes' and 'Social/professional role and identity' domains in the primary reference source

Stage 1: Identification of determinants of adherence

The framework method was used to systematically index and chart data into a framework matrix (Gale et al. 2013). TDF1 was used as the analytical framework whereby each of the 12 domains served as the coding categories (Michie et al. 2005). Following transcription of focus group recordings, an in-depth familiarisation process was undertaken through repeated reading of focus group transcripts, as well as listening to audio recordings ('familiarisation' phase of framework method). Each transcript was coded independently by at least two members of the research team (DP, CR, CH) ('indexing' phase of framework method). Coding was compared and agreed between the coders and any discrepancies were resolved by discussion. The data were managed using NVivo QSR 10 before being imported into a Microsoft Excel spreadsheet to generate a framework matrix ('charting' phase of framework method).

Qualitative content analysis was then performed inductively on the framework matrix to identify emerging themes relating to determinants (i.e. barriers and/or facilitators) of adherence within each TDF domain. A summary of the qualitative content analysis was reviewed by three members of the research team (DP, CR, CH) and content themes were agreed upon.

Stage 2: Identification of key TDF domains

The second stage of data analysis involved identifying key domains to target as part of an intervention. As discussed in Section 3.3.2, qualitative TDF-based studies have often involved the use of semi-structured interviews and comparatively fewer studies have used focus groups (Francis et al. 2012). The study by Bussières et al. (2012) was the only focus group study identified by the research team that outlined the methods used to assess the importance/relevance of domains with respect to the target behaviour. This involved the use of frequency counts (i.e. the number of times that beliefs/statements were mentioned per domain) as one of the assessment criteria.

Although frequency counts have commonly been used as a criterion to assess the relevance of domains in TDF-based interview studies, there are challenges involved in applying this type of quantitative content analysis approach to focus group data (Atkins et al. 2017). For example, in a focus group context, there are many verbal and non-verbal ways that participants can indicate their agreement with other participants (e.g. short verbal responses, head nodding) which can be difficult to capture accurately from audio recordings (Krueger and Casey, 2009). Hence, relying solely on strict frequency counts from the analysed

transcripts of the audio-recordings of focus groups may underestimate the relevance of a theoretical domain. To overcome these challenges, the research team also took into consideration the expression of strong beliefs (whereby an individual emphasised or re-iterated a belief) as an indicator of a domain's relevance/importance, in addition to the verbal agreement amongst participants in each group or similarities across focus groups. This adapted criterion (i.e. 'evidence of verbal agreement or strong beliefs expressed by an individual') guided decisions regarding the relevance/importance of each domain to the target behaviour (i.e. adherence to multiple medications).

Although a domain could be deemed as relevant/important to the behaviour it may not be feasible to target identified barriers (or necessary to enhance facilitators) with an intervention in the proposed setting. For example, in the study by Cadogan et al. (2015) (described previously in Section 3.1) it was not considered possible to overcome barriers identified under the 'Knowledge' domain, such as the lack of evidence available to support prescribing and dispensing decisions for multimorbid older adults by GPs and CPs, respectively. In the current study, key domains to target in an intervention were selected based on the feasibility of overcoming barriers (or enhancing facilitators further) in the proposed setting of community pharmacies and using the wider project's resources. All decisions involved a consensus-based approach.

Stage 3: Mapping of key TDF domains to BCTs

The process for mapping theoretical domains to BCTs was guided by methods reported by Cadogan et al. (2015) which involved the use of a two reference sources (Michie et al. 2008; Cane et al. 2015). A mapping table (Appendix 3.2) published by Cane et al. (2015) was used as the primary reference source as it provided the most up-to-date guidance on BCT mapping using the current available BCT taxonomy (BCTTv1) (Michie et al. 2013). During group discussions a number of limitations were noted with the primary reference source (Cane et al. 2015). Firstly, BCTs had not been mapped to two domains ('Memory, attention and decision processes' or 'Social/professional role and identity'), and secondly the mapping process was carried out with TDF2, whereas the current study was based on TDF1. To overcome these limitations, the original mapping matrix developed by Michie et al. (2008) was consulted as a secondary reference source. This matrix linked 35 BCTs (from a provisional list of BCTs established prior to BCTTv1) to domains in TDF1 as agreed by four experts.

The BCT selection process involved a consensus-based approach and was informed by the summary of findings from the qualitative content analysis of focus group data. In selecting

BCTs to target key domains, the research team considered two main factors: (1) the applicability of particular BCTs to the target group (i.e. older adults prescribed polypharmacy), (2) the expected feasibility of BCT delivery with regards to contextual constraints of the community pharmacy setting (e.g. time-limited interactions with HCPs). Potential implementation issues (such as likely BCT preparation and delivery time) were also taken into consideration at this early stage of intervention development to help exclude BCTs that were unlikely to be feasible for delivery in primary care by CPs. Using this approach, the study outlined in this Chapter follows the latest WIDER guidelines which recommend reporting on: '1) The intervention development; 2) The change techniques used in the intervention; 3) The causal processes targeted by these change techniques' (Albrecht et al. 2013).

3.4 Results

3.4.1 Participant characteristics

Seven of the ten general practices that participated in the previous linked study (Section 3.3.3) agreed to facilitate patient recruitment and seven focus groups were convened (one at each practice) (Cadogan et al. 2015). In total, 382 letters were sent out to patients by NICRN nurses from the seven general practices and 50 participants (60% female) were recruited into the study. Numbers of non-responders or those declining to participate were not recorded. Each focus group consisted of between five and 10 participants (see Table 3.2) and all those in attendance were active participants. The duration of each focus group ranged from 65 to 123 minutes (618 minutes in total). Data saturation was reached by the seventh focus group as no new relevant themes were emerging at this point.

Table 3.2: Characteristics of focus groups

Focus group number	Number of participants	Male: female ratio	Duration (minutes)	Health and Social Care Trust area (urban/rural)[1]
1	10	3:7	102	1 (urban)
2	9	5:4	123	2 (urban)
3	7	2:5	88	3 (rural)
4	6	2:4	87	4 (rural)
5	6	2:4	65	2 (urban)
6	7	3:4	84	4 (urban)
7	5	3:2	69	3 (rural)

[1] *In NI '...the divide between urban and rural lies among settlements whose populations are between 3,000 and 5,000'* (Northern Ireland Statistics and Research Agency, 2005)

3.4.2 Summary of findings from Stage 1 (Identification of determinants of adherence)

The main determinants (i.e. barriers, facilitators) of older patients' adherence to polypharmacy that were identified within each theoretical domain are listed in Table 3.3 together with illustrative quotes. This is followed by a narrative summary that outlines the main findings.

Table 3.3: Determinants (barriers, facilitators) of older patients' adherence behaviour identified within each TDF domain and illustrative quotes

TDF domain	Determinants (barriers, facilitators) of adherence to polypharmacy	Illustrative quotes
Knowledge	• Lack of/incorrect knowledge of clinical indication, treatment duration or administration timing *(barrier)* • Lack of/incorrect knowledge of the consequences of adherence or non-adherence *(barrier)* • Extent of knowledge on medication side effects (barrier or *facilitator)*[1]	*"I wasn't aware, and I'll have to read the boxes again. I wasn't aware of, of the time of the day or night…"* (FG07PT02) *"You know, a build-up of this, that and the other, you just sort of wonder can that be good or would you be better off taking a break…"* (FG05PT02) *"Sometimes the less you know the better, just take it."* (FG05PT01)
Beliefs about consequences	• Concerns about medication side effects/long term consequences of adherence or non-adherence *(barrier)* • Beliefs that missed doses cause no harm *(barrier)* • Beliefs that medications are unnecessary and/or lack benefit *(barrier)* • Beliefs that non-adherence has negative outcomes (e.g. hospitalisation, mortality) *(facilitator)* • Beliefs that medications are necessary and/or beneficial (e.g. improves quality of life, prolongs survival) *(facilitator)* • Return of symptoms *(facilitator)*	*"Well, blood pressure is very serious, I would take my blood pressure tablet every day. I'm on aspirin, I take that every day. See this is why I laughed when I got the letter and it said, you know, 'Four tablets plus'. I am officially down as four tablets plus but I don't take four tablets plus…"* (FG03PT06) *"I remember at one stage thinking I don't think them tablets are doing me any good, I would say to the wife, 'You wouldn't be taking them no more'. I said, 'I want to stop, I don't think they're doing me a lot of good…'"* (FG02PT04) *"…I've never stopped taking them but I sort of wondered if I stopped taking these what would happen but I tried it for a wee while but my blood pressure went away up. And then it takes a wee while for the tablets to be effective again."* (FG04PT01)
Emotion	• Anxiety about side effects/long term consequences of adherence or non-adherence *(barrier)* • Anxiety about potential consequences of non-adherence *(facilitator)*	*"Well, I would worry about the side effects but I know I have no choice but take them."* (FG01PT04) *"I'd be afraid of not taking them, I don't know what the effect would be but I'd be afraid if I didn't take them that it would affect me badly."* (FG07PT02)
Skills	• Lack of physical skills to take medicines as prescribed (e.g. ability to swallow medications, poor manual dexterity) *(barrier)*	*"But I couldn't, I couldn't actually physically get them out, [Out of the thing, yeah] trying to get the back open."* (FG01PT09) *"Sometimes it's quite difficult to, to pop them out of the foil."* (FG06PT02)

Table 3.3 (cont'd): Determinants (barriers, facilitators) of older patients' adherence behaviour identified within each TDF domain and illustrative quotes

TDF domain	Determinants (barriers, facilitators) of adherence to polypharmacy	Illustrative quotes
Beliefs about capabilities	• Belief about lack of physical capability (see 'Skills' domain) *(barrier)* • Belief that medication use is not difficult *(facilitator)*	*"And I would say, 'Excuse me, I can't take those, [Can't swallow] no, can you give me those ones that's in the water?'…"* (FG01PT01) *"But it's the top, if you've one of those tops they're impossible if you've arthritic hands."* (FG01PT06) *"I've no difficulty there with anything… there, as long as I'm able to take the tablets that's the main thing…"* (FG04PT05)
Environmental context and resources	• Access to medications (e.g. at weekends) *(barrier)* • Changing environment (e.g. on holidays, day trips) *(barrier)* • Physical resources (e.g. MDS, medication lists) *(barrier)*	*"…you have to make sure you have everything with you and sometimes you'd be in meetings or something like here and the time you're supposed to take it is gone by."* (FG03PT03) *"I get it in a bubble pack* [MDS] *for the week and he leaves it out morning and evening, it's just so easy in case you forget them…."* (FG05PT04)
Motivations and goals	• Goals to reduce the total number of prescribed medications *(barrier)* • Relative priority placed on medications that patients deem to be of greater importance *(barrier/facilitator)*[2] • High intrinsic motivation to take medicines as prescribed *(facilitator)* • Health goals such as goals to avoid hospital admission, maintain driving license, clinical goals (e.g. symptom control) *(facilitator)*	*"You decide what's the serious ones and if you run out of a lesser tablet, well it's not as dangerous, you can wait till you get to the pharmacist, you know. There's a couple of my tablets that, well I need to take them but they're not as important if you know what I mean as the blood pressure tablets…"* (FG03PT03) *"Well I think it's very important for me too because I would have…kidney failure or kidney disease and I think if I didn't do me things right I might end up in hospital again where I don't want to be."* (FG07PT03)
Behavioural regulation	• Systems that alert patients to missed doses (e.g. MDS) *(facilitator)* • Practical and reminder strategies (e.g. placement of medication in a visually prominent place) *(facilitator)* • Action planning (e.g. planning administration times) (facilitator) • Self-monitoring of medication use and outcomes (e.g. blood glucose, symptom control) *(facilitator)*	*"And I put it* [MDS] *down beside the kettle because I know I'm going to the kettle in the mornings, the tablets are there for me."* (FG07PT03) *"I have a wee weekly box and I take so many tablets in the morning they're divided between two compartments but I do all my week's drugs on a Sunday night so they're all done.*" (FG01PT09)

Table 3.3 (cont'd): Determinants (barriers, facilitators) of older patients' adherence behaviour identified within each TDF domain and illustrative quotes

TDF domain	Determinants (barriers, facilitators) of adherence to polypharmacy	Illustrative quotes
Memory, attention and decision processes	• Forgetting to take medicines as prescribed (barrier) • Paying attention to medications deemed to be of greater importance *(barrier/facilitator)*[2] • Paying attention to medications when out of normal context (e.g. o holidays, at meetings) *(facilitator)* • Making decisions regarding medication use without consulting a HCP (e.g. reducing doses, non-persistence) *(barrier)* • Involving HCPs in decisions regarding medications *(facilitator)*	*"So obviously I've forgotten, not that I'm that fond of statins anyway because they keep giving me pains, they're desperate."* (FG06PT07) *"I have at several times… with different medications cut down to see how I can go, I've never actually stopped… that I cut it out altogether, no I haven't done that."* (FG04PT02) *"Sometimes when I go on holiday I don't take my fluid one. I just– but it's combined with my blood pressure tablet… so I'm cutting both of them out but I do, for a few days anyway."* (FG01PT06)
Social influences	• Social support/pressure from family *(facilitator)* • Social support/pressure from HCPs *(facilitator)* • Lack of (or withdrawal of) social support from family (e.g. death of spouse) *(barrier)*	*"'You're not taking your tablet, I know by the look on your face'… that sort of reacts to you because the girl* [Diabetic nurse] *knows you and you know the girl, it's not as if she's a stranger."* (FG01PT01) *"My wife passed away last Christmas and I, I find it difficult to manage* [my] *tablets. She remembered every time I had to take a tablet and sometimes I was going days without certain tablets…"* (FG01PT10)
Social/ professional role and identity	• Patient autonomy (i.e. viewing medication use as their own responsibility) *(facilitator)*	*"Everyone would be responsible for themselves*." (FG04PT06) *"… I'm the one that's been affected by it so… as far as I'm concerned… it's my responsibility to do it."* (FG06PT01)
Nature of the behaviours	• Having a personalised routine (e.g. linked to meal times) *(facilitator)* • Lack of routine or ineffective routine *(barrier)* • Return of symptoms (direct experience) *(facilitator)*	*"Well, I used to worry about, as I say, taking the tablets and so I developed a wee routine, you know. Here's me, I'll take them this way. So I take the, the wee one in the morning and then start eating my porridge…"* (FG02PT06) *"It's no difficulty for me because as soon as I have my breakfast into the kitchen, into the cupboard, get them out, that's it. It's just routine."* (FG01PT08)

Many of the focus group participants did not perceive their knowledge of the medications they were prescribed to be a barrier to adherence. However, some participants did not know the expected length of treatment duration or the appropriate time to take their medication and this posed barriers to adherence. There was a lack of consensus amongst participants in relation to the desired amount of knowledge on medication side effects (domain: 'Knowledge'). Based on their level of knowledge of the outcome of taking medications as prescribed, participants reported various beliefs about the consequences of adherence or non-adherence (domain: 'Beliefs about consequences') which in turn influenced their decisions to take their medications in accordance with the prescribed directions (domain: 'Memory, attention and decision processes'). For some participants, beliefs about potential harms of non-adherence led to feelings of anxiety (domain: 'Emotion').

A number of participants placed higher priority on medicines that they believed to be of greater importance (e.g. warfarin) often to the detriment of other medicines. This acted as a barrier to their overall adherence to polypharmacy. For example, some patients were less concerned about having a supply of other medications that they deemed to be less important (domains: 'Motivation and goals', 'Memory, attention and decision processes'). Participants also noted that setting goals (e.g. to avoid hospital admission), either with or without a HCP, facilitated adherence to polypharmacy. However, this was conditional on an appropriate goal being set as some participants aimed to decrease the overall number of prescribed medications and this acted as a barrier to adherence (domain: 'Motivation and goals').

For most participants, taking several medications was not seen as a difficult task (domain: 'Beliefs about capabilities'). However, some participants indicated that this would likely change if they became cognitively impaired. The only physical difficulties reported by participants in taking their medication as prescribed were in relation to the opening of medication packaging and swallowing oral dosage formulations. These problems were often attributed to poor manual dexterity skills, medication formulation and packaging (domains: 'Skills', 'Environmental context and resources').

Participants cited a number of resources and practical strategies that facilitated adherence, including MDS, medication lists prepared in secondary care (including details of administration times) and routine medication reviews by GPs (domains: 'Environmental context and resources', 'Behavioural regulation'). A lack of access to medication supplies outside of normal general practice hours (e.g. over the weekend) was perceived as a barrier to adherence (domain: 'Environmental context and resources').

In discussing their decisions to take their medicines as prescribed, participants commonly stated that they felt they had no choice but to follow their GPs' directions (domains: 'Memory, attention and decision processes', 'Social influences'). For some participants, these decisions were not as clear-cut and were based on their 'knowledge' of the clinical outcome of medication use and personal 'beliefs about consequences' of taking medications as directed. Decisions were also informed by the patients' direct experience which included return of symptoms following trial periods of stopping their medication without consulting their GP (domains: 'Nature of behaviours', 'Beliefs about consequences'). Participants' adherence behaviour was influenced by their interactions with HCPs and good relationships with HCPs, such as GPs and CPs, were perceived as a facilitator of adherence. The social support provided by family members was also perceived as a facilitator of adherence (e.g. reminders, encouragement) (domain: 'Social influences'). Irrespective of the level of available social support, participants reported that it was their own personal responsibility to take their medicines as prescribed and this facilitated adherence (domain: 'Social/professional role and identity').

Participants in all seven focus groups discussed how taking several medications formed part of their normal 'routine' and everyday life (domain: 'Nature of the behaviours'). These routines which were often highly individualised and generally linked to meal times facilitated adherence to polypharmacy (domain: 'Behavioural regulation'). However, difficulties with adherence were encountered by participants when they had to take medications at particular times of the day (e.g. evening doses) or where their normal routine was disrupted (e.g. holidays) and this often led to participants forgetting to take their medicines as prescribed (domains: 'Environmental context and resources', 'Memory, attention and decision processes', Behavioural regulation).

3.4.3 Summary of findings from Stage 2 (Identification of key domains)

Based on the research team's review of the summary findings from data analysis Stage 1 (Section 3.4.2), all 12 domains met the criterion 'evidence of verbal agreement or strong beliefs expressed by an individual' and were therefore considered to be relevant/important to the target behaviour (adherence to multiple medications). Through group consensus, eight of the 12 domains were selected as key domains to target as part of an intervention ('Knowledge', 'Beliefs about consequences', 'Motivation and goals', 'Environmental context and resources', 'Social influences', 'Memory, attention and decision processes', Behavioural regulation' and 'Nature of the behaviours'). Four domains were not selected as key domains

to target ('Social/professional role and identity'; 'Beliefs about capabilities'; 'Skills'; 'Emotion'). The reasons for this are discussed in Section 3.5.1.

3.4.4 Summary of findings from Stage 3 (Mapping of key domains to BCTs)

The eight key domains identified in Stage 2 (Section 3.4.3) were mapped across to BCTs using the two reference sources discussed previously (Section 3.1) (Michie et al. 2008; Cane et al. 2015). Forty-one potential BCTs were identified using this method and subsequently considered for inclusion in an intervention to improve adherence to polypharmacy in older adults (See Table 3.4). Based on discussion among the research team eleven BCTs were subsequently selected for inclusion in an intervention: 'Information about health consequences', 'Feedback on behaviour', 'Goal-setting (outcome)', 'Goal-setting (behaviour)', 'Review of outcome goal', 'Review of behaviour goal', 'Action planning', 'Prompts and cues', 'Self-monitoring (of the behaviour)', 'Restructuring the physical environment', 'Social support (unspecified)' (see Table 3.4). BCTs that were not selected and the reasons for this are outlined in Table 3.4.

Table 3.4: Mapping of key domains to behaviour change techniques (BCTs) for inclusion in an intervention to improve medication adherence in older adults prescribed polypharmacy

Key TDF domain	**BCTs** [a]=Primary reference source (Cane et al. 2015) [b]=Secondary reference source (Michie et al. 2008)	**BCT selected** ✓ = YES X = NO	**Rationale for selection (or non-selection) of BCT(s) to include in the patient-targeted intervention**
Knowledge	• Information about health consequences[a] /Information regarding behaviour, outcome[b]	✓	Verbal information could be provided by outlining positive consequences of adhering to medications and negative consequences of non-adherence. This BCT also mapped to 'Beliefs about consequences' and 'Motivation and goals'—see below. *Note: The BCT 'Information regarding behaviour, outcome' encapsulates the BCT 'Information about health consequences'.*
	• Feedback on behaviour[a]	✓	Patients could be provided with verbal feedback on their adherence behaviours. This BCT also mapped to 'Beliefs about consequences'—see below.
	• Antecedents (e.g. distraction, adding objects)[a]	X	Due the restricted time environment in the proposed setting of primary care, BCTs in this grouping were not deemed to be necessary in addition to previously selected BCTs–see above.
	• Biofeedback[a]	X	Providing feedback on the outcomes of behaviour (e.g. improvements in clinical parameters) would be difficult to achieve in the context of community pharmacy and with the current intervention which targets a heterogeneous patient group.
Beliefs about consequences	• Comparative imagining of future outcomes[a] • Pros and cons[a] • Covert conditioning[a]	X	Due the restricted time environment in the proposed setting of primary care, these BCTs were not deemed to be necessary in addition to BCTs previously selected to target the 'Knowledge' domain ('Feedback on behaviour', 'Information about health consequences') which also map to the 'Beliefs about consequences' domain—see below.
	• Emotional consequences[a]	X	It is beyond the scope of the current study to target patients' emotions directly and this BCT would likely require extensive delivery over a long period of time.
	• Salience of consequences[a]	X	This BCT would likely require significant and detailed preparation which would be difficult to achieve in the context of the current intervention which targets a heterogeneous patient group.
	• Covert sensitization[a] • Anticipated regret[a]	X	These BCTs were not considered to be appropriate for inclusion, as the current intervention will focus on improving medication adherence (i.e. a wanted behaviour) rather than an unwanted behaviour
	• Social and environmental consequences[a]	X	This BCT is not applicable to the target audience as participants in the focus groups focused more on the health consequences of the target behaviour.

Table 3.4 (cont'd): Mapping of key domains to behaviour change techniques (BCTs) for inclusion in an intervention to improve medication adherence in older adults prescribed polypharmacy

Key TDF domain	**BCTs** [a]=Primary reference source (Cane et al. 2015) [b]=Secondary reference source (Michie et al. 2008)	**BCT selected** ✓ = YES X = NO	**Rationale for selection (or non-selection) of BCT(s) to include in the patient-targeted intervention**
Beliefs about consequences (cont'd)	• Vicarious reinforcement[a]	X	This BCT is not applicable to the target audience as the behaviour is highly individualised based on the patients' own medications and medical conditions.
	• Threat[a]	X	Threats were not considered to be appropriate for attempting to change patient's adherence behaviour as they could evoke negative emotions and harm the patient-HCP relationship.
	• Self-monitoring[a]	✓	Patients could self-monitor their medication use via a personalised daily medication diary. This BCT also mapped to 'Behavioural regulation' and 'Memory, attention and decision processes'– see below.
	• Persuasive communication[b]	X	This BCT would likely require delivery over an extended time period which was not seen as feasible in the proposed setting of community pharmacies.
	• Information regarding behaviour/outcome[b]	✓	Equivalent to 'Information about health consequences'. See 'Knowledge' domain above.
	• Feedback[b]	✓	Equivalent to 'Feedback on behaviour'. See 'Knowledge' domain above.
Environmental context and resources	• Restructuring the physical environment[a]/ Environmental changes[b]	✓	Changes to the physical environment, such as non-child resistant bottles, re-packaging medications in MDS, could be made to facilitate adherence. *Note: These BCTs were deemed equivalent.*
	• Discriminative (learned) cue[a]	X	It is beyond the scope of this project to offer rewards or incentives.
	• Prompts and cues[a]	✓	Patients could use reminder stickers or strategic placement of medications in a visually prominent place to prompt medication use (e.g. kitchen bench). This BCT also mapped to 'Behavioural regulation' and 'Memory, attention and decision processes'
	• Restructuring the social environment[a]	X	It is beyond the scope of this project to restructure patients' social environment.
	• Avoidance/changing exposure to cues for the behaviour[a]	X	This BCT was not considered to be appropriate for inclusion, as the current intervention will focus on improving medication adherence (i.e. a wanted behaviour) rather than an unwanted behaviour.

Table 3.4 (cont'd): Mapping of key domains to behaviour change techniques (BCTs) for inclusion in an intervention to improve medication adherence in older adults prescribed polypharmacy

Key TDF domain	**BCTs** [a]=Primary reference source (Cane et al. 2015) [b]=Secondary reference source (Michie et al. 2008)	**BCT selected** ✓ = YES X = NO	**Rationale for selection (or non-selection) of BCT(s) to include in the patient-targeted intervention**
Motivation and goals	• Goal setting (outcome)[a] • Goal setting (behaviour)[a] • Review of outcome goal[a] • Review of behaviour goal[a] • Goal/target specified: behaviour or outcome[b]	✓	Patients could be prompted to set goals related to positive outcomes of medication use (e.g. fewer symptoms, avoiding hospital admissions) and/or medicine use (i.e. behaviour) goals tailored to their own medications. These goals could be reviewed at follow-up appointments. These BCTs also mapped to the 'Behavioural regulation' domain. *Note: 'Goal/target specified: behaviour or outcome' encompasses the following four BCTs: 'Goal setting (outcome)', 'Goal setting (behaviour)', 'Review of outcome goal' and 'Review of behaviour goal'.*
	• Action planning[a]	✓	Patients could make explicit plans with their HCPs as to how to use their medication. This BCT also mapped to 'Memory, attention and decision processes' and 'Behavioural regulation'.
	• Contract[a,b] • Graded tasks, starting with easy tasks[b] • Behavioural commitment[a]	X	Due to the limited available time in the proposed setting of primary care, these BCTs were not deemed to be necessary in addition to previously selected BCTs (e.g. 'Goal-setting', 'Action planning').
	• Rewards; incentives[b]	X	It is beyond the scope of this project to offer rewards or incentives.
	• Increasing skills: problem solving, decision making, goal setting[b]	X	This BCT encapsulates some aspects of previously selected BCTs (e.g. 'Goal setting (behaviour)'.
	• Social processes of encouragement, pressure, support[b]	✓	Patients could be advised to seek additional support from family or friends or HCPs could encourage adherence. This BCT also mapped to 'Social influences'—see below.
	• Persuasive communication[b] • Motivational interviewing[b]	X	These BCTs would likely require delivery over an extended time period which was not seen as feasible in the proposed setting of community pharmacies.
	• Information regarding behaviour, outcome[b]	✓	This BCT is equivalent to 'Information about health consequences'. See 'Knowledge' domain above.
Behavioural regulation	• Self-monitoring (of behaviour)[a]	✓	Refer to 'Beliefs about consequences' domain above.
	• Goal/target specified: behaviour or outcome[b]	✓	Refer to 'Motivation and goals' domain above.

Table 3.4 (cont'd): Mapping of key domains to behaviour change techniques (BCTs) for inclusion in an intervention to improve medication adherence in older adults prescribed polypharmacy

Key TDF domain	**BCTs** [a]=Primary reference source (Cane et al. 2015) [b]=Secondary reference source (Michie et al. 2008)	**BCT selected** ✓ = YES X = NO	**Rationale for selection (or non-selection) of BCT(s) to include in the patient-targeted intervention**
Behavioural regulation (cont'd)	• Contract[b] • Use of imagery[b]	X	Due to the restricted time environment in the proposed setting of community pharmacies, these BCTs were not deemed to be necessary in addition to previously selected BCTs.
	• Planning, implementation[b]	✓	Equivalent to 'Action planning'. Refer to 'Motivation and goals' domain above.
	• Prompt/triggers/cues[b]	✓	Equivalent to 'Prompts and cues'. Refer to 'Environmental context and resources' domain above.
Memory, attention and decision processes	• Self-monitoring[b]	✓	Equivalent to 'Self-monitoring (of behaviour)'. Refer to 'Beliefs about consequences' domain above.
	• Planning, implementation[b]	✓	Equivalent to 'Action planning'. Refer to 'Motivation and goals' domain above.
	• Prompts/trigger/cues[b]	✓	Equivalent to 'Prompts and cues'. Refer to 'Environmental context and resources' domain above.
Social influences	• Social support (unspecified)[a]/ Social processes of encouragement, pressure, support[b]	✓	Refer to 'Motivation and goals' domain above. *Note: these BCTs were deemed equivalent.*
	• Social comparison[a] • Vicarious reinforcement[a] • Identification of self as role model[a]	X	These BCTs are not applicable to the target audience as the behaviour is highly individualised based on the patients' own medications and medical conditions (Brown and Bussell, 2011).
	• Information about others approval[a] • Social reward[a]	X	Due the restricted time environment in the proposed setting of primary care, these BCTs were not deemed to be necessary in addition to the previously selected BCT—see above.
	• Social support (emotional)[a] • Social support (practical)[a]	X	These BCTs encapsulate aspects that are already covered by the previously selected BCT 'Social support (unspecified)'.
	• Restructuring the social environment[a]	X	It is beyond the scope of this project to restructure the social environment.
	• Modelling or demonstrating the behaviour[b]	X	This BCT would require significant and detailed preparation which would be difficult to achieve in the context of the current intervention which targets a heterogeneous patient group.
Nature of the behaviours	• None identified	N/A	This domain was not included in either reference source, therefore, no BCTs were mapped to this domain. This domain will be targeted indirectly using BCTs that were mapped to the other key domains (e.g. 'Prompts/cues' that mapped to 'Environmental context and resources').

3.5 Discussion

This chapter describes the findings from the systematic process that was undertaken to select components of a theory-based intervention to improve medication adherence in older adults prescribed polypharmacy. This study involved a detailed exploration of determinants of older adults' adherence behaviour as part of a focus group study, using TDF as the underpinning theoretical model of behaviour (Michie et al. 2005). Key theoretical domains that could be targeted in a CP-led intervention were then mapped to BCTs from an established taxonomy (BCTTv1) (Michie et al. 2008; Michie et al. 2013; Cane et al. 2015). The selected BCTs will form the proposed active components of an intervention.

3.5.1 Behavioural determinants and selection of key TDF domains to target

The focus group findings highlight the wide range of determinants perceived to be influencing older patients' adherence behaviour, as well as the challenge for researchers in selecting key domains to target as part of an intervention. Participants across all seven focus groups described their adherence behaviour as 'routine' and emphasised the importance of their own bespoke routines in facilitating adherence to multiple medications. Participants who lacked a routine, or encountered disruptions to their normal routine (e.g. during holidays), reported difficulties in taking their medication as prescribed. The importance of routine to patients' adherence behaviour is consistent with previous qualitative studies which, in contrast to the current study, were not underpinned by a theoretical framework of behaviour change (Tordoff et al. 2010a; Tordoff et al. 2010b; Sanders and Van Oss, 2013). As 'routine' was coded under the 'Nature of the behaviours' domain which has since been removed from the framework in TDF2, the focus group findings support our rationale for the selection of TDF1 as the underpinning model for the study (Michie et al. 2005). Based on the focus group findings, it was evident that the 'Nature of the behaviours' domain would need to be targeted, albeit indirectly, in an intervention to improve adherence to polypharmacy.

Both 'Environmental context and resources' and 'Social influences' were identified as key target domains for an intervention. Despite recommendations in the WHO's 2003 report that those attempting to change adherence behaviour should consider the impact of environmental and social factors on adherence, such factors are not always taken into consideration when designing adherence interventions (Sabate, 2003; Nieuwlaat et al. 2014). Although it is beyond the scope of this project to directly target some of the barriers identified under these domains, it is possible to provide alternative solutions to the issues identified. For example, to address a lack of access to medications at weekends when GP

surgeries are closed (domain: Environmental Context and resources) CPs could recommend strategies to remind patients to re-order medications in a timely manner (BCT: 'Prompts/cues').

Previous interventions targeting adherence have also rarely focused on setting goals that are important to patients (Bosworth et al. 2011; Allemann et al. 2016). This study identified a number of barriers and facilitators under the 'Motivation and goals' domain that are relevant to patients prescribed multiple medications (e.g. some patients placed higher importance on medicines they deemed more important, often to the detriment of other medications). It is important that appropriate treatment goals, relevant to patients, are discussed and jointly agreed between patients and HCPs. This will be achieved in the intervention by delivering goal-based BCTs [e.g. goal-setting (outcome), goal-setting (behaviour)].

Domains not selected for targeting

Four domains were not selected to target in an intervention because they did not contain barriers and facilitators that were considered as feasible to target within the available project resources and selected setting of community pharmacies ('Social/professional role and identity'; 'Emotion'; 'Skills'; 'Beliefs about capabilities').

Although the 'Social/professional role and identity' domain was considered to be relevant/important to the behaviour, participants reported awareness that the responsibility of medication use was their own and so this facilitator did not need to be enhanced further. Participants did indicate that this might change in the future should they become cognitively impaired. However, as this research did not seek to focus on patients with cognitive impairment, this domain was not selected as a key target for behaviour change. Non-adherent patients with cognitive impairment (e.g. with a diagnosis of dementia) would likely require an intervention of a different nature (e.g. enhanced practical support from carers).

In terms of the 'Beliefs about capabilities' domain the majority of patients believed that, provided they had no cognitive impairment, they had the psychological capability required to manage and take their medicines. Physical capability was discussed rarely by only a few participants in the context of medication packaging, and this linked to the 'Skills' and 'Environmental context and resources' domains. Patients discussed the physical skills involved in opening mediation packaging (manual dexterity) and swallowing oral dosage formulations, and this influenced participants' beliefs about their physical capabilities ('Beliefs about capabilities'). The findings in this study correlate with findings in the literature, for example, a study by Philbert et al. (2014) demonstrated that over a quarter (28.4%) of

older adults experienced difficulties opening packaging (e.g. removing tablets from blister packs). These are recognised issues that are important to consider in ensuring the appropriate use of polypharmacy in older adults (Hughes et al. 2016) but it was beyond the scope of the current project to improve patients' physical skills relating to manual dexterity or swallowing ability. Hence, the 'Skills' domain was not considered for intervention targeting. Instead, it was intended that the barriers identified under both the 'Skills' and 'Beliefs about capabilities' domains would be addressed indirectly by ensuring that appropriate types of formulations (e.g. liquids) and medication packaging (e.g. non-child resistant medication caps) were issued to patients where required ('Environmental context and resources'). Patients' cognitive ability, which could be seen as a psychological skill, was coded under the domain 'Memory, attention and decision processes' and patients' ability to organise their medications was coded under the domain 'Behavioural regulation' (i.e. action planning). Both of these domains were identified as key target domains for behaviour change.

In relation to the domain 'Emotion', participants' emotion (e.g. fear) generally stemmed from their' beliefs about the consequences of medication adherence or non-adherence. Targeting patients' emotions directly was considered to be beyond the scope of the current project as it would likely require extensive training of CPs and delivery of BCTs over a long period of time. It was also considered inappropriate to directly illicit negative emotions (e.g. anxiety/fear) in an attempt to improve adherence. By targeting the 'Beliefs about consequences' domain (e.g. using the BCT 'information on health consequences'), it is proposed that patients' emotions would be indirectly altered.

3.5.2 Selection of BCTs to include in an intervention

As outlined previously (Section 3.1), this study formed part of the development phase of the MRC framework in that it endeavoured to establish the theoretical underpinning for a novel complex intervention. In operationalising the MRC framework, practical implementation issues were also considered during initial BCT selection. As noted in the MRC framework, failure to consider these practicalities at an early stage can result in 'weaker interventions that are harder to evaluate, less likely to be implemented and less likely to be worth implementing' (Medical Research Council, 2008). Hence, the research team's decisions about whether or not to select a BCT for inclusion in the intervention were based on the applicability to the target group (i.e. older adults) and the expected feasibility of BCT delivery by CPs.

Throughout the decision-making process regarding BCT selection, the research team was also conscious of the time constraints in the primary care setting which have been well-publicised (George et al. 2010; Smith et al. 2010; Wallace et al. 2015). Drawing on knowledge of relevant literature that argues multifaceted interventions are not necessarily more effective in changing target behaviours than single component interventions, we aimed to keep the intervention as simple as possible (Squires et al. 2014). It was clear that inclusion of all 41 BCTs would make the intervention too complex and impossible to implement in the community pharmacy setting. Hence, it was beneficial if BCTs targeted multiple key domains and this was taken into consideration during the selection process. For example, the BCT 'Action planning' was selected instead of the BCT 'Graded tasks, starting with easy tasks', as the former targets three key domains ('Motivation and goals', 'Behavioural regulation' and 'Memory, attention and decision processes'), whereas the latter targets only one key domain ('Motivation and goals'). The BCT 'Threats' was considered to be an inappropriate and unethical method for attempting to change older adults' 'Beliefs about consequences' of adherence/non-adherence and was therefore excluded. This is because threats can evoke negative emotions which could be detrimental to the patient-HCP relationship. Conversely, the BCT 'Information about health consequences' was considered more appropriate for the target intervention recipients.

As discussed previously in Section 3.1, a number of BCTs in the two reference sources have similar names and overlapping characteristics (Michie et al. 2008; Cane et al. 2015). Therefore, to avoid potential duplication in the intervention, the research team considered these BCTs to be equivalent and opted for the most up-to-date terminology, as reported by Cane et al. (2015), thereby retaining the BCT labels proposed in BCTTv1 (Michie et al. 2013).

The 'Nature of the behaviours' domain was the only domain that did not map directly to any BCTs in either reference source (Michie et al. 2008; Cane et al. 2015). This is because this domain is considered to be distinct from the other domains, in that it represents the 'essential characteristics of the behaviour' (dependent variable), rather than a predictor of the behaviour (independent variable) (Cane et al. 2012). However, it is proposed that BCTs (e.g. 'Prompts/cues') selected to target other key domains (e.g. 'Memory, attention and decision processes') will influence the routine/habitual nature of patients' adherence behaviours and, hence, target the 'Nature of the behaviours' domain indirectly. Habits are defined in psychology as 'actions that are triggered automatically in response to contextual cues that have been associated with their performance' (Gardner et al. 2012). For example, getting into a car (cue), triggers the action of putting on the seatbelt. In the case of

medication-taking, other common routines, such as teeth brushing, morning coffee, may be recommended as cues to trigger medication-taking. Through associative learning, the repetition of this action over time will become habitual and part of the patient's daily routine (Lally et al. 2010).

3.5.3 Methodological advancements

While the TDF was originally developed to investigate the implementation of evidence-based practices by HCPs, it is increasingly being used to explore patient behaviours (Cahir et al. 2015; McCullough et al. 2015). This study contributes to the growing body of literature that is extending the application of the TDF in the development of patient-targeted behaviour change interventions. It also highlights the usability of the TDF as the underpinning theoretical model in focus group studies examining patient behaviours.

To date, only one study has documented the process of mapping from TDF domains to BCTs to include in patient-targeted interventions. McCullough et al. (2015) employed the original mapping matrix developed by Michie et al. (2008) to map TDF domains to BCTs in designing an intervention to improve adherence to treatments in bronchiectasis patients. The approach undertaken in the current study updates this process by using the most recent work by Cane et al. (2015) as the primary reference source (supplemented with the original mapping matrix to overcome identified limitations with the primary reference source). The current approach represents an advancement of the application of the TDF and BCTTv1 in the development of patient-targeted behaviour change interventions.

3.5.4 Study strengths and limitations

This study follows the latest WIDER guidelines by reporting on the BCTs that will be included in the intervention and the domains targeted by these (i.e. 'proposed causal processes') (Albrecht et al. 2013). The qualitative component of this study has also been reported in accordance with the COREQ checklist (see completed checklist in Appendix 3.8).

As a limitation of the study, it must be noted that focus group participants were self-selected and their level of adherence was not formally measured. Nonetheless, variation in the sample of participants was evident, ranging from those who reported no issues with adherence to those who reported frequent non-adherence behaviours. The inclusion of both adherent and non-adherent patients strengthens the findings by enabling the exploration of both facilitators and barriers to the target behaviour.

It must also be noted that the intervention development work is underpinned by a qualitative study. The qualitative findings were not validated in this study by conducting further quantitative research (e.g. a cross-sectional survey). At the time of this study, the majority of TDF-based studies had employed qualitative research methodologies (e.g. interviews) to explore the target behaviour and develop theory-based interventions (French et al. 2012; Cadogan et al. 2015). However, more recently, researchers have adopted a mixed methods approach (qualitative and quantitative) using the TDF, to overcome known limitations of qualitative methods (such as the limited generalisability of study findings) (Alqubaisi et al. 2016). Although the selected qualitative approach allowed for an in-depth exploration of the target behaviour, the findings are not readily generalisable to the wider population of older adults in primary care. However, the sampling strategy incorporated participants from both urban and rural areas from across the regions of NI which helps to increase the transferability of the focus group findings. Credibility of the qualitative findings was enhanced by giving a short oral summary of the key discussions to participants at the end of each focus group, which gave participants the opportunity to correct any misinterpretations. Dependability (i.e. qualitative equivalent of reliability in quantitative research) of the findings was increased by having the focus group transcripts independently coded by two researchers.

3.6 Conclusion

This chapter has outlined the systematic process that was undertaken to identify key domains (n=8) to target as part of an intervention to improve adherence to polypharmacy in older adults and to map these domains to BCTs (n=11) for inclusion in an intervention as the active ingredients. By making explicit links between the intervention components and key determinants of behaviour change, this will facilitate our understanding of how the intervention will exert its effect (Michie and Abraham, 2004). Specifying the intervention content in terms of BCTs from an established taxonomy will facilitate implementation of the intervention in future evaluations and, ultimately, into clinical practice, if the intervention is shown to be effective (Michie et al. 2013). Chapter 4 outlines how the selected BCTs have been incorporated into an intervention and delivered by CPs to older adults as part of a small-scale feasibility study at two community pharmacy sites.

Chapter 4

Design and feasibility testing of a theory-based intervention to improve medication adherence in older adults prescribed polypharmacy

4.1 Introduction

Following the systematic selection of intervention components (i.e. BCTs) using theory, the next stage is to operationalise each of these and combine them into an intervention package. Following this, the feasibility of delivering the intervention in clinical practice should be explored (Medical Research Council, 2008). Accordingly, the focus of the current chapter is on how the 11 BCTs identified in Chapter 3 were combined into a complex intervention package and tested in a small-scale feasibility study in the community pharmacy setting. As discussed in previous chapters, it was decided at the outset of the current project that any developed intervention would be delivered to older adults prescribed polypharmacy in the community pharmacy setting on an individual (i.e. one-to-one) basis. Individual delivery was deemed most suitable due to the heterogeneity of the target audience. A brief introduction to intervention design (including operationalising BCTs) and feasibility testing is provided below.

4.1.1 Intervention design

Once the overall mode of delivery for the intervention package has been decided (in this case face-to-face, on an individual basis), the next step is to consider the mode and/or format of delivery of each individual BCT. Potential modes of BCT delivery for an overall face-to-face intervention can include: verbal face-to-face delivery, printed materials (e.g. leaflets) delivered in-person or digital delivery (e.g. via a smartphone or wearable device) delivered initially in-person (by providing digital devices). Formats of BCT delivery can include: text/written information, images/pictures, videos or audio. Definitions for each BCT have been provided in BCTTv1 to assist in the selection of the most suitable mode(s)/format(s) of delivery (Michie et al. 2013). For example, the BCT 'Self-monitoring of the behaviour' is defined in BCTTv1 as, 'Establish a method for the person to monitor and record their behavior(s) as part of a behavior change strategy'.

Based on each BCT definition provided, potential modes/formats of delivery can be considered. For example, the BCT 'Self-monitoring of the behaviour' could be delivered via two modes: (1) using printed materials (e.g. providing patients with a written medication diary) or (2) providing patients with digital technology to use [e.g. a mobile telephone application (app) to record medication use each day]. Final decisions should be made based on the suitability of each mode/format to the selected setting, target audience and target behaviour (Michie et al. 2014a). The APEASE criteria has been introduced by Michie et al. (2014a) to help researchers decide on the overall mode of intervention delivery (e.g. face-to-

face on an individual or group basis; distance-based such as media broadcast) and also the mode/format of delivering each individual BCT. The six criteria in APEASE are outlined in Table 4.1 below.

Table 4.1: APEASE criteria for deciding on the most suitable mode/format for delivery of behaviour change techniques (BCTs) (Adapted from: Michie et al. 2014a)

APEASE criterion	Description
Affordability	Intervention designers should take into consideration any costs associated with designing and delivering the BCT using each proposed BCT delivery format/mode
Practicability	Intervention designers should take into consideration whether it is practical to design and deliver the BCT using each proposed format/mode
Effectiveness/cost-effectiveness	Where evidence is available, intervention designers should consider the effectiveness/cost-effectiveness of delivering the BCT using each proposed format/mode
Acceptability	Intervention designers should consider the likely acceptability of each proposed format/mode from the view point of intervention providers and recipients
Side effects/safety	Intervention designers should identify if there are likely to be any safety concerns or side effects from using each proposed BCT delivery format/mode
Equity	Intervention designers should consider whether the proposed modes/formats of BCT delivery will reach all participants or disadvantage certain groups

The APEASE criteria go beyond examining the likely effectiveness/cost-effectiveness of proposed modes/formats of delivery, and also consider how affordable and practical each option is likely to be. It also takes into consideration any potential safety concerns/side effects and potential reach of the intervention to disadvantaged groups. These are all important factors to consider when selecting how to deliver individual BCTs as part of a complex intervention package. For example, opting to deliver the BCT 'Self-monitoring of the behaviour' via a smartphone app may disadvantage older patients who do not own a smartphone, and it would be very costly to supply all patients with these.

After deciding on the most suitable modes/format(s) for BCT delivery, the next step is to develop any required supporting materials (e.g. paper-based record for self-monitoring of behaviour, leaflets etc.). An intervention manual and training package should also be developed to outline exactly how the intervention should be delivered; this helps to ensure consistency in delivery by intervention providers (Horner et al. 2006). To ensure that the interventions can be easily interpreted and replicated by others, the intervention content should be reported in detail in line with the TIDieR (Template for Intervention Description and Replication) guidelines (Hoffmann et al. 2014). Following the development of supporting intervention materials and piloting within the research group, the next stage recommended

in the MRC framework for complex interventions is to conduct feasibility testing with the target audience.

4.1.2 Feasibility testing

Feasibility testing is recommended by experts in trial methodology and also by funding bodies in advance of undertaking larger definitive trials (Medical Research Council, 2008; Thabane et al. 2010). As discussed in Chapter 1, feasibility studies do not seek to evaluate intervention effectiveness; instead their purpose is to determine whether the intervention can be delivered in practice or if modifications are required. A feasibility study also provides the opportunity to explore uncertainties with key study parameters (e.g. patient recruitment procedures) and optimise these in advance of future studies (Arain et al. 2010).

A feasibility study can be used to assess the following: usability/acceptability of the intervention; need for refinements to the mode/format or intervention materials; feasibility of study screening, recruitment and data collection procedures (a definition for 'Feasibility studies' can be found at http://www.nets.nihr.ac.uk/glossary).

Usability and acceptability of intervention

Gaining feedback from feasibility study participants (e.g. via questionnaires or qualitative interviews) can help researchers understand which intervention components are most useful and acceptable to providers and recipients and identify where improvements could be made. This information can then be used to refine the intervention mode/format of delivery and content prior to future testing (Arain et al. 2010).

Fidelity of intervention delivery

Feasibility studies also provide the opportunity to explore fidelity of intervention delivery (i.e. whether the intervention can be delivered as outlined in the intervention manual) (Michie et al. 2014a). Larger effect sizes have been reported where interventions have been implemented with high fidelity (Durlak and DuPre, 2008). Consequently, it is important that researchers attempt to improve fidelity at all stages of intervention development and testing. During the design phase, fidelity can be maximised by producing a detailed intervention training manual and intervention record (e.g. a booklet that guides each intervention appointment and includes space for recording notes) which can act as 'blueprints' for the intervention (Knittle, 2014). Although measuring fidelity is most useful in the latter stages of intervention testing (e.g. to help interpret the study outcomes in a large-scale RCT), measuring fidelity as part of early feasibility testing can help researchers optimise the

intervention design (Horner et al. 2006). Fidelity (of intervention delivery) can be measured via self-report, in-person observations or video or audio-recordings (Bellg et al. 2004; Breitenstein et al. 2010; Walton et al. 2017). Self-report methods (e.g. feedback interviews, provider-completed checklists) are less costly, less time-consuming and less intrusive than other methods, however, they are potentially limited by social desirability and recall bias (Breitenstein et al. 2010; Borrelli, 2011).

Feasibility of screening and recruitment procedures

Another key aspect of feasibility testing is in exploring important study procedures such as patient screening and recruitment. These procedures are critical to the success of a trial because a study that fails to recruit the required number of participants may not be adequately powered to detect differences between intervention and control groups (Treweek et al. 2013). As a result, clinically significant differences may be reported as non-significant, resulting in potential abandonment of an effective intervention.

Feasibility of data collection procedures

Feasibility testing also offers the opportunity to test important data collection procedures, such as proposed outcomes for a future RCT. A wide range of outcomes have been measured by studies that aim to examine the effectiveness of medication adherence interventions; these can be broadly divided into adherence outcomes and clinical/humanistic outcomes (Nieuwlaat et al. 2014).

As discussed previously (Chapter 1), direct measures of medication adherence (e.g. measurement of drug levels in blood) are expensive and not practical for research purposes. Consequently, indirect measures are often selected, such as self-report questionnaires, pill counts, electronic monitoring and measures calculated from dispensing data. It is recommended that at least two non-direct adherence measures are selected due to known limitations reported with individual approaches (Sabate, 2003).

Most adherence measures have been developed with a view towards measuring adherence to individual medications. Despite being of clinical importance, measurement of adherence to multiple medications (i.e. polypharmacy) has not been extensively studied and there is no guidance or consensus as to the best approach (Basak et al. 2014). Pednekar et al. (2016) sought to compare measures used to measure adherence to multiple medications. From the 151 articles that they identified, the main adherence measures employed included self-report questionnaires (most commonly the Morisky Medication Adherence Scale; MMAS) (n=81) and the use of dispensing data to calculate the MPR (n=25) and PDC (n=29).

In addition to adherence outcomes, it has been recommended that researchers should measure clinical/humanistic outcomes (Nieuwlaat et al. 2014). Examples of clinical outcomes commonly measured in adherence research include disease-specific outcomes (e.g. BP, blood glucose and cholesterol levels). HRQOL is an example of a humanistic outcome. As discussed previously (Chapter 2), generic clinical/humanistic outcome measures are more appropriate for the current study which focuses on patients prescribed polypharmacy to treat a range of potential medical conditions. Examples of generic outcomes include: HRQOL, GP visits, hospitalisations, mortality. Although HRQOL is deemed an important outcome for patients, it is not commonly measured when testing the effectiveness of adherence interventions (Nieuwlaat et al. 2014). There are a range of tools available to measure HRQOL, such as the EuroQol (EQ-5D-5L) and Short-Form (SF-36) surveys (McHorney et al. 1993; Ware et al. 1996; Herdman et al. 2011). The latest guidance from the UK body NICE indicates that the EQ-5D-5L is the preferred measurement tool for HRQOL (National Institute for Health and Care Excellence, 2013).

This current chapter outlines how the 11 BCTs identified from previous research (Chapter 3) were combined into an intervention package. This package was given the acronym: ID-MAP (IDentification of Medication Adherence Problems) intervention. The chapter also outlines the findings from a small-scale feasibility study that explored the feasibility of delivering the ID-MAP intervention in the community pharmacy setting, and the utility of key study parameters to inform future evaluations.

4.2 Aims and objectives

The overall aim of the study presented in this chapter was to design the ID-MAP intervention using the 11 BCTs identified in previous research (Chapter 3) and test the feasibility of delivering this intervention in the community pharmacy setting. The specific objectives were to:

- Operationalise each of the previously selected BCTs (n=11) and combine these into an intervention package
- Recruit and train community pharmacists at two sites to deliver the intervention to older patients prescribed polypharmacy (five patients per site)
- Test the usability and acceptability of the intervention from the viewpoint of both CPs and older patients
- Conduct a self-report assessment of fidelity to intervention delivery to help optimise the intervention

- Investigate the need for refinements to the content and mode of delivery of the intervention package
- Assess the feasibility of selected patient screening and recruitment procedures
- Assess the feasibility of collecting outcome data on medication adherence and HRQOL from older patients

To address these study objectives two sequential phases were undertaken: Phase 1- Intervention design, followed by Phase 2- feasibility testing. Both of these phases are outlined in the current chapter with the methodology and results from Phase 1 presented first (Sections 4.3 and 4.4), followed by the methodology and results from Phase 2 (Sections 4.5 and 4.6).

4.3 Phase 1-Intervention Design: Research methodology

4.3.1 Selection of format for the delivery of each BCT

The research team identified all potential modes/formats available for delivering the selected 11 BCTs as part of a face-to-face intervention delivered by CPs to patients (on a one-to-one basis) in the community pharmacy setting (e.g. verbal, written). The research team agreed on the most suitable mode/format(s) for each BCT using a consensus-based approach. Decisions were informed by considering whether each proposed mode/format for delivery of BCTs met the following APEASE criteria: 'Affordability', 'Practicability', 'Acceptability' and 'Equity' (see descriptions in Table 4.1 in Section 4.1). The 'effectiveness/cost-effectiveness' and 'safety/side effects' criteria from APEASE were not applied in this project due to the lack of strong evidence currently available on the effectiveness and safety of individual BCTs in relation to improving medication adherence in older adults. The 'Equity' criterion mostly relates to population-based interventions (e.g. the reach of media campaigns). However, where possible, 'Equity' considerations were identified and considered, for example, an electronic medication diary delivered via a mobile app may not reach those who lack access to a smartphone.

4.3.2 Tailoring BCTs: selection of 'Core' and 'Optional' BCTs

Findings from the previous chapter highlighted that older patients' reasons for non-adherence (to polypharmacy) were often individual and it would therefore be unnecessary and inappropriate to deliver all 11 BCTs to each patient. Hence the research team recognised the need for tailoring BCT delivery to each individual patients' needs. As there is currently no guidance on how to undertake this process, three members of the research team used a

group consensus approach to select BCTs that could be potentially useful for all patients (classified as 'Core' BCTs e.g. 'Self-monitoring of the behaviour') and BCTs that could be delivered based on an assessment of individual patients' needs (classified as 'Optional' BCTs e.g. 'Prompts and cues' for patients who reported forgetfulness). To be considered a 'Core' BCT, the BCT had to be potentially relevant to all patients irrespective of their underlying reasons for non-adherence (e.g. intentional and/or unintentional reasons). BCTs that were not considered to be relevant for all patients were classified as 'Optional' BCTs and delivered based on patients' needs. Decisions about the potential relevance of BCTs to all patients or only some patients were informed by findings from the qualitative focus groups with older patients (as outlined in Chapter 3). For example, a patient who reported non-adherence due to forgetfulness (unintentional non-adherence) would likely require different types of BCTs in comparison with a patient who reported non-adherence due to misinformed beliefs about medication side effects (intentional non-adherence).

4.3.3 Number and structure of intervention appointments

Following classification of BCTs as 'Core' or 'Optional', the next stage was to combine these into an intervention package for delivery in the community pharmacy setting. It was recognised that it would not be possible to deliver all of the required BCTs at one face-to-face appointment in this setting. For example, it would not be possible to deliver all goal-based BCTs at one appointment (e.g. the 'Core' BCT 'Review of behaviour goal' could only be delivered after a period of time from delivering the BCT 'Goal setting-behaviour'). The number of appointments was therefore decided based on: the minimum anticipated number of appointments required to deliver BCTs included in the intervention (minimum of 2), knowledge of the proposed setting and research team members' experience of developing similar interventions.

The structure of appointments, including the time period between appointments, was also determined, based on knowledge of the proposed setting and research team members' experience of developing similar interventions and working in this environment. For example, it was estimated that a maximum of 1-2 weeks would be sufficient to allow for any communication between CPs and GPs prior to delivering BCTs. It was deemed likely that CPs would be unfamiliar with the terms 'behaviour change technique' or 'BCT'. Consequently, to avoid confusion the 11 BCTs were grouped into four categories; these categories were termed 'adherence solution categories' (see Section 4.4.3 for further details of categories). This also helped to structure the delivery of the intervention.

4.3.4 Intervention materials

To support the delivery of BCTs, a range of intervention materials were developed. This included: an intervention record to record notes on the delivery of BCTs (adherence solutions), an adherence assessment tool to assist tailoring of 'Optional' BCTs (adherence solutions), supporting materials (e.g. leaflets to provide to patients), a paper-based intervention manual and a training package.

All intervention materials were developed based on: findings from the systematic review (Chapter 2) and other relevant literature, findings from the qualitative focus groups conducted with older patients (Chapter 3), research team members' experience of developing interventions for the target audience and knowledge of the selected setting. All intervention materials were reviewed extensively within the research team and piloted with three pharmacists (two of which were practising in the community setting at the time of the study) from within the Primary Care Research Group (QUB).

The training package was developed based on relevant literature and research team members' previous experience of providing similar intervention training for HCPs. The training consisted of a didactic presentation using Microsoft PowerPoint. To start the training session the following information was covered in the presentation: background information on the problem of non-adherence in older patients, the different types of non-adherence (e.g. intentional, unintentional) including examples, potential consequences of non-adherence, importance of the intervention and a summary of findings from the patient focus groups including illustrative quotes. Part of the training session focused on feasibility study procedures, such as screening and recruitment of patients and data collection (see Section 4.5). The remainder of the training session focused on delivery of the intervention and outlined how to deliver this in the context of the community pharmacy setting. This focussed on three main aspects: (1) How to identify adherence problems in older adults prescribed polypharmacy; (2) How to deliver tailored adherence solutions; (2) How to review adherence solutions. Step-by-step information was provided for each of these aspects and where possible, pictures of intervention materials were used to engage CPs. All of the information provided in the training package was covered in the paper-based intervention manual. CPs were encouraged to ask questions throughout the presentation to clarify and discuss any potential queries. The training session was piloted with the three pharmacists mentioned previously and estimated to take approximately 1.5 hours to deliver. Example patient scenarios were also developed by the researcher (DP) and reviewed among the research team. These examples were based on similar scenarios discussed by older patients who

participated in the patient focus groups (Chapter 3). The purpose of these examples was to illustrate the processes involved in delivering the intervention.

4.4 Phase 1-Intervention Design: Results

4.4.1 Selection of format for the delivery of each BCT

Based on the definition of each BCT provided in BCTTv1 and application of the subset of APEASE criteria ('Affordability', 'Practicability', 'Acceptability', and 'Equity'), an agreement on the final format for delivering each of the 11 BCTs was reached. The findings from this process are summarised in Table 4.2.

Table 4.2: Selected mode/format(s) for the delivery of each behaviour change technique (BCT) (including reasons for selection)

BCT	Definition from BCT Taxonomy Version 1 (BCCTTv1) (Michie et al. 2013)	Potential modes/formats for BCT delivery	Selected mode/format(s) for BCT delivery (including reasons)
Health consequences	'Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour'	**Option 1:** Verbal information provided by the pharmacist **Option 2:** Printed written information provided by the pharmacist	**Options 1 and 2** were both selected as these were considered practical to deliver in a time-restricted environment and also likely to be acceptable to patients. Generic written information could be pre-prepared (e.g. leaflets about importance of taking medications as prescribed). Both options were identified as low-cost. Selection of both options would also help avoid equity issues (e.g. low literacy levels).
Feedback on behaviour	'Monitor and provide information or evaluative feedback on performance of the behaviour (e.g. form, frequency, duration, intensity)'	**Option 1:** Verbal information provided by pharmacist **Option 2:** Printed written information provided by pharmacist	**Option 1** was selected as this was deemed most practical to deliver in a time-restricted environment and likely to be acceptable to providers/patients. It was identified as a low-cost format of delivery. Option 2 was not selected as it would be time-consuming to prepare written patient-specific information during the appointments. The selected option would also avoid any equity issues (e.g. low literacy levels).
Prompts/ Cues	'Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of the performance'	**Option 1:** Situational/visual prompts already in place (e.g. time, location) **Option 2:** Reminder stickers **Option 3:** Electronic (Reminder alarm clock/app/ Smartwatch)	**Options 1 and 2** were selected as these were deemed low-cost, practical to provide/recommend in the proposed setting and likely to be acceptable to participants. Option 3 was not selected due to the higher cost associated with providing such devices to patients and concerns over equity for, and acceptability to, older patients.
Self-monitoring of the behaviour	'Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy'	**Option 1:** Paper-based medication diary **Option 2** Electronic record (e.g. a mobile app)	**Option 1** was selected as it was low-cost, practical to provide/recommend and likely to be accepted by older patients. Option 2 was not selected due to the high cost (app design, provision of smartphones), user-training required, and concerns over equity.

Table 4.2 (cont'd): Selected mode/format(s) for the delivery of each behaviour change technique (BCT) (including reasons for selection)

BCT	Definition from BCT Taxonomy Version 1 (BCCTTv1) (Michie et al. 2013)	Potential modes/formats for BCT delivery	Selected mode/format(s) for BCT delivery (including reasons)
Restructuring the physical environment	'Change or advise to change the physical environment in order to facilitate performance or create barriers to the unwanted behaviours (other than prompts/cues, rewards and punishment)'	**Option 1:** Verbal instructions outlining change to be made by patient/pharmacist/ GP **Option 2:** Written instructions outlining change to be made	**Options 1 and 2** were selected to deliver each of these BCTs as both may be required, depending on the individual's circumstances. Both options were deemed to be low-cost (i.e. affordable), likely to be accepted by participants and practical to deliver in the community pharmacy setting. Selection of both options would also help avoid equity issues (e.g. low literacy levels).
Social support (unspecified)	'Advise on, arrange or provide social support (e.g. from friends, relatives, colleagues, 'buddies' or staff) or non-contingent praise or reward for performance of the behaviour. It includes encouragement and counselling but only when it is directed at the behaviour'	**Option 1:** Verbal instructions detailing social support plan **Option 2:** Written instructions detailing social support plan	
Goal setting-behaviour	'Set or agree a goal defined in terms of the behaviour to be achieved'	**Option 1:** Verbal discussion/agreement of behavioural goal(s) **Option 2:** Written record of agreed behavioural goal(s)	**Options 1 and 2** were selected to deliver all of these BCTs as a written record would aid their delivery. Both options were deemed to be low-cost, practical to deliver in the community setting and likely to be accepted by providers and recipients. Selection of both options would also help avoid equity issues (e.g. low literacy levels).
Review of behaviour goal	'Review behaviour goal(s) jointly with the person and consider modifying goal(s) or behaviour change strategy in light of achievement. This may lead to re-setting the same goal, a small change in that goal or setting a new goal instead of (or in addition to) the first, or no change.'	**Option 1:** Verbal discussion/review of behavioural goal(s) **Option 2**: Written record of review of behavioural goal(s)	
Goal setting-outcome	'Set or agree a goal defined in terms of a **positive** outcome of wanted behaviour'	**Option 1:** Verbal discussion/agreement of outcome goal(s) **Option 2**: Written record of outcome goal(s)	
Review of outcome goal	'Review outcome goal(s) jointly with the person and consider modifying goal(s) in light of achievement. This may lead to re-setting the same goal, a small change in that goal or setting a new goal instead of, on in addition to the first'	**Option 1:** Verbal discussion and review of the outcome goal(s) **Option 2:** Written record of review of outcome goal(s)	
Action planning	'Prompt detailed planning of performance of the behaviour (must include at least one of context, frequency, duration and intensity). Context may be environmental (physical or social) or internal (physical, emotional or cognitive'	**Option 1:** Verbal discussion and agreement of action plan **Option 2:** Written record of action plan provided to patient	

4.4.2. Tailoring BCTs: selection of 'Core' and 'Optional' BCTs

Five out of the 11 BCTs were selected as 'Core' BCTs as these were deemed relevant for all patients, irrespective of their underlying reason for non-adherence (see Table 4.3). The remaining six BCTs were classified as 'Optional' as they would not be relevant for all patients i.e. they could be delivered if required based on an assessment of each patient's underlying reasons for non-adherence (e.g. intentional non-adherence or unintentional forgetfulness) (See Table 4.4).

Table 4.3: 'Core' BCTs that were recommended for delivery to all patients

'Core' BCT	**Brief description**
Self-monitoring of the behaviour	A paper-based medication diary could be used by all patients to monitor and record their medication-taking behaviour.
Goal-setting (behaviour)	A goal that focuses on the behaviour to be achieved could be jointly set between each patient and pharmacist (e.g. to take their medication every night).
Review of behaviour goal	The 'behaviour goal' could be jointly reviewed by each patient and pharmacist.
Action planning	A detailed plan of how to perform the behaviour could be developed (e.g. including time and location).
Feedback on behaviour	Feedback on performance could be given to each patient based on a review of their medication diary.

Table 4.4: 'Optional' BCTs that were recommended for delivery only when deemed necessary by CPs based on an adherence assessment of underlying reasons for non-adherence

'Optional' BCT	**Brief description**
Health consequences	This BCT would be most beneficial for patients who are intentionally non-adherent. Information on the health consequences of adherence/non-adherence could be given to these patients.
Social support (unspecified)	Not all patients require additional social support and so this BCT could be delivered based on each patient's needs. A verbal (and/or written) plan for obtaining support from relevant individuals (e.g. family, HCPs) could be developed.
Prompts and cues	This BCT would be most beneficial for patients who are forgetful. An environmental or social stimulus that acts as a prompt or cue to the behaviour could be recommended/provided to these types of patients.
Restructuring the physical environment	This BCT would be most beneficial for patients who are non-adherent for practical reasons (e.g. related to medication packaging). A change in the physical environment could be recommended in these circumstances.
Goal setting (outcome)	These BCTs would be most beneficial for patients with low motivation. A goal that focuses on the positive outcome of performing the behaviour (e.g. reduction in symptoms) could be set jointly between the patient and pharmacist to try and improve motivation.
Review of behaviour goal	

4.4.3 Number and structure of intervention appointments

The intervention was separated into three face-to-face appointments that would be delivered in the community pharmacy by CPs. Most services currently offered in the community setting in NI are delivered over one or two appointments, such as the Medicine Use Review (MUR) service (Business Services Organisation, 2014) and the Managing Your Medicines (MYM) service (Business Services Organisation, 2010). These services are discussed in more detail in Chapter 5. A two appointment model was initially considered by the research team, because a number of the BCTs could only be delivered after a period of implementing another BCT. For example, the core BCT 'Feedback on behaviour' could only be delivered to all patients following a period of 'Self-monitoring of the behaviour' using a medication diary. However, following further discussions among the research team, an additional appointment was added to allow time to prepare any resources required to deliver BCTs (e.g. prepare the medication diary) and also time for communication between the CP and the patients' GP. Further details of the content of each of the three appointments are provided below.

The purpose of Appointment 1 was to identify the underlying nature of each patient's adherence problems using an adherence assessment tool (see Section 4.4.4 for further details). BCTs would then be delivered over Appointments 2 and 3 based on findings from the initial adherence assessment. Table 4.5 outlines the BCTs that were proposed for delivery at each of the three appointments.

Table 4.5: Behaviour change techniques (BCTs) delivered at each appointment in the community pharmacy

Appointment number	'Core' BCTs delivered during appointment to all patients	'Optional' BCTs delivered during appointment if deemed necessary based on adherence assessment
Appointment 1	Not applicable: assessment of underlying reasons for non-adherence using adherence assessment tool (ID-MAP Tool; see Section 4.4.4 for details)	
Appointment 2	• Self-monitoring of the behaviour • Goal-setting (behaviour) • Action planning	• Restructuring the physical environment • Prompt/cues • Social support (unspecified) • Health consequences • Goal setting (outcome)
Appointment 3	• Feedback on behaviour • Review of behaviour goal	• Review of outcome goal

It was proposed that the three appointments would take place over a five to eight week period. CPs were advised to schedule Appointment 2 one to two weeks after Appointment 1

to allow sufficient time to prepare any necessary resources and contact the patients GP if necessary. A final review appointment (Appointment 3) was then recommended after a period of at least four weeks to allow the patient time to implement any suggested changes (i.e. BCTs). At Appointment 3, CPs were asked to review suggested changes provided at the previous appointment (e.g. the medication diary). Figure 4.1 illustrates the recommended timeline for delivery of the intervention.

Figure 4.1: Timeline of appointments proposed for the ID-MAP intervention

As discussed in Section 4.3.3, to provide structure to the intervention and avoid the use of the term 'BCT', the 11 BCTs were separated into four adherence solution categories (A, B, C, D). The BCTs assigned to each category are outlined below in Figure 4.2. Solutions (and BCTs) highlighted in colour (shaded boxes) were recommended for delivery to all patients.

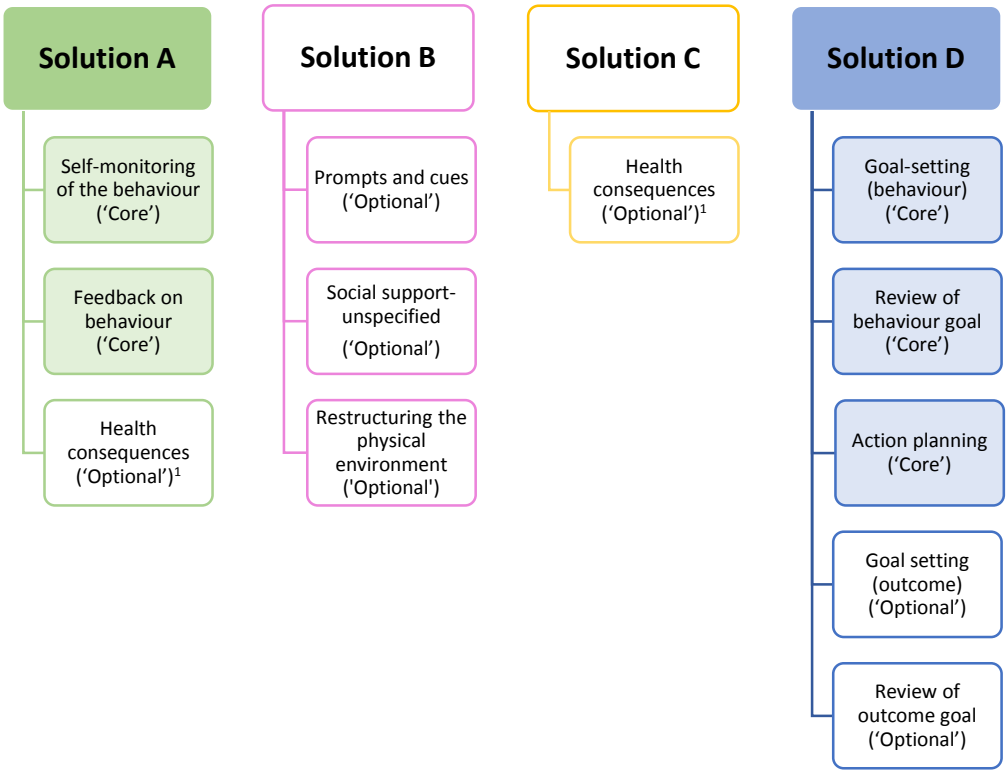


Figure 4.2: Structuring of 'Core' and 'Optional' BCTs into adherence solution categories
[1]The BCT 'Health consequences' was placed into two solution categories

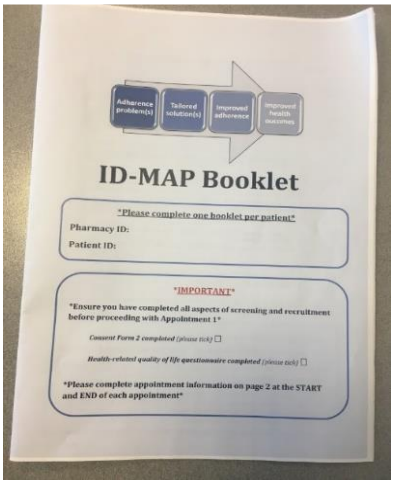
Findings from the previous study (Chapter 3) provided important contextual information that informed exactly how each of the selected BCTs was operationalised as part of the intervention package. For example, a number of patients reported receiving medication lists from secondary care which they found useful. Due to the large numbers of medications commonly prescribed to this group of patients, inclusion of a similar list as part of the medication diary (BCT 'Self-monitoring of the behaviour') was deemed important. Focus group participants also indicated places that they stored their medications as reminders which they found helpful. This informed the types of reminder strategies (BCT: prompts and cues) suggested, for example, placing medications in a visually prominent place such as on the kitchen bench.

4.4.4 Intervention materials

Intervention record (ID-MAP Booklet)

An intervention record (Image 4.1) for guiding each intervention appointment and making brief notes was developed by the research team (see Appendix 4.1 for full contents). The booklet contained four sections as detailed below in Box 4.1.

Image 4.1: Picture of Intervention record (ID-MAP Booklet)



Box 4.1: Sections of ID-MAP Booklet

Section 1: Space to record the patient's medication history in advance of Appointment 1

Section 2: Adherence assessment Tool (ID-MAP Tool; see below) for use at Appointment 1

Section 3: Space to record notes of adherence solutions (i.e. BCTs) delivered at Appointment 2

Section 4: Space to record notes following review of adherence solutions (i.e. BCTs) at Appointment 3

Adherence Assessment Tool (ID-MAP Tool)

An adherence assessment tool (ID-MAP Tool) was developed by the research team to assist CPs in selecting which 'Optional' BCTs should be delivered to each patient in addition to 'Core' BCTs. This tool was included in the intervention record (ID-MAP Booklet; see full contents in Appendix 4.1) and consisted of seven open style questions to identify the nature of adherence problems (i.e. underlying reasons for non-adherence). The questions were developed based on the findings from the previous qualitative research (Chapter 3). These

questions were designed to aid identification of adherence problems related to the following: knowledge of medications (Q1), routine or organisational barriers (Q2), practical barriers (Q3), level of social support (Q4), forgetfulness (Q5), intentional non-adherence (Q6) and level of motivation (Q7). CPs were advised to tick any relevant problems identified during discussions with the patient and then map these to potential adherence solutions. An example question from the ID-MAP Tool is shown in Figure 4.3.

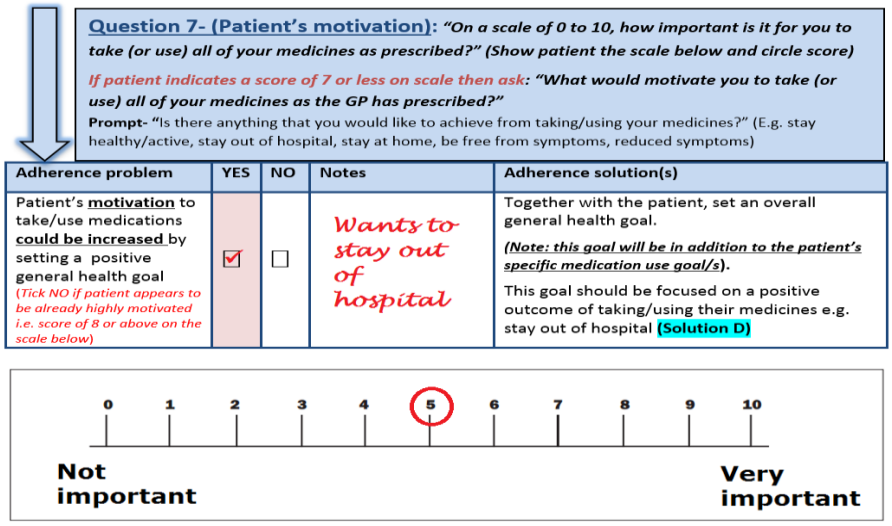


Figure 4.3: Example of a completed question from the adherence assessment tool (ID-MAP Tool)

Supporting materials

Other resources that were developed to assist CPs in delivering the BCTs are shown below in Image 4.2 and briefly described in Table 4.6.

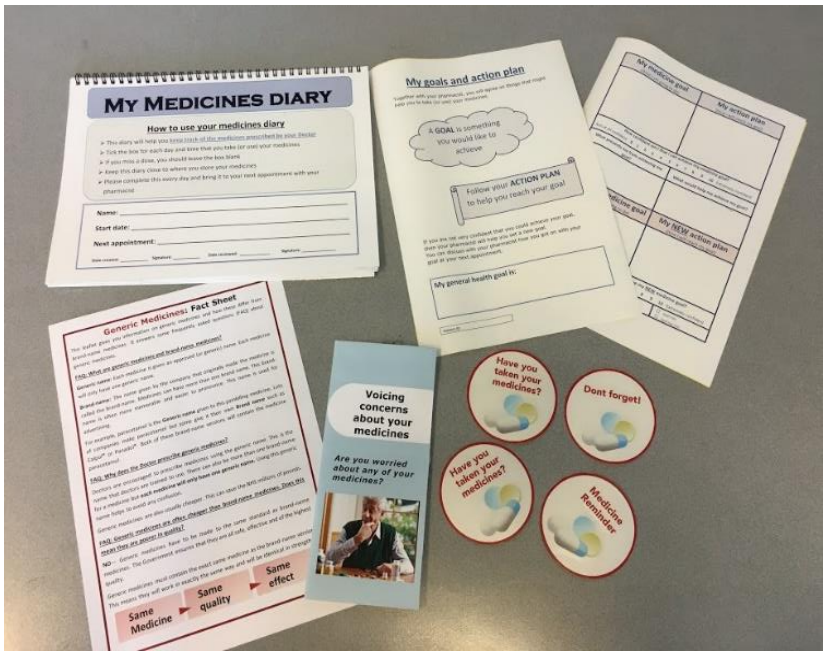


Image 4.2: Supporting materials for intervention delivery

Table 4.6: Materials developed by the research team to assist delivery of BCTs

BCT	Materials developed by research team to assist CPs in delivering the BCT(s)
Self-monitoring of the behaviour	Paper-based medication diary which included space for documenting a list of the patients' regular medications (Appendix 4.2).
Health consequences	Leaflets on 'voicing concerns about your medications' and 'generic medications' which could be used as discussion aids (Appendices 4.3 and 4.4)
Goal setting-behaviour Review of behaviour goal Goal setting-outcome Review of outcome goal Action planning	Goals and action plan activity sheets for CPs to document the patient's personalised goals and action plans on. These were duplicate pages so that the patient could be provided with a copy to take home and a copy could be retained by the pharmacist (Appendix 4.5)
Prompts and cues	Reminder stickers were developed to act as visual prompts (Appendix 4.6).
Restructuring the physical environment	A GP communication form was developed to allow CPs to communicate any recommended changes to the patient's GP (Appendix 4.7).
Feedback on behaviour Social support (unspecified)	Not applicable: verbal delivery only

Intervention manual and training package

An intervention manual (Appendix 4.8) was developed to support intervention delivery. The manual included content on how to: identify adherence problems, deliver/recommend adherence solutions (BCTs) and review adherence solutions (BCTs). The 26-page manual also covered training on study procedures, such as screening and recruitment procedures (see Section 4.5). An accompanying training package for CPs (Microsoft PowerPoint presentation and example patient scenarios) was also developed as discussed in Section 4.3.4 (Appendix 4.9).

4.5 Phase 2-Feasibility study: Research methodology

4.5.1 Overview of study design

CPs at two sites were recruited and trained to deliver the ID-MAP intervention to older patients who were prescribed polypharmacy (five patients per site). Following participation, both CPs and patients provided feedback on the usability and acceptability of the intervention during semi-structured qualitative interviews. In addition, supporting materials that were completed by CPs during the study period were returned to the research team for an assessment of fidelity to the intervention. Self-reported fidelity was also assessed by asking CPs (and patients) about the delivery (and receipt) of intervention components during the qualitative feedback interviews. Information on screening and recruitment was obtained

from CPs and outcome data (on medication adherence and HRQOL) were collected at baseline and three months follow-up to evaluate the feasibility of undertaking these key study procedures. Ethical approval for the study was granted by the ORECNI (Research Ethics Committee reference 16/NI/0028) (Appendix 4.10).

4.5.2 Recruitment of community pharmacists

Due to the small sample size required for this study, a convenience sampling approach was used to recruit CPs from two community pharmacy sites (a maximum of two CPs per site). A sample of CPs who were part of the undergraduate QUB Community Pharmacist Placement Network (used for undergraduate placement experience) were contacted with a letter of invitation (Appendix 4.11) and a study information sheet (Appendix 4.12). The researcher (DP) followed up with a telephone call, seven days after posting the invitation letter to allow CPs sufficient time to decide if they would be interested in participating in the study.

To be eligible to take part, community pharmacy sites needed to have a private consultation room/area and printing facilities. A meeting at the community pharmacy site was arranged with CPs who expressed interest in taking part in the study. During this meeting, the researcher provided an overview of the feasibility study and answered any questions. At this stage CPs were provided with written consent forms (Appendix 4.13) and pre-paid return envelopes for posting back to the research team. CPs (n=3) from the first two community pharmacies who agreed to participate in the study were recruited. CPs who took part (n=3) were provided a certificate of participation for their Continuing Professional Development record (Appendix 4.14). Each community pharmacy site was provided an honorarium of £200 as recognition of the time allocated to this study.

4.5.3 Training of community pharmacists

Once written informed consent was obtained from participating CPs, a date for face-to-face training sessions was arranged at each community pharmacy site. A short training session (approximately 1.5 hours) was delivered on-site using a PowerPoint presentation. As discussed in Section 4.3.4, the brief training session included an introduction to the research study, instructions on study procedures (e.g. screening and recruitment of patients), how to deliver the intervention (identify adherence problems, deliver adherence solutions, review adherence solutions) and make use of the intervention manual (Appendix 4.8). At this training session, CPs were given all of the documentation required to deliver the ID-MAP intervention, including supporting materials. CPs were also given an electronic and paper

version of the PowerPoint training presentation. As discussed in Section 4.3.4, two patient scenarios, of varying complexity (Appendix 4.9), were provided to CPs as illustrative examples. CPs were advised to contact the research team with any further questions about any aspect of the study procedures, delivery of the intervention or anything discussed during the training session.

4.5.4 Screening patients for eligibility

Upon successful completion of training, each participating CP was instructed to screen patients (who attended the community pharmacy in which they worked) using the inclusion and exclusion criteria outlined in Table 4.7.

Table 4.7: Patient inclusion and exclusion criteria for feasibility testing of the ID-MAP intervention

Inclusion criteria	Exclusion criteria
• 65 years or older • Prescribed ≥ four regular medications (polypharmacy)[1] • At least six months' dispensing data available on the pharmacy-held patient medication record (PMR), from the time of screening • Only attended study site pharmacy for regular medications • Lived in their own home • Had an identified adherence problem as detected by eligibility screening questionnaire (MMAS-8) (see below)	• Prescribed medications for the treatment/management of dementia[2] • Unable to provide written informed consent • High adherence identified from the eligibility screening questionnaire (MMAS-8) (see below) • Could not complete the eligibility screening questionnaire (MMAS-8) (see below)

[1]Excluding medications bought over-the-counter and short-term medications (prescribed for less than eight weeks e.g. antibiotics); [2]Acetyl cholinesterase inhibitors (donepezil, galantamine or rivastigmine) or an N-methyl-D-aspartate (NMDA) receptor antagonist (memantine)

CPs documented the patient's eligibility status on the Eligibility Screening Form provided (Appendix 4.15). Patients who were prescribed medications for the treatment of dementia were excluded from this study, as the intervention was not designed to account for the additional challenges faced by these patients. It was, however, recognised that dementia could be undiagnosed in this patient population group and CPs could have identified the need for further testing. A Standard Operating Procedure was therefore developed to account for such situations (Appendix 4.16) and CPs were provided information on this during training. In addition, a standard operating procedure for handling the situation where a participant became upset or distressed during the study was developed and covered during the CP training session (Appendix 4.17)

Patients were asked to provide written informed consent (Consent Form 1; Appendix 4.18) before completing the eligibility screening questionnaire (MMAS-8). The MMAS-8 (Appendix 4.19) was used as the eligibility screening questionnaire as it is a validated self-report measure of the patient's medication adherence (Morisky et al. 2008; Krousel-Wood et al. 2009; Morisky and Dimatteo, 2011). Permission for use of the MMAS-8 was granted by the developer (see signed licence contract in Appendix 4.20). This questionnaire contained seven 'yes or no' response questions and one question with five possible response options, where the patient was asked to select only one option. Based on the scoring system (provided by the developer) the patient was assigned a level of adherence: low (scored <6 out of 8), medium (scored 6 to 7.75 out of 8) or high (scored 8 out of 8). Patients with low and medium adherence were invited to take part in the study as these patients were deemed most likely to benefit from the intervention. Although patients with high adherence were not deemed eligible for this study, they were invited to ask their CP any questions they had about their medications at any time. Due to the tendency for patients to over-report adherence, this cut-off point of perfect adherence (score of 8) versus imperfect adherence (scores of less than 8) was used to dichotomise those who were adherent versus those who were non-adherent and select who to include in the intervention (Simoni et al. 2006; Stirratt et al. 2015).

4.5.5 Recruitment of patients

Following the initial screening process, CPs were asked to recruit patients into the study who met the eligibility criteria (see Table 4.7 in Section 4.5.4) (five patients per site). CPs were advised to briefly explain what the research study would involve and provide each patient with a study information sheet (Appendix 4.21) and study consent form (Consent Form 2) to read at home (Appendix 4.22). CPs were then advised to telephone patients one week later to allow the patient time to consider taking part. If a patient agreed to participate, the CP was required to document the date of verbal consent on the recruitment/retention form (Appendix 4.23). A date for Appointment 1 could then be scheduled at a time that was convenient for both the patient and the pharmacist. CPs were instructed to obtain written informed consent at the start of Appointment 1 (Consent Form 2; Appendix 4.22). CPs were advised to contact local GP practices to inform them that patients registered at their practice would be participating in the research study. A letter from the research team was prepared for pharmacists to provide to GPs if they wanted further information (Appendix 4.24). This briefly outlined the nature of the study and indicated that the CP may be in contact if any issues arose during the study that they deemed important to communicate.

4.5.6 Intervention delivery

As outlined in Section 4.4.3, it was proposed that the intervention should be delivered over three (30-40 minute) appointments over a period of five to seven weeks.

Appointment 1

In advance of Appointment 1, CPs were advised to obtain an up-to-date list of medications prescribed for the patient using the PMR. This list was to be documented in the intervention record (ID-MAP Booklet; one per patient). If necessary, CPs were advised to contact the patient's GP to confirm the definitive list of prescribed medications (e.g. where a potential prescribing issue was identified). When the patient arrived at the pharmacy, CPs were instructed to obtain consent for participating in the full research study (Consent Form 2; Appendix 4.22). Patients were then asked to complete a paper version of the EQ-5D-5L to measure their HRQOL (baseline) (Appendix 4.25). Permission for use of the EQ-5D-5L in the current study was granted by the EuroQol office (Appendix 4.26). The purpose of this was to assess the feasibility of collecting this type of data (see Section 4.5.7). The pharmacist then proceeded with the intervention and completed relevant sections of the ID-MAP Booklet. This included assessing the nature of the patient's adherence problems using the ID-MAP adherence assessment Tool. CPs were then advised to conclude the appointment and schedule a second appointment to take place in 1-2 weeks. If any adherence problems were identified that required immediate attention, CPs were asked to use their professional judgement and contact the patient's GP initially via telephone and then using the 'GP communication form' if required (Appendix 4.7). CPs were advised to inform the research team of such incidents as soon as possible.

Appointment 2

Identified adherence problems could then be mapped across to recommended adherence solutions using the ID-MAP Tool in advance of Appointment 2. As discussed previously, the BCTs were separated into four adherence solution categories (A, B, C and D) (see Figure 4.2 in Section 4.4.3). CPs were advised to deliver Solution A and Solution D to all patients as these categories contained 'Core' BCTs, suitable for delivery to all patients, irrespective of their underlying reasons for non-adherence. Solutions B and C were optional and could be delivered if deemed necessary based on the adherence assessment conducted at Appointment 1; these solutions contained only 'Optional' BCTs that would not be relevant for all patients. Table 4.8 provides examples of BCTs delivered during Appointment 2. 'Core' BCTs are highlighted in bold text.

Table 4.8: Examples of adherence solutions (BCTs) delivered at Appointment 2

Solution Category	BCT ('Core' or 'Optional')	Example of delivery
A	**Self-monitoring of the behaviour ('Core')**	**All patients should have been provided a medication diary to record daily medication use. This included a list of their regular prescribed medications (Appendix 4.2).**
	Health consequences ('Optional')	A patient who did not know why they were taking their BP medicine would have been educated on the reason why they needed to take it.
B	Social support (unspecified) ('Optional')	A patient's spouse could have become involved in helping the patient order and organise their medications.
	Prompts and cues ('Optional')	A patient who routinely forgot to take their bedtime medications could have been offered a reminder sticker to place on their bathroom mirror or advised to place their medication in a visually prominent place (e.g. on their bedside table) (Appendix 4.6).
	Restructuring the physical environment ('Optional')	A patient who had difficulties opening the medication packaging could have been provided with more appropriate packaging (e.g. non-child resistant bottle caps).
C	Health consequences ('Optional')	A patient who reported not taking their medication for the treatment of hypertension when on holiday would have been informed of the consequences of uncontrolled BP. Patient leaflets were designed to facilitate discussions around medication concerns (Appendices 4.3 and 4.4).
D	**Goal-setting (behaviour) ('Core')**	**A patient who routinely forgot to use their preventer asthma inhaler could have been prompted to set a medicine-related goal, such as 'Remember to use my preventer inhaler every day' (Appendix 4.5).**
	Action planning ('Core')	**A patient who reported forgetting to take their cholesterol medication at night could have developed the following action plan: 'IF I see my medication reminder sticker on the bathroom mirror, THEN I will take my cholesterol medication' (Appendix 4.5).**
	Goal setting (outcome) ('Optional')	A patient who reported having low motivation for taking medications as prescribed could have been prompted to set a goal that helped them to focus on the positive outcomes of correct medication use, such as a goal 'to stay out of hospital' (Appendix 4.5).

Key: = Solution A = Solution B = Solution C = Solution D

CPs were required to document any actions taken on the patient's intervention record (ID-MAP Booklet) and a final review appointment was arranged (at least 4 weeks later). Patients were advised to contact their CP if they experienced any difficulties with the resources/recommendations or if their medication regimen changed during the interim period.

Appointment 3

During Appointment 3, any adherence solutions that were used by the patient during the interim 4-5 week period (e.g. medication diary, behaviour goal) were to be reviewed by the pharmacist. Table 4.9 provides a summary of the BCTs delivered at Appointment 3. 'Core' BCTs are highlighted in bold text.

Table 4.9: Examples of adherence solutions (BCTs) delivered at Appointment 3

Solution Category	BCT ('Core' or 'Optional')	Example of delivery
A	**Feedback on behaviour ('Core')**	**A patient who routinely missed doses of medication on weekends could be given the following feedback: 'I see from your diary that you missed most of your doses at weekends'.**
D	**Review of behaviour goal ('Core')**	**Based on a review of the diary and discussions with the patient, the pharmacist should have judged if the patient met their medication-related goal that was set at Appointment 2.**
	Review of outcome goal ('Optional')	The pharmacist was advised to review the outcome goal set at Appointment 2 (e.g. 'to stay out of hospital') and check if this still motivated the patient to take medicines as prescribed.

Key: = Solution A = Solution D

CPs were asked to document brief notes from their discussions (and any further actions taken if required) in the ID-MAP Booklet. Patients were informed that this was the last official appointment of the study but they could seek advice in relation to their medications at any time in the future. Where completed medication diaries were returned, CPs were advised to retain these for the research team to examine.

4.5.7 Data collection and analysis

The primary outcomes that were of interest in this feasibility study were the usability and acceptability of the ID-MAP intervention from the view point of those delivering it (CPs) and those receiving it (patients). This was deemed essential to ensure the intervention would be practical for, and accepted by, the end-users, before moving onto larger evaluations. Secondary outcomes included addressing self-reported fidelity to the intervention, as well as testing the feasibility of key study parameters (e.g. screening procedures) that will be required as part of future evaluations to test the effectiveness of the intervention.

Primary outcome: Usability/acceptability of the intervention from the viewpoint of community pharmacists

CPs were interviewed following delivery of the intervention to their recruited patients using a semi-structured interview guide (Appendix 4.27). CPs were asked about their views on the following: training and support provided by the research team; the intervention manual and supporting materials; the structure and number of appointments; adherence solutions and general views on the intervention. The interviews were completed at the community pharmacy site (face-to-face), digitally recorded with the pharmacist's consent and transcribed verbatim. All identifiers were removed from the transcripts and each pharmacist was assigned a unique identifier (e.g. S01CP01 to indicate Site 01, Community Pharmacist 01). Data analysis consisted of reviewing transcripts for emerging themes and generating a descriptive overview of the feedback received.

Primary outcome: Usability/acceptability of the intervention from the viewpoint of patients

Patients were interviewed shortly after receiving the intervention (i.e. post-Appointment 3), using a semi-structured interview topic guide (Appendix 4.28). Patients were asked about their views on the following: structure and number of appointments; questions asked by the pharmacist during the adherence assessment; adherence solutions and materials provided by the pharmacist; support provided by the pharmacist and their overall experience of the intervention. The interviews were conducted via telephone, digitally recorded with the patient's consent and transcribed verbatim. All patient identifiers were removed and each patient was assigned a unique identifier (e.g. S01PT01 to indicate Site 01, Patient 01). Data analysis consisted of reviewing transcripts for emerging themes and generating a descriptive overview of the feedback received.

Secondary outcome: Feasibility of patient screening and recruitment procedures

CPs were asked to record information for all patients who were approached during the study, including details of their eligibility status, recruitment status and reasons for drop-out (if appropriate). At the end of the study, CPs provided the research team with this data by completing a 'Summary of patients' form (Appendix 4.29). These data were used to calculate a refusal rate (i.e. number of patients who refused on initial approach out of the total number approached), eligibility rate (i.e. number of eligible patients out of the number of patients fully screened), recruitment rate (i.e. number of patients recruited out of the number of eligible patients) and retention rate (i.e. number of patients who completed the study out of the number who were recruited). Eligibility screening and recruitment/retention forms

(Appendices 4.15 and 4.23) were also examined for their completeness to help identify any problems associated with these procedures. CPs and patients provided feedback about screening and recruitment procedures in the qualitative interviews. This information was used to assess the feasibility of these procedures and identify where changes needed to made.

Secondary outcome: Fidelity of intervention delivery

The aim of the fidelity assessment at this stage in the research process was solely to help identify any obvious teething issues with implementing the intervention. Consequently, self-report methods (i.e. checklists completed by intervention providers, notes made in intervention records and interviews with participants) were deemed sufficient. Although objective measures of fidelity (e.g. audio or video recordings) could have provided more in-depth information, these were not selected at this early stage of testing as it would have required additional resources (audio recorders for each site) and time (e.g. transcription of each intervention appointment) and would have been an unnecessary burden on research participants.

All intervention materials were returned to the research team upon completion of the study. This included intervention records (ID-MAP Booklets) that were completed for each patient. These booklets contained written notes on what was delivered to patients and checklists at the end of each appointment to indicate that adherence solutions (i.e. BCTs) had been delivered. All returned booklets and supporting materials were examined for completeness and any omissions or reporting errors were noted.

CPs and patients were asked about the delivery and receipt of adherence solutions (i.e. BCTs) during the qualitative interviews (see primary outcomes above). This self-reported information was triangulated with information obtained from the review of completed intervention materials. The triangulated information was used to assess whether BCTs were delivered with high fidelity, low fidelity or unclear fidelity. A BCT was deemed to have been delivered with high fidelity if there was sufficient evidence available from written intervention materials and/or qualitative feedback from patients and CPs to support this. Where evidence (from the above sources) indicated that the BCT was not delivered as intended (i.e. as outlined in the intervention manual), this was deemed to have been delivered with low fidelity. If insufficient evidence was available (from the above resources) to make a judgement, then the level of fidelity was deemed to be unclear.

Secondary outcome: Feasibility of measuring adherence to polypharmacy using a validated self-report measure

Patients were asked to complete the MMAS-8 as part of the eligibility screening process (as discussed in Section 4.4.5) in-person in the community pharmacy; this also acted as a baseline measure of self-reported medication adherence. For the three month follow-up, the MMAS-8 was mailed to patients along with the EQ-5D-5L questionnaire (see later), a covering letter and a pre-paid return envelope. The feasibility of using the MMAS-8, to measure self-reported adherence to polypharmacy in older adults was assessed as part of this study.

Secondary outcome: Feasibility of calculating objective measures of adherence to polypharmacy from dispensing data

As discussed previously, self-reported measures of medication adherence have known limitations and should therefore be supplemented with more objective measures of adherence (Horne et al. 2005). PDC and MPR measures (which can be calculated using dispensing data) were identified as the two most commonly used objective measures of adherence to multiple medications (Pednekar et al. 2016). As it was unclear in the literature which established method was most suitable, both measures were calculated and compared (Andrade et al. 2006; Choudry et al 2009; Murphy et al. 2012; Arnet et al. 2014).

Using the pharmacy dispensing software, CPs generated printouts of all medications dispensed in the six months prior to intervention delivery (i.e. pre-Appointment 1) and three months following intervention delivery (i.e. post-Appointment 3) for each patient who completed the study. This included the following information: medication name, strength and form; directions for use; quantity of medication supplied and date of dispensing. Where possible, this information was used to calculate a pre- and post-intervention MPR and PDC for each patient using the methods described in Boxes 4.2 and 4.3 respectively.

Box 4.2: The method used for calculating MPR

The MPR was calculated using the following five steps:

Step 1: The measurement period was defined (i.e. number of days between date of first and last refills in the six months pre- or three months post-intervention).

Step 2: The number of days' supply obtained during the measurement period (minus the days' supply of the last refill in period) was calculated for a given medication.

Step 3: The number of days' supply of a given medication in the measurement period (**Step 2**) was divided by the total number of days in the measurement period (**Step 1**). This was multiplied by 100 to obtain a percentage MPR for a given medication (this value was capped at 100%). See the equation below.

$$\textbf{MPR (\%)} = \frac{\text{Total number of days' supply obtained during the measurement period}}{\text{Number of days in measurement period}} \times 100$$

Step 4: Steps 1-3 were repeated for each regular[1] medication the patient was prescribed and an average MPR will be calculated.

Step 5: Patients with an av. MPR of >80% were considered adherent to polypharmacy.

[1]Due to the short time frames in this study, a regular medication was defined as a medication that is commonly used in the treatment of LTCs and was prescribed (i.e. dispensed) for 8 weeks (56 days) or longer

Box 4.3: Method used for calculating PDC

The PDC was calculated using the following four steps:

Step 1: The measurement period was defined (i.e. number of days between date of first and last refills in the six months pre- or three months post-intervention).

Step 2: The number of days that the patient was 'covered'[1] by all regular medications in the measurement period was calculated. If the patient refilled early and there was a period of overlap, then the prescription start date for the early refill was adjusted to the day after the previous refill had ended.

Step 3: The number of days covered by all regular medications[2] in the measurement period (**Step 2**) was divided by the total number of days in the measurement period (**Step 1**)**.** This was multiplied by 100 to obtain a percentage PDC for all medications. See the equation below.

$$\textbf{PDC (\%) =} \frac{\text{Number of days 'covered' by all medications in the measurement period}}{\text{Total number of days in the measurement period}} \times 100$$

Step 4: Patients with a PDC of >80% were considered adherent to polypharmacy.

[1]A day was only considered covered if a supply of all medications to treat long-term conditions was available on that day; [2]Due to the short time frames in this study, a regular medication was defined as a medication that is commonly used in the treatment of LTCs and was prescribed (i.e. dispensed) for 8 weeks (56 days) or longer

The following medications were excluded from calculations: short-term medications (prescribed for less than 8 weeks during the six months pre-intervention and/or 3 months post-intervention such as antibiotic tablets, antibiotic creams), when-required medications (e.g. short-acting beta-agonist reliever inhalers), liquid medications and medications with variable dosing instructions (e.g. take one or two tablets daily). MPR and PDC calculations required a minimum of two refills in the study period to be calculated (i.e. in the six months pre-intervention or three months post-intervention). The feasibility of collecting baseline and three month follow-up pharmacy dispensing data, and the subsequent use of these data to calculate pre- and post-intervention MPR and PDC for each patient was assessed as part of this study.

Secondary outcome: Feasibility of measuring health-related quality of life using a validated measure

HRQOL was measured in-person at baseline using the EQ-5D-5L (beginning of Appointment 1) and at three months follow-up (i.e. post-Appointment 3) using a postal questionnaire (along with the MMAS-8 questionnaire, a cover letter and freepost return envelope). The EQ-5D-5L (Appendix 4.25) was selected because it is an internationally recognised generic self-report measure of HRQOL that has been validated for use in the UK and Ireland across a wide range of patient populations (e.g. CVD, arthritis, diabetes). It has also been recommended as the tool of choice by NICE (National Institute for Health and Care Excellence, 2013). The updated EQ-5D-5L has retained the dimensions of the earlier version (EQ-5D-3L) but has improved sensitivity and greater reliability (Janssen et al. 2013). The questionnaire contained five statements about mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Patients were instructed to select one of five options for each statement. These descriptive responses were then converted into an index value (van Hout et al. 2012). A Visual Analogue Scale (VAS) was also included in which the patient was asked to rate how good their own health state was on that day, on a scale of 0 to 100. The feasibility of using the EQ-5D-5L questionnaire to measure HRQOL, in older patients prescribed polypharmacy, was assessed as part of this study.

4.6 Phase 2-Feasibility study: Results

CPs at two community pharmacy sites were recruited into the study. Three CPs were involved in the study in total (one pharmacist at Site 01 and two CPs at Site 02). Both sites had several CPs (two or more) on duty during the working week, except on Saturdays. Characteristics of CP participants are presented below in Table 4.10

Table 4.10: Characteristics of community pharmacist participants

Participant ID	Number of years qualified	Current position in community pharmacy	Number of years in current position	Type of community pharmacy
S01CP01	3 years	Support pharmacist	2 years	Independently owned
S02CP01	21 years	Pharmacy manager	4 years	Small/medium chain (2-9 stores)
S02CP02	20 years	Support pharmacist	14 years	Small/medium chain (2-9 stores)

Each pharmacy site recruited five patients into the study. One patient dropped out of the study (from Site 01) after attending the first intervention appointment and was not replaced. The CP indicated that the reason for drop out was due to concerns over confidentiality of his personal details, particularly in relation to the HRQOL questionnaire and his welfare payments (see Section 4.6.7). Table 4.11 provides further details of the numbers of patients who were approached, screened and recruited into the study.

Table 4.11: Information on screening and recruitment of patient participants

	Site 01	Site 02	Total
Total number of patients approached	17	7	24
Number of patients who refused on initial approach	4	0	4
Number of patients who underwent full screening process	13	7	20
Number of ineligible patients (high adherence)[1]	8	2	10
Number of eligible patients	5	5	10
Number of patients recruited	5	5	10
Number of patients who dropped out	1	0	1
Number of patients who completed the study	4	5	9
Refusal rate[2] (%)	23.5	0	16.7
Eligibility rate[3] (%)	38.5	71.4	50
Recruitment rate[4] (%)	100	100	100
Retention rate[5] (%)	80	100	90

[1]Identified using eligibility screening questionnaire (MMAS-8); [2]Number of patients who refused on initial approach out of the total number approached; [3]Number of patients who were eligible out of the number of patients who were fully screened; [4]Number of patients who were recruited out of the number of eligible patients; [5]Number of patients who completed the study out of the number who were recruited

CPs at Site 02 delivered the content of Appointment 1 and Appointment 2 together in one longer appointment to their five patients (i.e. patients attended the pharmacy on two occasions instead of three). CPs indicated that two appointments were sufficient for the

patients they identified and this reduced number of appointments would help to keep patients engaged with the intervention. One patient at Site 02 could not attend the pharmacy for her final follow-up appointment and so this was conducted over the telephone. The pharmacist at Site 01 delivered the intervention over three appointments as intended. The appointments were delivered over five to eight weeks at Site 01 and over five to 12 weeks at Site 02.

The CP at Site 01 recorded the exact duration of each appointment by noting the exact start time and finish time to the nearest minute on the intervention record (ID-MAP booklet). At Site 01 Appointment 1 for patients ranged from 26 to 47 minutes, Appointment 2 ranged from 15 to 35 minutes and Appointment 3 ranged from 10 to 33 minutes. CPs at Site 2 did not accurately record the duration of each appointment (start and finish times for each appointment were either missing from the intervention record or had been rounded up to the nearest 15 minutes). However, they estimated that each initial appointment (equivalent to Appointments 1 and 2) lasted one hour per participant and each final appointment (equivalent to Appointment 3) lasted less than half an hour.

Five males and four females completed the study. Participants were aged 65 years or older (ranging from 66 to 88 years) and were prescribed four or more regular medications (ranging from 4 to 13 regular medications). Characteristics of patient participants who completed the study are shown below in Table 4.12.

Table 4.12: Characteristics of patients who completed the study

Participant ID	Age	Sex	Number of regular prescribed medications[1]	Number of appointments with pharmacist
S01PT01	69	Male	9	Three
S01PT03	68	Male	4	Three
S01PT08	88	Male	5	Three
S01PT13	66	Male	12	Three
S02PT02	80	Female	8	Two[2]
S02PT03	73	Female	13	Two[2]
S02PT04	69	Female	9	Two[2,3]
S02PT06	77	Female	9	Two[2]
S02PT07	73	Male	11	Two[2]

[1]Excluding short-term medications (prescribed for less than 8 weeks e.g. antibiotics, vitamins) and over-the-counter medications; [2]Appointment 1 and 2 combined by study CPs for these patients; [3]Follow-up appointment conducted via telephone

4.6.1 Usability/acceptability of the intervention from the viewpoint of community pharmacists

Overall, CPs reported that the ID-MAP intervention (and training package) was useful/acceptable and therefore feasible to deliver in the community pharmacy setting, although some modifications were proposed to enhance this. In summary, CPs indicated that the number of appointments should be tailored to each patient and suggested that goal-based solutions were not necessary for all patients. CPs found the medication diary the most useful adherence solution and indicated that this alone was sufficient for some patients. Further details of feedback from CPs are provided below along with illustrative quotes.

Training and support provided by the research team

CPs were satisfied with the level of support and communication they received throughout the study from the research team. CPs found the on-site training session comprehensive and beneficial and particularly found the example patient scenarios useful.

> *"I thought it was very good, it was very involved and it covered all the, the main parts and em, it was very informative…"* (S02CP01)

> *"…the training material I received in terms of the em, the mock, eh, patient packs, em, I found really beneficial especially with my first couple of patients…"* (S01CP01)

However, CPs indicated that their confidence was low at the beginning of the study and thought that the opportunity to role-play the scenarios would improve this.

> *"I think it's like everything, once you do one, the second one's a lot easier so you just might be a wee bit apprehensive about doing the first one."* (S02CP02)

> *"I'd think I'd maybe like to maybe role play it, you know, would, would have been, you know, I think would have been good."* (S02CP01)

Intervention manual and ID-MAP Booklets

The intervention manual was described as user-friendly and CPs particularly liked the variety of colour, layout and use of flowcharts throughout.

> *"…the training manual, em, I thought were really good, they were very well laid out. And, eh, it made me– left me feeling that I had all the information I needed…"* (S01CP01)

> *"I thought the flow charts were very good, so it was very easy to follow." (S02CP02)*

The ID-MAP Booklet was seen as a useful tool for guiding the appointments and recording notes. A few suggestions were made in relation to the format and sequencing of questions.

> *"I thought was fantastic really. It really, really helped with, eh, taking notes and everything else and em, I knew exactly what I was meant to be doing…"* (S01CP01)

Although CPs found the paper version of the ID-MAP Booklets useful, they expressed positive views towards an electronic version due to the large volume of paperwork.

> "*...if there was finance available for an IT sort of, em, you know, sort of thing…. I think that would maybe be an improvement…"* (S02CP01)

> *"Yeah that* [an electronic version of ID-MAP Booklet] *would be fantastic actually that's, that's a good idea … 'cause as I said there was so much paperwork… that would be a fantastic way to do it…"* (S01CP01)

Structure and duration of appointments

CPs at Site 02 reduced the number of appointments from three to two indicating that three appointments were not necessary for the patients they identified. Although the pharmacist at Site 01 delivered the intervention over three appointments as intended, he also indicated that Appointments 1 and 2 could be combined. Nonetheless, CPs recognised that more appointments may be necessary in particular circumstances and so this should be tailored to each patient's circumstances.

> *"Oh three appointments yes aye. That, that was what we sort of, em, felt was a bit too much, you know, so we actually had our Appointments 1 and 2 at the same time and then bring people back…"* (S02CP01)

> *"I thought… em, you could perhaps put, em, Appointment 1 and 2 together… 'cause the… workbook is laid out so well… you can map across to the, to the intervention really, really easily."* (S01CP01)

Delivery of compulsory adherence Solution A (medication diary)

CPs expressed positive views about the medication diary and indicated that they received positive feedback from patients.

> *"I thought the diary was absolutely fantastic. I thought it was a great idea, thought it was really well laid out. Em, the feedback I got from patients, from all of them was extremely positive."* (S01CP01)

> *"Brilliant. Loved it. I think everybody should have one. Everybody really loved the diary; that was the best thing… everybody wanted to keep their diaries." (S02CP02)*

One CP reported receiving feedback from a patient suggesting modifications to improve the usability of the medication diary. CPs also reported using the medication diary to assist patients with reordering medications or monitoring their symptoms.

> *"…somebody said it's a pity, you know, if they'd something just to hook it on, just to the wall…"* (S02CP01)

CPs at both sites also indicated that they provided additional medication diaries to those who wished to continue with this adherence solution. They thought that it should be a long-term solution that is recommended to all non-adherent older patients. However, one pharmacist thought that a list of medications may be sufficient for some patients.

> *"I think longer term. Short term… it really worked but what I found people who were actually finished the study, when they gave back the diary were asking me if they could get another one because they wanted to keep one all the time."* (S01CP01)

> *"I don't think everybody needs this, sort of, format* [full diary]… *because it might be sufficient just to follow that* (medication list at back of diary)." (S02CP01)

CPs did report reviewing the medication diary when asked about this but answers provided were often vague.

> *"I just checked to see where they, had they adhered to whatever and had they filled it in and they liked it and they were very happy with it."* (S02CP02)

> *"…if there were missed doses then, then we'd have chatted maybe about it but I think some patients that had maybe said, 'Oh no I did take me tablets then but I didn't record it on here'."* (S02CP01)

Delivery of optional adherence solutions (Solutions B and C)

Optional adherence solutions (Solutions B and C) were provided less frequently to patients as these were deemed unnecessary using the ID-MAP tool. Reminder strategies (BCT: prompts/cues) were suggested most frequently (e.g. reminder stickers or visual placement of medications) but the effectiveness of such solutions was seen as mixed.

> *"I think most of the patients, maybe it was just a case of trying to say look have their medication beside them at the table with their breakfast and* [that] *worked well"* (S02CP01)

> *"…the two people that took the stickers found that, em, at least for the first few weeks, they were useful as reminders but then they, sort of— I think they'd stopped paying attention to them."* (S01CP01)

Concerns about medications were only reported by one patient in the study and the CP did not think it was necessary to provide the suggested leaflet on this occasion.

> *"… there was one gentleman was concerned… I didn't have to give him a leaflet or anything like that but what I did do was just sat him down and talked him through it for about 10 or 15 minutes"* (S01CP01)

CPs indicated that the adherence solutions they did not provide (e.g. 'generic medications' leaflet) might be beneficial for other patients under different circumstances in the future and should not be discarded from the intervention. CPs did not recommend the addition of any solutions to the intervention package.

> *"…there are people who are not compliant because, you know, maybe they have concerns about their medication. Em, so it is good to have that but, you know, em, I wouldn't remove it just in case…"* (S02CP01)

> *"I think you know, everything was, sort of, covered like, em, there was nothing that, no there was nothing missing so there wasn't"* (S02CP01)

Although the ID-MAP Tool acted as the main guide for choosing adherence solutions, CPs reported involving patients in the decision making process.

> *"…I didn't mind really what they did but as long as they had some, sort of, system that worked well for them and they came up with it themselves."* (S02CP01)

> *"Well I would probably have went through the options and then I think– the best thing, they seemed happier with the diary."* (S02CP02)

Delivery of compulsory adherence Solution D (Goals and action plan activity)

One pharmacist thought the 'Goals and action plan' activity might be more effective for younger patients or those with lower levels of motivation. All CPs indicated that this should be an optional adherence solution.

> *"…for some of the elderly people or whatever I'm just not sure… if you just say 'Look, this is how you go about, just take it', they were happy enough with that so I don't know whether it really… it, it helped some of the people…"* (S02CP01)

> *"…I don't know if all patients would be up for it… you could say, 'Would you like to do this maybe or as part of the project? This is an option that you could do.' and see if they'd be up for it."* (S02CP02)

CPs indicated that patients expressed some reluctance in relation to the goals and action plan activity and suggested that patients may not have understood its purpose. One pharmacist suggested modifications to the written sheet to reduce the complexity of this.

> *"I didn't think they quite copped on to why I was, why I was, why we were setting a goal."* (S01CP01)

> *"…when they saw they sheet, it's quite, it's quite busy and then when they were looking at it I think they were quite like, sort of, taken aback and okay this seems pretty complicated…"* (S01CP01)

Overall experience, feasibility and future implementation of intervention

Overall, CPs reported that their experience of taking part in the study was highly positive and that patients obtained benefits from the delivery of the intervention. The most positive aspects were time spent interacting with patients and providing the medication diary.

> *"I thought it was nice to help somebody and to actually make a difference and… actually something's worked for somebody and even giving the diary home with them and they used it and they came back. I thought it was beneficial."* (S02CP02)

CPs felt that they were the most appropriate HCP to deliver this type of intervention due to their accessibility and frequency of contact with patients. CPs reported that it would be feasible to implement the intervention in their own practice provided there was forward planning and funding available.

> *"I definitely think there's no reason why it shouldn't– it couldn't be implemented in everyday practice but em… I think it just would require a bit more forward, forward thinking from, from the pharmacy's point of view"* (S01CP01)

One pharmacist indicated that the intervention could be an extension to existing services.

> *"… I think ideally if you could use this as part of your, your MUR* [Medicines Use Review service]*, like a bigger MUR or your medicines management* [Managing Your Medicines service]*".* (S02CP02)

The only reported barrier to implementation was having only one pharmacist working in the pharmacy. If the intervention was to be rolled out as a service in the community pharmacy setting, advertisement was seen as a potential facilitator of implementation.

> *"Obviously, every community pharmacy's different and it depends on your level of cover. If you're the only pharmacist on it isn't going to be feasible but there's very little's going to be feasible, MURs aren't feasible and, and everything else isn't…"* (S01CP01)

> *"…advertising I think so that patients would know that if they need help that's where they could go and there is something available there to help them…"* (S02CP02)

4.6.2 Usability and acceptability of the intervention from the view point of patients

Overall, patients reported very high levels of satisfaction with the intervention they received from their CP, with all patients reporting that they would recommend the intervention to others. Only minor modifications were suggested to improve the acceptability of the intervention, such as making the goal-based adherence solution optional. Patients were highly satisfied with the medication diary they all received and reported that this self-monitoring activity increased awareness of their behaviour and led to improvements in adherence. Further details of feedback from patients are provided below along with illustrative quotes.

Patients' views on the structure and duration of intervention

All patients reported satisfaction with the number and structure of appointments that they were invited to attend in their community pharmacy.

> *"…none of the meetings were in any way too long or—… No I thought… they were all very useful and em, doable."* (S01PT01)

> *"You weren't just going one week and then the same time next week and all that so the appointment system was very, very good so it was, to give you time."* (S02PT04)

The majority of patients reported no issues with the length of appointments, however two patients (from the site which combined Appointments 1 and 2) reported that the first appointment they attended was quite lengthy.

> *"Well the length of it* [Appointment 1 and 2 combined], *you know, at the beginning I thought it was very, very long, you know. By the time you got to the end of it, you forgot the first of it."* (S02PT04)

A couple of patients reported feeling apprehensive about the intervention at first but this was alleviated when the pharmacist explained that it was for their own benefit.

Patients' views on compulsory Solution A (medication diary)

Patients provided positive feedback on their experience of using the medication diary and reported that it acted as a reminder for medication-taking and confirmation that they had taken their medications as prescribed.

> *"I think it's* [medication diary] *a fantastic idea, a fantastic idea"* (S01PT13)

> *"…I think it's* [medication diary] *a good idea for elderly people. Especially if they're a wee bit forgetful. It's been a real help to me that."* (S02PT03)

> *"And I found it* [medication diary] *helped though…'cause some days I would have forgot to take my tablets."* (S02PT06)

> *"And every day I filled it* [medication diary] *in, so it done me good, you know it really done me good knowing what I, what I was taking and I had taken them, you know."* (S02PT04)

The majority of patients felt that long-term use of the diary would be beneficial for their adherence, whereas other patients indicated that short-term use was sufficient.

> *"I could see me using it* [medication diary] *on a long term basis, yes, very much so, very much so. 'Cause when I started to use it, the diary then, then I hadn't forgot one day which was great."* (S02PT04)

All patients reported receiving verbal instructions on how to use the diary but one patient misinterpreted these. This patient thought that additional instructions would be beneficial. All other patients found the diary simple and easy to use.

> *"Definitely very helpful but what I did do wrong was I only put one X at the top… of each day… instead of ticking each medicine* (Inaudible) [on the medication diary]. *I was bamboozled by so many squares."* (S02PT07)

> *"…it was simple… tick off each day, your morning time, your night time, whatever. I thought it* [medication diary] *was very good."* (S02PT02)

Most patients were generally satisfied with the size and content of the diary, although a few patients made suggestions to improve its usability.

> *"Well with a pair of glasses I'd no trouble at all. No I… I have no complaints or even advice to improve it* [medication diary]*."* (S01PT08)

> *"You know it's such a big, em, diary, you know. Maybe if it was brought down a wee bit better, is something you could throw into your handbag…"* (S02PT04)

All patients reported that they would recommend use of the diary to other patients who were taking multiple medications.

> *"…sort of taught me here you, you don't know enough about what you're taking and when to take it etcetera… so yes the diary, I would recommend the diary."* (S01PT01)

Patients' views on optional adherence solutions (Solutions B and C)

Only a limited number of solutions from solution categories B and C (optional solutions) were recommended to patients, such as: reminder stickers (BCT: Prompts/cues), additional information on dispensing labels or synchronising medication supplies (BCT: Restructuring the physical environment). Patients who were provided with reminder stickers did not find these particularly effective.

> *"I put them up but they came down fairly quickly. Em… I didn't find them— I didn't find the stickers that, terribly, that terribly helpful."* (S01PT01)

> *"…they put on it* [the dispensing label] *what exactly it was for which was a great, great help to me…"* (S02PT04)

> *"I felt it was better to synchronise the medications so that they all finished at the same time and I reordered all four…"* (S01PT03)

All patients were offered the opportunity to raise and discuss any worries or concerns they had in relation to their medications but only a few patients reported having concerns.

> *"I definitely got the opportunity to, to discuss anything that I was worried about or anything, you know."* (S02PT03)

Only one additional adherence solution, that was not part of the intervention, was suggested by a patient. This was in relation to having the day inscribed on the foil side of the blister packaging of medications.

> *"Maybe there were things but I certainly didn't miss them… I don't think there's anything else that, eh, that he could have done."* (S01PT01)

Patients' views on compulsory adherence solution D (Goals and action plan activity)

Most patients reported finding the goals and action plan exercise useful but a few patients indicated that it was of limited benefit to them.

> *"It was, it was good because it's like anything in life, you know, you set a goal and you look at it and you, you aim for that."* (S02PT04)

> "*I don't– in my case quite truthfully I don't think it* [goals and action plan activity] *was a great deal of benefit to me."* (S01PT08)

Patients indicated that it was helpful to have their goals and action plan documented on the written sheet. However, one patient reported that she never received the written sheet to take home. All other patients found the information on the 'Goals and action plan sheet' clear and understandable.

> *"…it was very clear… all of the language in all of the stuff that I've seen has been, em, has been pitched at a, at a very good level for understanding wise so."* (S01PT01)

> *"…I read these at the very beginning and sometimes when I was sitting there in the evening time I would actually read over these again… it all became very clear to me, you know, it was well laid out actually and well written."* (S02PT04)

One patient indicated that the general health goal (BCT: goal setting-outcome) set by the pharmacist was not her true goal. The same patient also indicated that she aimed to reduce the number of prescribed medications that she was taking.

> *"…cause I was really ill that day and he put down that day* (Inaudible) *but that's not— my goal in life is to take my medication, be sure that everything is in order with me and enjoy my life. So the level of goal… was a wee bit, a wee bit, you know."* (S02PT02)

A few patients reported satisfaction from achieving their goal and indicated that their pharmacist provided praise for this. However, one patient who incorrectly completed the medication diary reported that he did not think he met his goal because of this, despite indicating that he took all of his medication as prescribed.

> *"Yes, yes and you know you do look over it and it's satisfaction… satisfaction. It's there and it, it, it encourages you…"* (S02PT07)

> *"Yes he did, he did and I think he was pleased by, by what he heard…I certainly (did) what I supposed to do and mind you I don't often do that."* (S01PT01)

Patients' experience of care from the intervention provider

Patients generally felt comfortable discussing their medications with their CP due to established relationships, although one patient reported feelings of embarrassment.

> *"Very relaxed because eh, yes I suppose, I get my medication through my pharmacist and you, you're often asking information… and have a good relationship with my pharmacist…"* (S01PT03)

> *"I get embarrassed to be quite honest… I have been a naughty boy… my better half was with me so I couldn't* (Inaudible) *I couldn't tell any fibs."* (S01PT03)

Patients reported a shared decision-making approach to selecting adherence solutions. They also felt that all possible options were considered and discussed.

> *"…he just took all that I said, he just asked me the questions and I answered them and we came to the conclusion that we're both on the same, same wavelength you know, we had the same thoughts."* (S02PT03)

Patients were satisfied receiving this type of intervention from their pharmacist and did not report a preference for receiving it from another type of HCP involved in their care (e.g. GP, nurse).

> *"No, I was happy enough with the pharmacist doing it… I know they're not doctors per se, but they're fairly knowledgeable about a whole range of issues obviously to do with health and well-being."* (S01PT03)

Impact of the intervention on adherence behaviours

Patients discussed how the intervention increased awareness of their current adherence behaviour and reported that the intervention helped to improve their adherence.

> *"…it does open your eyes because you are actually… you're actually— the medication you are taking… so it (makes) you a little bit more alert."* (S02PT02)

> *"Well it helped me, I knew for if I had taken my medicines or if I hadn't taken it there was a blank. So I knew then I hadn't taken my medicine so I made sure I took it the next day."* (S02PT06)

> *"I think I missed out once—didn't take it at the proper time. But I'll tell you the truth now, I'm so pleased with myself, it encouraged me."* (S02PT07)

Some patients felt they had high adherence prior to the intervention, although the intervention helped to emphasise the importance of continuing this.

> *"…well I would have been quite good anyhow but I suppose it's reinforced in me the importance of, you know, in making sure you do be, that I am diligent about taking my medication…"* (S01PT03)

Overall experience of receiving the intervention

Patients reported high satisfaction levels with the intervention and overall service provided. For some patients, the diary was described as the best part of the intervention.

> *"I thought everything from start to finish was ock, 100 percent, thought everything was class, I really did… Nothing but praise for it, really haven't."* (S01PT13)

> *"I would say very, very good, very, very good experience, em,* (Inaudible) *you know. It puts you into routine, I suppose that's the word."* (S02PT04)

> "*The calendar… I must admit it was a good idea."* (S02PT07)

All patients said that they would recommend the intervention to other patients who were prescribed several medications.

> *"I would recommend it to everybody, that's the truth, I really would. I would recommend it to everybody that's on medication..."* (S01PT13)

4.6.3 Fidelity of intervention delivery

Completeness of intervention records (ID-MAP Booklets)

The majority of sections in the intervention records (ID-MAP Booklet) were completed by CPs as intended; however, a small number of items were omitted or incorrectly completed. For example: the duration of appointments was not always recorded, signatures were missing on medication lists, boxes were left unticked in the assessment tool and written notes were missing.

Delivery of behaviour change techniques (BCTs)

Table 4.13 provides an overview of the assigned level of fidelity (high, low or unclear) based on a review of completed intervention materials and/or qualitative feedback from CPs and patients.

Table 4.13: Levels of fidelity of delivery of BCTs based on self-report

BCT ('core' or 'optional')	Total number of patients for whom the BCT was recommended using the ID-MAP Tool	Level of fidelity of BCT delivery[1]
Self-monitoring of the behaviour ('core')	9	High (n=9)
Feedback on behaviour ('core')	9	High (n=3) Low (n=1)[2] Unclear (n=5)
Prompts/cues ('optional')	8	High (n=8)
Restructuring the environment ('optional')	4	High (n=4)
Social support (unspecified) ('optional')	2	High (n=2)
Information on health consequences ('optional')	8	High (n=6) Low (n=1) Unclear (n=1)
Goal-setting (behaviour) ('core')	9	High (n=9)
Goal-setting (outcome) ('optional')	0	Low (n=5)[3]
Review of behaviour goal ('core')	9	High (n=7) Low (n=2)
Review of outcome goal ('optional')	0	Low (n=5)[3]
Action planning ('core')	9	Low (n=9)

[1] Assessment was made at the individual patient level based on self-reported feedback from CPs and patients and evidence from completed intervention materials (including checklists); [2] It was not possible for the CP to provide feedback as the patient's diary was misplaced; [3]This BCT was delivered to all patients at Site 02, even though it was not recommended according to the ID-MAP Tool

The BCT 'Self-monitoring of the behaviour' was delivered to all patients as recommended in the intervention manual (i.e. high fidelity). All CPs reported providing medication diaries to each patient and all patients reported receiving these. Eight out the nine diaries were returned by patients and had been completed, although one patient had misinterpreted the instructions and completed it incorrectly. One diary was not returned as the patient misplaced it.

It is unclear in some cases whether the BCT 'Feedback on behaviour' was delivered to all patients as recommended in the intervention manual. During the qualitative interviews, CPs reported providing feedback to patients based on a review of their medication diary, however only vague descriptions were offered. There was evidence to indicate that the pharmacist at Site 01 provided feedback to some patients (n=3) based on written notes (i.e. high fidelity), but written notes were omitted in other cases (n=5) (i.e. unclear fidelity). This BCT could not be provided to the patient who misplaced her medication diary.

The BCTs 'Prompts and cues' (n=8), 'Restructuring the physical environment' (n=4), 'Social support (unspecified)' (n=2) were all delivered to patients as recommended in the intervention manual (i.e. high fidelity). This was evident from written notes and/or feedback provided from CPs and patients in the qualitative interviews.

Delivery of the BCT 'Health consequences' was mainly in line with recommendations in the intervention manual (n=5) and evidence to support this was available in the written materials. However, for one patient the BCT was not delivered as intended as the recommended leaflet was not provided (i.e. low fidelity). For another patient it was unclear if this BCT was delivered due to the lack of written notes (i.e. unclear fidelity).

The BCT 'Goal-setting behaviour' was delivered to all patients as intended in the manual (i.e. high fidelity). Each patient was set at least one medicine-related goal which was documented on the 'goals and action plan sheet' (e.g. 'To take my simvastatin tablet at night-time instead of during the day'). This was evident from the written materials and feedback provided from CPs and patients in the qualitative interviews. However, the BCT 'Review of behaviour goal' was not always delivered as recommended in the intervention manual. For example, some patients' goals were deemed to be met by the pharmacist despite their medication diary suggesting otherwise (i.e. low fidelity) (n=2). In other cases, the BCT was delivered as intended which was evident from the written materials and qualitative feedback (i.e. high fidelity) (n=7).

The BCTs 'Goal setting (outcome)' and 'Review of outcome goal' were not delivered to patients as recommended in the intervention manual (i.e. low fidelity). All patients in this study reported high levels of motivation, therefore in accordance with the manual, these two BCTs were not required. However, CPs at Site 02 delivered these BCTs to all of their patients (n=5).

The BCT 'Action planning' was not delivered to patients as recommended in the intervention manual (i.e. low fidelity). CPs did not use the suggested IF-THEN format for developing action plans (e.g. IF I see my medication on my bedside table, THEN I will take it). Although CPs reported in the feedback interview that they found the format helpful, it was evident from the written materials that they did not make use of this.

In comparing fidelity of BCTs across the two pharmacy sites, it was evident that more BCTs were correctly delivered by the CP at Site 01 in comparison to the CPs at Site 02.

4.6.4 Feasibility of patient screening and recruitment procedures

Completeness of screening and recruitment documentation

All patients correctly completed the eligibility screening questionnaire (MMAS-8). The questionnaire was incorrectly scored by a pharmacist on one occasion, although this had no impact on the patient's overall level of adherence and subsequent eligibility status.

Just under three-quarters (73.7%) of eligibility screening forms and 60% of recruitment forms were fully completed by CPs as instructed. Examples of missing information included: missing dates, unticked boxes, missing dates of birth. Just over half (57.7%) of patient consent forms were correctly completed. Examples of missing information included: missing dates, missing full patient names, boxes not initialled. Only one recommendation was made to the GP during the study (change of formulation from capsules to liquid due to swallow difficulties) and a GP referral form was accurately completed for this. Another patient was advised to see their GP for investigations after reported nausea did not subside; a GP referral form was not completed on this occasion.

Feedback on screening and recruitment procedures from qualitative interviews

All patients found the screening procedures acceptable and reported no difficulties with completing the eligibility screening questionnaire (MMAS-8). Patients felt comfortable answering the types of questions presented in the questionnaire. One patient discussed how the questionnaire prompted him to think about his adherence behaviour.

> **"***I found that useful, eh, that I had to actually consciously start thinking about it." (*S01PT01)
>
> *"…there was no… embarrassing questions in other words, you know, or anything like that. It was straight forward." (S02PT03)*
>
> *"The questionnaire was very simple… sensible... I was quite comfortable."* (S02PT07)

The study information sheet provided was seen as comprehensible to patients and provided all the information required to make an informed decision about participating in the study.

> *"I think it was nicely balanced. Eh, too much would have been off putting and obviously too little wouldn't have been of much use. No I think it was good."* (S01PT01)
>
> *"There was, there was enough information for me. Yes, there definitely was, yes, definitely."* (S02PT04)

CPs' views on the screening process varied across the two sites with one site experiencing challenges with the process. One pharmacist initially felt uncomfortable approaching patients, which was further exacerbated by the time-pressured environment.

> *"Yeah, the actual screening, no it was, it was fine… we're lucky here we have a large… eh, a lot of elderly people would be part of our patient base so, em, you know, there was no problem really." (S02CP01)*

> *"The screening process is probably what I found most, most difficult about the whole, eh, the whole study, em… initially the difficulty was actually in approaching patients at the counter…"* (S01CP01)

The eligibility criteria were mainly acceptable to CPs, however some suggested changes were proposed. For example, it was suggested that the inclusion age could be reduced to 55 years or 60 years.

> *"The criteria's very good. Maybe you could go 60 years and older rather than 65, 'cause I do know there was a couple of people that, em, I thought could benefit but they were maybe 62 or 63" (S01CP01)*

> *"Em… yes 65 or older, four or more, yeah the four or more, that was… that was fine, it— four was quite low."* (S02CP02)

CPs found the eligibility screening questionnaire (MMAS-8) useful for identifying non-adherent patients. However, one pharmacist suspected that some patients were not entirely truthful when completing this.

> *"Yeah, no I think it was a good starting point, you know, it was, it was user-friendly and it wasn't, sort of, em, too complicated for people." (S02CP01)*

> *"I still got the feeling that some people were telling me what I wanted to know basically… or what they thought I wanted to know I should say…"* (S01CP01)

When CPs were asked about the involvement of pharmacy support staff in the screening process, the views expressed were mixed. If support staff were to be involved it was suggested that training would be essential.

> *"… if I were to have made the criteria known to everyone in the pharmacy, they could have turned round and told me, approach this person or this person might benefit or have a look at this person's record to see would they be eligible for the study as well. So yes I, I really do think that they* (pharmacy support staff) *could be…"* (S01CP01)

> *"…I think… there is maybe a role for… somebody maybe trained the counter staff or dispensing assistants... Em but I think that… I think probably I, I think it, it's really, I think maybe a pharmacist role because… we're the ones that's maybe sort of dealing with the issues..."* (S02CP01)

The recruitment process was mainly seen as straightforward; however CPs did think that the consent-taking process was burdensome.

> *"…the recruitment process was, was actually really smooth, em, from once we got over the initial screening process..." (S01CP01)*

> *"I think they, sort of, felt do I have to initial all these parts* (of consent forms)*… maybe in the future if they just… had an overall thing because some of them, sort of, said, 'Do I have to do everything?' and kind of felt it was maybe a wee bit much for them to do that." (S02CP01)*

One pharmacist received feedback from a patient who reported difficulties understanding the study information sheet. He indicated that more time may need to be spent with those types of patients. The amount of paperwork was also seen to be difficult to manage at times and a suggestion was made to condense information.

> *"…there was just a lot of, em, paperwork and…. it was tough to keep all the… paperwork…"* (*S01CP01)*

4.6.5 Feasibility of measuring adherence to polypharmacy using a validated self-report measure (MMAS-8)

All returned MMAS-8 questionnaires were correctly completed by patients, however, one questionnaire was incorrectly scored by a pharmacist as discussed in Section 4.6.4. Five out of nine patients returned the three month follow-up questionnaire (containing MMAS-8 and also EQ-5D-5L; see later). No follow-up calls were made in this study. MMAS-8 scores and adherence level at baseline and three-month follow-up are presented in Table 4.14 below. Due to non-response, these were not available for four patients.

Table 4.14: MMAS-8 scores at baseline and three months post-intervention delivery

Patient ID number	Baseline adherence score (adherence level[1]) (MMAS-8)	Three-month follow up adherence score (adherence level[1]) (MMAS-8)
S01PT01[2]	6.75 (Medium)	—
S01PT03	7.75 (Medium)	7 (Medium)
S01PT08[2]	4.5 (Low)	—
S01PT13	7 (Medium)	7 (Medium)
S02PT02	7 (Medium)	8 (High)
S02PT03[2]	3.5 (Low)	—
S02PT04	5.25 (Low)	6.75 (Medium)
S02PT06	5.75 (Low)	6.75 (Medium)
S02PT07[2]	5.25 (Low)	—

[1] Low (score <6), medium (Score 6 to 7.75) or high (score of 8); [2] Three month follow-up questionnaire not returned

Feedback on MMAS-8 questionnaire from qualitative interviews

As discussed in Section 4.6.1, patients reported that they understood all of the questions posed in the MMAS-8 questionnaire (which also served as the eligibility screening questionnaire). Patients felt comfortable completing the MMAS-8 in the community pharmacy setting. CPs also indicated that patients experienced no difficulties completing the questionnaire, however one pharmacist did think that patients may not have been honest.

4.6.6 Feasibility of calculating objective measures of adherence to polypharmacy from dispensing data

Using dispensing data, pre-intervention MPR and PDC percentages were calculated for eight out of the nine patients who completed the study. One patient received medications on a weekly basis and as the pharmacist took responsibility for prescription ordering and generated labels each week, it was not deemed to be a true picture of the patient's adherence. Post-intervention MPR and PDC percentages were calculated for three out of the nine patients who completed the study. The remaining five patients did not have at least two refills in the post-intervention period to allow these measures to be calculated. Short-term medications (prescribed for less than 8 weeks e.g. antibiotics), when required medications (e.g. glyceryl trinitrate spray, salbutamol inhaler) and those with unclear or variable instructions (e.g. take one or two tablets daily, insulin products), were excluded from all of the calculations. Medications that were changed during the observation period (e.g. strength changed, product switched) were also excluded from the calculations. The MPR and PDC results are presented in Table 4.15.

Table 4.15: Pre- and post-intervention Medication Possesion Ratio (MPR) and Proportion of Days Covered (PDC) (%)

Patient ID number	MPR		PDC	
	Pre-intervention[1]	Post intervention[2]	Pre-intervention[1]	Post-intervention[2]
S01PT01[3]	89.0%	—	43.1%	—
S01PT03	99.4%	100%	99.0%	100%
S01PT08[3]	97.9%	—	96.3%	—
S01PT13[3]	99.7%	—	90.4%	—
S02PT02	96.0%	97.7%	91.1%	98.9%
S02PT03[3]	59.0%	—	1.2%	—
S02PT06[3]	90.5%	—	29.9%	—
S02PT07	93.6%	96.0%	65.8%	91.5%
S02PT04[4]	—	—	—	—

[1] Six months pre-Appointment 1; [2] Three months post-Appointment 3; [3] Did not have two refills in three months post intervention observation period; [4]Weekly dispensing patient (not feasible to calculate MPR or PDC)

4.6.7 Feasibility of measuring HRQOL using a validated measure (EQ-5D-5L)

All returned EQ-5D-5L questionnaires were correctly completed by patients. Five out of nine patients returned the three-month follow-up questionnaire (containing EQ-5D-5L). Table 4.16 below indicates each patient's EQ-5D-5L index value and VAS scores at baseline and three-month follow-up. Due to non-response, these were not available for four patients.

Table 4.16: EQ-5D-5L index value and Visual Analogue Scale (VAS) scores at baseline and three months post intervention delivery

Patient ID number	Baseline[1] EQ-5D-5L index value	Three-month follow-up EQ-5D-5L index value	Baseline VAS score	Three-month follow-up VAS score
S01PT01[2]	0.304	—	70	—
S01PT03	1.000	1.000	95	90
S01PT08[2]	0.735	—	60	—
S01PT13	0.683	0.778	90	80
S02PT02	0.345	0.221	50	35
S02PT03[2]	0.837	—	80	—
S02PT04	0.620	-0.081	50	50
S02PT06	0.666	0.449	50	70
S02PT07[2]	0.639	—	60	—

[1] Completed at the start of Appointment 1; [2]Three month follow-up questionnaire not returned

Feedback on EQ-5D-5L questionnaire from qualitative interviews

Patients who completed the study reported no major concerns with completing the EQ-5D-5L. All patients reported that they felt comfortable answering the types of questions posed by the questionnaire.

> *"I had no qualms* (Inaudible) *a professional, the same as a doctor… you can't, you can't see your symptoms… it's not like a—you have to tell them. So I mean it doesn't annoy me."* (S02PT07)

> *"I was actually glad to, to have to look at them and think about them and, you know, answer them..."* (S01PT01)

Some patients reported having good health which made answering the questionnaire straightforward. Others felt that the questionnaire provided the opportunity to discuss health-related issues with their pharmacist and acted as an ice-breaker. One participant found the pain question on the EQ-5D-5L challenging to answer due to its subjective nature and potential for variance on a day-to-day basis.

> *"…it was a good way of opening up because you know there's a lot of things we talk about and we don't always go in to things in-depth so for somebody to sit and ask me those questions, eh, it was good because then I could really say how I felt."* (S02PT06)

> *"I think the level of pain was awkward for me. Cause I— for me personally, I couldn't either tell you what my level of pain is— you know what I mean?"* (S02PT02)

Mixed views were expressed by CPs in relation to the EQ-5D-5L questionnaire. One pharmacist indicated that patients were sceptical about completing this.

> *"…definitely the patients seemed sceptical, one or two, one especially, em, there was a couple of other patients were a bit like, were kind of looking at me as if to say, 'Why are you asking me these questions, I thought it was about medicine, now you're asking me about my health, my general health?'.*(S01CP01)

The other two CPs expressed positive views but did discuss the subjective and cross-sectional nature of the questionnaire and day-to-day variances in patients' HRQOL.

> *"Well I give it to the people and they were happy enough, you know… with older people I think… they're quite, you know, they will tell you if they have any problems..."* (S02CP01)

> *"…they said to me, 'Look I'm grand today but, you know, tomorrow I could be down or whatever' so I suppose it's, it's really, em, it's just a point in time…"* (S02CP01)

Although patients who completed the study reported no difficulties with completing the EQ-5D-5L, the patient who dropped out of the study did so after Appointment 1. It was at the start of this appointment that he was asked to complete the EQ-5D-5L questionnaire to

measure HRQOL. Despite reassurance from his CP, the patient expressed concerns over the confidentiality of the collected data and impact this may have had on his welfare payments. The patient study information sheet (Appendix 4.21) indicated that all information collected would be treated with the strictest of confidence and the pharmacist confirmed this with the research team and reassured the patient that this was the case. However, despite this, the patient was unwilling to continue to participate in the study.

4.7 Discussion

This chapter has outlined the intervention design process and findings from preliminary testing of the ID-MAP intervention in a small-scale feasibility study. The ID-MAP intervention was designed to incorporate the 11 BCTs that were identified from previous research with older patients (Chapter 3). These BCTs, which were grouped into four 'adherence solution' categories, formed the proposed active ingredients of an intervention that aimed to improve medication adherence in older patients prescribed polypharmacy. Following intervention design and piloting of materials within the research team, CPs (n=3) working at two community pharmacy sites were successfully recruited to test the feasibility of delivering the intervention in their clinical practice. Ten older patients were recruited and the intervention was delivered fully to nine of these patients (retention rate: 90%). Following intervention delivery, CPs (n=3) and patients (n=9) provided feedback on the intervention and study procedures during qualitative interviews.

4.7.1 Usability/acceptability of the intervention

The primary outcome of this study was to assess the usability and acceptability of the intervention from the viewpoint of both intervention providers (CPs) and recipients (patients). Assessing usability/acceptability early on in the design and testing of a complex intervention is vital to the success of future evaluation studies. Gaining patients' views on the intervention content also aligns with the goals of patient-centred care (Richards et al. 2015).

Overall, both CPs and patients reported high levels of satisfaction with the ID-MAP intervention package stating that they found it both useful and acceptable. CPs and patients provided feedback on each of the adherence solutions (i.e. BCTs) they delivered or received, respectively, and also commented on associated materials. Participants highlighted where adaptions could be made to further enhance the acceptability of the intervention. Based on feedback from both CPs and patients, delivery of the BCTs 'Goal-setting-behaviour', 'Review

of behaviour goal' and 'Action planning' may not be necessary and useful for all older patients, particularly those with relatively minor issues such as occasionally forgetting to take medications. These BCTs were originally deemed 'Core BCTs', however, they may be more appropriate as 'Optional BCTs' and delivered to patients with low levels of motivation or a complex range of issues (i.e. tailored to individual patients' needs). This study has also helped to identify formats for delivering BCTs that were less useful to patients, such as the reminder stickers that were used to deliver the BCT 'Prompt/cues'. Alternatively, patients found that placing medications in a visually prominent place (e.g. on their kitchen bench) acted as a more successful reminder strategy. This information will help to refine the delivery of the BCT 'Prompts and cues' and improve the acceptability of the intervention in the target audience. These are important findings, as we aim to deliver an optimal combination of BCTs to patients in the most efficient and acceptable manner. It is thought that the limited effectiveness of some complex adherence interventions could be a result of sub-optimal design and so feasibility and pilot studies offer the opportunity to optimise the intervention design (Levati et al. 2016). However, there is currently no guidance as to when an intervention design should be deemed 'fully optimised' and is therefore ready for testing in a large RCT.

Aside from changes to the manufacturers' packaging (which is beyond the scope of this project), no additional adherence solutions were suggested by patients or CPs. This highlights the usefulness of using the TDF-to-BCT mapping approach in ensuring the intervention package was comprehensive and included solutions to address all possible adherence problems faced by older patients prescribed polypharmacy. Future research in a larger number of patients is needed to confirm this finding.

4.7.2 Fidelity of intervention delivery

Based on self-report (from checklists, notes in intervention records, qualitative feedback), there was evidence to indicate that CPs were able to deliver most BCTs (n=7) with high levels of fidelity, such as 'Self-monitoring of the behaviour', 'Prompts/cues', 'Restructuring the physical environment'. For other BCTs, the self-reported evidence suggested that CPs experienced some difficulties in delivering these. For example, 'Goal setting-outcome' and 'Action planning' were not delivered as outlined in the intervention manual (low fidelity). This could be due to a lack of experience in delivering such techniques in the community pharmacy setting or due to insufficient training. In general, intervention fidelity was higher at Site 01, which could be due to this CP's engagement with the intervention manual which he discussed extensively at the feedback interview. The extent to which the CPs at Site 02

engaged with the intervention manual was unclear. CPs at Site 02 had been practising as pharmacists for longer and perhaps judged it unnecessary to study the manual in great detail. Ensuring high levels of intervention fidelity in a future RCT is essential so that if the intervention was deemed to be ineffective, then this outcome could be attributed to a genuine ineffectiveness of the intervention and not due to poor intervention delivery by providers (i.e. low fidelity) (Levati et al. 2016).

Intervention training can help to improve the fidelity of intervention delivery, which in turn can impact on the effectiveness of an intervention. The short on-site session (1.5 hours) which briefly covered both study procedures and how to deliver the intervention to older patients may not have been sufficient in this study. CPs reported high levels of satisfaction with the intervention training they received, however, they indicated that additional training could have been beneficial. CPs thought the opportunity to practice/rehearse delivery of the intervention and discuss this with peers, would have improved their skills and confidence in this area. Due to the complex nature of providing adherence support, it is likely that CPs' behaviours will also need to change to allow this type of adherence intervention to be successfully implemented into everyday practice. There is limited research into what factors help or hinder CPs in providing this type of adherence support to patients (Huston, 2015). This feasibility study has highlighted the need for additional research to inform the development of a more comprehensive training package to support the future testing and implementation of the ID-MAP intervention.

4.7.3 Feasibility of patient screening and recruitment procedures

As a secondary outcome, this study also aimed to explore key study procedures to overcome potential hurdles in advance of a definitive trial. One site experienced challenges in identifying eligible patients using the suggested screening approach. For example, due to time restrictions in this setting, it was not feasible for CPs to approach every patient who met the criteria when they were waiting on (or collecting) their prescription. Alternative strategies should therefore be trialled to ensure the eligibility screening process is systematic and avoids selection bias (Pannucci and Wilkins, 2010). For example, potentially eligible patients could be identified from pharmacy-held records (PMRs) and mailed letters of invitation. Pharmacy support staff could be involved in this screening process to reduce the workload for CPs but it is recognised that CPs might prefer to oversee this process, and training for support staff would be essential.

All patients who completed the screening process and were deemed eligible were subsequently recruited into the study (100% recruitment rate). Just over 15% (16.7%; n=4) of patients who were approached in the pharmacy refused to undergo screening, with the most commonly cited reason being lack of time to commit to the study. CPs reported that the MMAS-8 was a suitable screening questionnaire to identify those with adherence problems that could potentially benefit from the intervention. Electronic PMRs have been identified as an alternative means of identifying patients who are non-adherent (National Institute for Health and Clinical Excellence, 2009). However, this feasibility study has shown that adherence may appear high using the PMR, despite self-reports of non-adherence. This could be due to older patients stockpiling or hoarding medications, a phenomenon that has been discussed in the literature previously (Thompson and Stewart, 2001). Discrepancies between self-report and pharmacy refill-based measures have been reported elsewhere in the literature (Guénette et al. 2005). The limitations of self-report adherence measures have been recognised, including recall bias and social desirability bias (Stirratt et al. 2015). However, to ensure patients engaged with all aspects of the intervention, it was important that they were able to show some insight into their medication adherence behaviour. A combination of methods for identifying non-adherent patients may be a more useful approach.

The informed-consent taking process undertaken as part of screening and recruitment was seen as burdensome for CPs. A two-stage consent process (consent to be screened and consent to be recruited into the full study) was adopted for this study requiring the completion of two separate consent forms (Appendices 4.17 and 4.21). For future evaluations, modifications should be considered to optimise this process. This could include reducing the amount of paperwork where possible and providing CPs with additional support and more in-depth training on informed consent to help them to understand the importance of this process. Monitoring of CPs' compliance with the study protocol will be required in future studies to ensure the consent process is correctly implemented. Potential strategies have been trialled in recent years to improve the consent process and enhance patients' understanding of what will be expected of them in research studies. For example, the use of interactive strategies (e.g. use of videos on an iPad) have shown promise in improving patient comprehension (Rowbotham et al. 2013; Sonne et al. 2013).

4.7.4 Feasibility of data collection procedures (adherence and HRQOL)

As the current study did not seek to examine the effects of the intervention in terms of the outcomes measured (medication adherence, HRQOL) and due to the small sample size (n=9),

it would be inappropriate to draw any inferences from the findings. Rather, this section focuses on the feasibility of collecting this type of data in the context of older patients prescribed polypharmacy and also in the community pharmacy setting.

Health-related quality of life (EQ-5D-5L)

This study has shown that it was feasible to measure HRQOL using the EQ-5D-5L survey at baseline in the community pharmacy setting. In relation to the follow-up measurement, this was not obtained for patients who did not return the postal questionnaire (n=4). Potential strategies to maximise the response rate could include telephone call reminders or trialling alternative methods of data collection (e.g. home visits to collect data).

Patient participants who completed feedback interviews (n=9) expressed no concerns with completing the EQ-5D-5L questionnaire. This was in contrast to feedback from one of the CPs who reported that the questionnaire took patients by surprise at their first appointment and potentially contributed to the patient drop-out in the study. Although the patient information leaflet stated that patients would be asked questions about their general health, this may need to be clearer. For example, it could include more specific details about the types of questions they will be asked (e.g. questions about pain, depression etc.). As the sole purpose of the EQ-5D-5L questionnaire is an outcome measure, alternative methods of data collection could be trialled. For example, patients could complete the questionnaire and seal their responses in an envelope so that CPs do not have access to their responses. HRQOL is an important concept that is not always measured as part of adherence studies and so it is important to collect this information (Marcum et al. 2017). The association between medication adherence and quality of life is unclear with some studies reporting a positive correlation and others reporting a negative or no correlation (Saleem et al. 2012; Hanus et al. 2015; Harlow et al. 2017). It is therefore important to assess the impact of interventions that seek to improve medication adherence on older patients' HRQOL.

Self-reported medication adherence (MMAS-8)

The MMAS-8 had a dual purpose in this study in that it served as an eligibility screening questionnaire and as an outcome measure of self-reported adherence. This study has shown that it was feasible to measure self-reported adherence using MMAS-8 at baseline. However, as discussed for the EQ-5D-5L, four patients did not return their three-month follow-up questionnaire and so strategies to improve this need to be considered.

The MMAS-8 was originally designed to encourage patients to think about medications prescribed for a particular condition (e.g. hypertension) as opposed to medications for all of

their chronic conditions. Although the change of wording to account for this was approved by the developer (Morisky), the impact of this on the validity of the measure is unknown. As previously discussed, the limitations of self-report are well-known (e.g. social desirability bias, recall bias). Nonetheless, research has shown that validated self-report questionnaires (e.g. MMAS) have moderate to high levels of correlation with other measures (e.g. electronic monitoring) (Garber et al. 2004; Stirratt et al. 2015). Stirratt et al. (2015), recommend that validated self-report scales should be used where possible and attempts made to improve the quality of such measures (e.g. attempting to reduce social desirability bias). Self-report measures have high specificity (i.e. good ability to correctly identify those with poor adherence) and low sensitivity (i.e. poor ability to correctly predict those without poor adherence). In other words, if a patient indicates that they are non-adherent, then this is likely to be reliable (Stirratt et al. 2015). In the current study, one pharmacist recognised the potential for social desirability bias and indicated that he could have benefited from training on how to avoid this. Despite the known limitations, MMAS-8 served as an efficient, low-cost method for both identifying non-adherent patients and measuring adherence (as an outcome) in a time-restricted environment.

Pharmacy dispensing data to calculate objective measures of adherence (MPR, PDC)

In addition to self-report, measures calculated using pharmacy dispensing data were selected as more objective measures of adherence. The collected information was used to calculate two commonly employed measures: MPR and PDC. Although both measures attempt to examine the amount of medication that the patient has available over the defined period (as a surrogate for consumption), they differ in how their values are calculated. It was evident from reviewing the MPR and PDC percentages obtained for each patient that there could be variability in how the findings are interpreted. For example, a patient who was deemed adherent (cut-off of 80%) in the six months pre-intervention delivery using the MPR measure (90.5%), was deemed non-adherent when employing the PDC measure (29.9%). If adherence was assessed solely using MPR, only one out of the nine included patients would have been deemed non-adherent pre-intervention (MPR < 80%), whereas using PDC, four out of nine patients would be deemed non-adherent pre-intervention (PDC <80%).

Measuring adherence is a recognised challenge in this field of research and further complicated when attempting to measure adherence to multiple medications (i.e. polypharmacy). The Multiple Medication Adherence Measurement Working Group of ISPOR (International Society For Pharmacoeconomics and Outcomes Research) have recently undertaken research to explore the accuracy of measures commonly used to measure

adherence to multiple medications (Malmenäs et al. 2016). Using simulated patient data, they estimated that an MPR (average) had an estimated sensitivity of 100% and specificity of 30%. In comparison, PDC (for all medications) has an estimated sensitivity of 97% and specificity of 96%. These findings illustrate that the PDC measure is better at identifying patients with poor adherence than the MPR measure in the context of polypharmacy (i.e. higher specificity) which aligns with the findings in this study.

The PDC measure could, however, be seen as too strict in this context as a patient is only deemed 'covered' on a given day when he/she has all medications in the polypharmacy regimen available. So, for example, if Patient A had only one out of ten medications available and Patient B had nine out of ten medications available on a given day, that day would be classified as 'not covered' for both patients, despite there being a notable difference in the level of availability of medications (proxy for medication adherence). A newer objective measure, termed the 'Daily Polypharmacy Possession Ratio' (DPPR) that has been proposed could provide a more conservative estimate of a patient's adherence to a polypharmacy regimen (Arnet et al. 2014). This method has been successfully utilised in a RCT which assessed the effectiveness of a 'Polymedicine Check' service in Switzerland using community pharmacy dispensing records (Messerli et al. 2016). The DPPR measure is similar to the PDC measure in that it also looks at every day in the measurement period, but the DPPR measure differs in that it takes into consideration the ratio of medications available on a given day. So in the example above, Patient A would be deemed to have a ratio of 0.1 coverage and Patient B a ratio of 0.9 coverage for that day. However, it should be noted that calculating DPPR and PDC values are much more time-consuming than calculating the MPR. This is because a 'supply diary' for each day has to be produced to account for early refills and assess the level of adherence on each given day in the observation period (Arnet et al. 2014).

There is a need for guidance in this area to ensure that studies measuring adherence to multiple medications can be easily compared and contrasted. There is currently ongoing work into the development of a 'Core Outcome Set' which seeks to identify a minimum set of outcomes that should be reported in clinical trials with patients prescribed polypharmacy (http://www.comet-initiative.org/studies/details/933). In addition to identifying 'what' should be to measured (e.g. adherence, hospitalisations), it will be important to identify exactly 'how' each outcome should be measured to ensure consistency across research studies.

4.7.5 Intervention tailoring

Due to the wide range of potential barriers and facilitators experienced by older patients in relation to taking multiple medications, the intervention was designed so that the content could be tailored to each individual patient's needs. Delivery of all components to all patients would have been a time-consuming and inefficient approach. This is one of the first studies to report tailoring of BCT delivery to patients' needs. CPs reported that the adherence assessment tool (ID-MAP tool) aided the selection of BCTs to deliver to each patient (i.e. tailoring of intervention components). The questions in the tool were also reported to be acceptable to patients and patients reported that a shared decision-making approach was used to select the most appropriate adherence solutions. However, it should be noted that CPs at one site incorrectly delivered two additional BCTs ('Goal setting-outcome', 'Review of outcome goal') to all of their patients despite the tool recommending that these were unnecessary. The development of an electronic version of the adherence assessment tool could help to avoid this in future studies. Based on a patient's response to each question (e.g. using a similar tick box selection style approach), an electronic tool could automatically generate options for an individualised adherence support plan. All CPs expressed positive opinions about the use of information technology (IT) in delivering the intervention (e.g. using an iPad) and so this warrants further investigation. This approach would also serve to reduce the volume of paperwork for CPs which was perceived as being potentially burdensome and also help ensure that all relevant sections are completed before advancing to the next stage.

This feasibility study has demonstrated that a rigid approach to appointments in this patient group may not be optimal. Adherence problems can range in severity and so patients require differing levels of contact and support. For the patients identified in this study, CPs at both sites thought it was unnecessary to leave a gap between Appointments 1 and 2 for preparation of adherence solutions as suggested in the manual and accordingly, CPs at one of the sites combined these appointments reducing the number of intervention appointments from three to two. Nevertheless, CPs did recognise that some patients may require more than two appointments and suggested that the number of appointments should be decided on a case-by-case basis (i.e. tailored). Telephone calls were also suggested as a useful method for following up with patients to check on the effectiveness of adherence solutions. These are important findings that reflect recent guidance published by NICE on managing multimorbidity in primary care (National Institute for Health and Care Excellence, 2016). This guidance recognises the heterogeneity of patients taking several medications for

multiple medical conditions and the need to adopt a tailored approach to providing healthcare.

Previous adherence interventions, have generally focused on delivering the same intervention components to all patients, despite research showing that there are a wide range of reasons for patients' non-adherence. Adopting a tailored approach to intervention design and delivery may improve the effectiveness of adherence interventions and so future research should focus on how best to tailor both intervention content (i.e. BCTs) and the number of appointments to each patients' needs in a consistent manner.

4.7.6 Study strengths and limitations

The intervention has been designed and tested in line with the MRC complex intervention development framework. The intervention content has also been reported in line with the TIDieR guidelines which aim to ensure that the interventions can be easily interpreted and replicated by others (see completed checklist in Appendix 4.30). The qualitative nature of the feedback interviews gave participants the opportunity to express their views on the intervention in-depth so that components of the intervention that worked well or less well could be identified. This will help to ensure that the intervention is refined so that it is most relevant to those that it seeks to help (older patients) and those responsible for implementing it (CPs).

A potential limitation of this study is that the pharmacist training and feedback interview sessions were conducted by the same researcher which may have led to social desirability. There were, however, changes suggested by all pharmacist participants to improve the intervention content and study procedures and so this level of bias is thought to be minimal. Patient participants had no prior contact with the researcher and were informed that any information provided during feedback telephone interviews would be confidential and not relayed back to their pharmacist. Although all feedback interviews were conducted as soon as possible after intervention delivery, slight delays in reaching participants and scheduling suitable interview dates/times, may have resulted in recall bias.

The sampling strategy for identifying community pharmacies for this study was based on pragmatism (i.e. convenience sampling of personal contacts) and was limited to one geographical area. To improve the transferability of findings, future research should test sampling and recruitment of community pharmacies on a larger scale.

The findings from the fidelity assessment are limited due to the self-reported nature of data which could have impacted on their validity (i.e. accuracy) (Breitenstein et al. 2010). Future

research should incorporate objective measures of fidelity (e.g. video or audio recordings, observations) to objectively measure if a modified version of the intervention package can be delivered by CPs as intended and ultimately link this with study outcomes (Borrelli, 2011).

4.8 Conclusion

This feasibility study has demonstrated the usability and acceptability of the ID-MAP intervention from the viewpoint of both older patients (intervention recipients) and CPs (intervention providers) and warrants further testing in a future pilot study. Although many of the findings from the feasibility study were positive, in order to optimise the intervention design/delivery, some modifications will be required. An important finding from this study was the need for additional training for CPs to enhance intervention fidelity. Chapter 5 presents findings from a mixed methods study that aimed to further explore CPs' training needs in relation to providing this type of adherence support intervention to older patients. The purpose of this is to guide the selection of components to include in a modified training package and to support the future delivery of the ID-MAP intervention.

Chapter 5

Selection of components for a theory-based community pharmacist training package and strategies to improve the provision of medication adherence support: a mixed methods approach

5.1 Introduction

The previous chapters of this thesis (Chapters 2 to 4) reported on the development and feasibility testing of the ID-MAP intervention, an intervention designed for the target audience of older patients prescribed polypharmacy (≥4 medicines) to improve the target behaviour of medication adherence. As highlighted in Chapter 4, findings from the feasibility study indicated that modifications are required to the training package that accompanies the ID-MAP intervention. This is necessary to ensure the intervention can be delivered by CPs as intended (i.e. with high fidelity) in future research studies and ultimately in clinical practice if the intervention is effective.

5.1.1. Targeting community pharmacists' behaviour to improve the provision of medication adherence support

As discussed in Chapter 1, there is growing recognition that in addition to targeting patients' adherence behaviour directly, it is important to consider the behaviours required of those who are responsible for delivering interventions to improve adherence (Sabate, 2003; National Institute for Health and Clinical Excellence, 2009; Huston, 2015). The 2003 WHO report recognised that HCPs require specific training in both assessing patients who are at potential risk of non-adherence, and in the delivery of interventions to improve it (Sabate, 2003). Supporting the WHO report, the latest guidance on medication adherence from NICE describes the provision of medication adherence support (MAS) as a complex clinical behaviour, consisting of both identifying non-adherent patients and providing tailored adherence support interventions (National Institute for Health and Clinical Excellence, 2009).

As alluded to previously, there has been limited research into exactly what helps and hinders CPs in providing MAS to patients (Huston, 2015). Preliminary qualitative and quantitative research has shown that potential barriers to the provision of MAS include a lack of time, perceived resistance from patients and CPs' lack of confidence, although the latter has varied across studies (Bacci et al. 2014; Lowrie et al. 2014; Mansoor et al. 2014; Marquis et al. 2014; Mansoor et al. 2015). The training package for CPs that will accompany the patient-targeted (ID-MAP) intervention provides a unique opportunity to overcome modifiable barriers to the provision of MAS such as CPs' lack of knowledge, skills and/or confidence. In addition, it is important to explore other perceived barriers and facilitators that need to be considered such as availability of resources, time and reimbursement as these are all factors that could impact on the future implementation of the ID-MAP intervention.

5.1.2 Current provision of medication adherence support by community pharmacists in Northern Ireland

In the context of NI, the extent to which CPs identify non-adherent older patients and provide adherence support is currently unclear. Despite non-adherence being a widespread problem (Bosworth et al. 2011), there is currently no commissioned service in NI that specifically focuses on improving medication adherence in older adults prescribed polypharmacy. Two currently funded services offer potential opportunities for CPs to identify non-adherence and provide adherence support. These include firstly, the MUR service, which in NI is targeted at patients who have a clinical diagnosis of asthma or diabetes (Business Services Organisation, 2014). Secondly, the MYM service is a medication review service available to support patients who are deemed to be at high risk or vulnerable (including patients taking four or more medications or taking high risk medications e.g. digoxin or warfarin) (Business Services Organisation, 2010). To be eligible for MYM, the service guidance indicates that patients should have either an identified lack of support for managing their medications, poor adherence or a significant change to their medication following recent hospital discharge. However, it is unclear exactly how poor adherence is defined, measured and addressed by CPs as part of either service. For example, MUR guidance indicates that CPs can provide 'advice on medicines usage (prescribed and OTC), aiming to develop improved adherence' (Business Services Organisation, 2014) and MYM guidance indicates that: 'The service should assist in achieving safe and cost-effective use of medication, improve adherence and ensure that all measures are implemented to achieve the best possible quality of life for the individual patient' (Business Services Organisation, 2010). One common component of both the MUR and MYM services is the provision of education to improve patients' knowledge. Although appropriate medication knowledge is an important prerequisite for adherence, recent evidence has shown that education alone is insufficient in changing patients' non-adherent behaviours (Nieuwlaat et al. 2014; Allemann et al. 2016). Both services currently offered in NI lack a clear structure with regards to improving medication adherence, and their effectiveness (in terms of adherence and clinical/humanistic outcomes e.g. HRQOL), and cost-effectiveness currently remains unknown (Wright, 2016).

CPs' current involvement in supporting medication adherence is likely to impact on future evaluations and implementation of the ID-MAP intervention (an intervention which focuses specifically on adherence). It is therefore important to explore exactly what CPs in NI are doing to support older patients with medication adherence in greater detail. It is also important to explore perceived barriers and facilitators faced by CPs in providing MAS to identify how these could be addressed as part of a future training package and/or to help identify strategies to

improve implementation (e.g. as part of future research studies). The target behaviour in this chapter is therefore the 'provision of MAS to older adults prescribed polypharmacy' and the target audience is CPs.

5.1.3. Using the Theoretical Domains Framework to explore community pharmacists' behaviour

Training packages for HCPs often contain multiple interacting components and can therefore be seen as a form of complex intervention. Thus, in line with recommendations from the MRC, theory could be useful in enhancing the content of this training package. The TDF, which was used previously to develop the patient-targeted (ID-MAP) intervention as outlined in previous chapters, was originally developed to act as a 'theoretical lens' to explore HCPs' clinical behaviours (Michie et al. 2005). The TDF can be used to gain a more comprehensive understanding of the key influences (barriers, facilitators) on the target behaviour and identify exactly what aspects should be targeted to bring about behaviour change.

As discussed previously, the vast majority of TDF-based studies have adopted qualitative research designs such as interviews or focus groups (Francis et al. 2012). More recently researchers have recognised the potential usefulness of quantitative research designs, such as surveys, in TDF-based research studies (Brotherton et al. 2010; Amemori et al. 2011; Gnich et al. 2015). For instance, Amemori et al. (2011) developed a 35-item questionnaire using the TDF to explore barriers and facilitators to the provision of smoking cessation counselling by dentists. As noted in Chapter 3, qualitative methods are limited by their generalisability (although the findings can often be transferred to other contexts i.e. transferability). Quantitative designs, such as surveys, offer an opportunity to increase the generalisability of findings, but one disadvantage is that they are restricted by the depth of information that can be obtained. This is of particular importance when little is known about the target behaviour, as is the case for the behaviour under investigation in the current study.

5.1.4 Mixed methods studies using the Theoretical Domains Framework

To overcome known limitations of both qualitative and quantitative research designs, a number of TDF-based studies have combined these two approaches (Brotherton et al. 2010; Clarkson et al. 2010; Dyson et al. 2011). For example, Brotherton et al. (2010) conducted TDF-based qualitative interviews initially to explore, in detail, the delivery of a Human Papillomavirus Vaccination programme by GPs, followed by a TDF-based quantitative survey to explore the views of a larger sample of GPs. The preliminary qualitative findings also helped to inform the content of the quantitative survey.

Upon identification of barriers and facilitators using both qualitative and quantitative approaches (with the former informing the content of the later), the findings can be triangulated. Triangulation has been defined as the process of combining different approaches or methods within a research study with the use of qualitative and quantitative approaches described as a 'mixed methods' study (Erzberger and Prein, 1997; Lingard et al. 2008; O'Cathain et al. 2010). The process of triangulation involves looking for convergence (i.e. similar information) and/or discrepancies (i.e. contradictory information) between findings of multiple approaches. This can help gain a more complete picture of the topic under question (O'Cathain et al. 2010) which can then inform the selection of theoretical domains to target for behaviour change. Key domains can subsequently be mapped across to BCTs for inclusion as the active ingredients of an intervention, such as a training package for CPs (Michie et al. 2008; Cane et al. 2015; Michie et al. 2015).

The current chapter outlines findings from a mixed methods study that focused on the identification of determinants (barriers, facilitators) perceived to be influencing the provision of MAS by CPs (specifically to older patients prescribed polypharmacy). In-depth qualitative interviews informed the content of a quantitative survey that aimed to gain a broader overview from a larger sample of CPs from across NI. Qualitative and quantitative findings were triangulated and informed the selection of key TDF domains to target for behaviour change. This chapter also outlines the process of mapping from key TDF domains to BCTs for inclusion in a training package for CPs and/or to deliver as part of a future research study to improve the provision of MAS and subsequent implementation of the ID-MAP intervention.

5.2 Aims and objectives

The overall aim of the current study was to select components (i.e. BCTs) to include in a theory-based training package for CPs (and/or to deliver as part of a future research study) to improve the provision of MAS (specifically to older adults prescribed polypharmacy). The key purpose of this was to improve the future implementation of the patient-targeted (ID-MAP) intervention. The TDF was selected as the underpinning theoretical framework of behavioural determinants for this mixed methods study. The main objectives were to:

- Identify determinants (barriers, facilitators) perceived to influence the provision of MAS from the viewpoint of CPs using TDF-based qualitative interviews
- Explore CPs' experiences of providing MAS (target behaviour) to older adults prescribed polypharmacy using a cross-sectional survey

- Identify determinants (barriers, facilitators) perceived to be influencing the provision of MAS by CPs using a TDF-based cross-sectional survey
- Triangulate data from qualitative and quantitative approaches to inform the selection of key TDF domains that could be targeted for behaviour change
- Map key TDF domains across to BCTs that could be included in a theory-based CP training package and/or delivered as part of a future research study to improve the implementation of the patient-targeted (ID-MAP) intervention

5.3 Research design and methodology

5.3.1. Rationale for choice of research design

As discussed previously, qualitative research designs have been the most commonly used approach in TDF-based research studies. However, it is recognised that this approach is limited by the lack of generalisability beyond the study sample. To explore the views of a larger number of CPs in order to increase the generalisability of findings, a mixed methods research design using both qualitative and quantitative approaches was adopted for the current study. Qualitative research design has been discussed in detail in Chapter 3 (Section 3.3.2). An overview of quantitative research design is provided below (Section 5.3.2).

5.3.2 Overview of quantitative research design

Quantitative research involves the collection and analysis of numerical data (Sukamolson, 2007). This encompasses experimental, cross-sectional and longitudinal research (Bryman, 2013). Experimental research includes clinical trials, such as RCTs, which compare findings between intervention and control groups. Cross-sectional studies collect data from a group of participants at a single point in time, whereas longitudinal studies collect data at multiple points in time (Neuman, 2013). Examples of cross-sectional studies include structured observations and surveys. Structured observations involve the researcher observing the phenomenon of interest (e.g. a specific behaviour) in the original setting, whereas surveys can be used to collect data on characteristics, attitudes and behaviours of individuals (Bryman, 2013). Surveys are the most commonly used cross-sectional research method in pharmacy practice research due to their efficiency and relatively low cost. Surveys will therefore be the focus of the following sections (Aparasu, 2011).

Administration of surveys

Questionnaires (i.e. a structured list of questions) are the measurement tool used to collect data in survey research; these can be administered by the researcher or self-administered (Bryman,

2013). Self-administered questionnaires are less time-consuming and negate the interviewer effect seen with researcher-administered questionnaires. However, self-administered questionnaires often achieve lower response rates than researcher-administered questionnaires. It is also not possible to prompt for additional information with self-administered questionnaires and they are restricted by the number of questions that can be asked (Bryman, 2013; Bresee, 2014). Self-administered questionnaires can be either electronic (participants are emailed a link to the questionnaire) or paper-based (a paper copy of the questionnaire is sent via post to participants) (Neuman, 2013). Electronic questionnaires generally achieve lower response rates than paper-based questionnaires, but the latter can be more expensive and time-consuming to prepare and analyse. It is necessary to have access to participants' email addresses for electronic questionnaires and postal addresses for postal questionnaires; thus the type of information available to the researcher may dictate the method that is adopted (Bresee, 2014).

Sampling and generalisability of surveys

One of the key advantages of quantitative survey research is the potential ability to generalise the research findings beyond the study sample, a concept referred to as external validity (Lavrakas, 2008). As it is generally not feasible to survey all of the population, a sample of the population is generally surveyed (Neuman, 2013). The preferred method of sampling is random (probability) sampling as this ensures that all individuals in the population have an equal chance of being selected, therefore generating a more representative sample. Non-random (non-probability) sampling strategies, such as convenience or purposive sampling are used in circumstances where the researcher does not have access to details of, or access to, every individual in the population (Bryman, 2013).

Survey response rates

The survey response rate is defined as the number of returned and completed questionnaires divided by the number of questionnaires that were distributed. A response rate of 60% or higher is desirable (Bryman, 2013) but this is often difficult to achieve in the context of health services research. As mentioned previously, the method of questionnaire administration (e.g. postal, electronic) has been shown to have an impact on the response rate. This has been illustrated in a US study by Hardigan et al. (2016) that explored differences in survey response rates from pharmacists (predominantly community-based) across three different methods: postal survey (21.0%), email link to online survey (6.8%), mailed postcard link to online survey (3.2%). The

postal method achieved the highest response rate in this study and was also deemed to be the most cost effective method.

Postal survey response rates reported from research studies involving healthcare professionals (HCPs) in the literature have ranged from as low as 20% up to as high as 90% (Smith, 1997; Paul, 2005; Barry et al. 2013; Cottrell et al. 2015; Millar et al. 2016). Smith (1997) indicated that postal survey response rates from CPs have ranged from around 30% to over 90%, although the cause of this wide variation is unknown. Cook et al. (2009) discussed how 'response rates to postal surveys of healthcare professionals are low and probably declining' which is likely due to survey fatigue. A recent Australian survey, similar to the one presented in this chapter, aimed to explore CPs' 'attitudes and perceived barriers to [the] provision of adherence support'. The study investigators distributed a postal questionnaire to 500 randomly selected community pharmacies in New South Wales (Australia) and obtained a response rate of 27.6% (Mansoor et al. 2014).

There are a range of factors that have been shown to improve postal survey response rates such as reminder mailings, assurances of confidentiality, incentives (monetary and non-monetary), pre-notification and follow-up telephone calls. However, some of these strategies can significantly increase the cost of the research study (e.g. incentives) or are time-consuming (e.g. follow-up telephone calls). In relation to the length of the questionnaire, shorter questionnaires have been shown to improve response rates (Edwards et al. 2009). There is a delicate balance between collecting sufficient information to explore the research questions and avoiding respondent fatigue and subsequent non-response. Despite this, there is a lack of evidence to indicate the optimal or maximum length of postal questionnaires (Nakash et al. 2006).

It is commonly suggested that low survey response rates lead to non-response bias, whereby there are potential differences in responses to survey items between responders and non-responders (Halbesleben and Whitman, 2013). Non-response bias can impact on the quality of the study and external validity (i.e. generalisability of findings beyond the study sample). Although response rates are often used as a proxy measure for non-response bias, Davern (2013) argues that this proxy measure lacks both strong reliability and validity. Instead of focusing solely on response rates, it is recommended that researchers take additional steps, where possible, to assess potential non-response bias (Davern, 2013; Halbesleben and Whitman, 2013). One suggested method of doing so is through the comparison of key characteristics (e.g. gender, age) of the study sample with those of the population of interest (MacDonald et al. 2009; Halbesleben and Whitman, 2013).

It is also important to recognise that the impact of a low response rate is likely to be of greatest significance when a random (probability) sampling strategy has been adopted. It has been argued that where non-random sampling strategies have been used, a low response rate is of less significance because even with a 100% response rate, the sample would still not be truly representative as the selection process was non-random (Bryman, 2013).

Question format and wording

When developing questionnaires, the nature of included questions need to be carefully considered. Questions can be broadly divided into closed and open-style formats. For self-administered surveys it is recommended that open-style questions should be kept to a minimum as these are both time-consuming for participants to answer and for the researcher to analyse (Bryman, 2013; Neuman, 2013). Although closed questions are easier to process, they can be restrictive in terms of the depth of information that can be obtained.

When designing survey questions, researchers should avoid ambiguous, double-barrelled, leading or double-negative questions/statements where possible (Neuman, 2013; Bresee, 2014). An example of a double-negative statement would be: 'It is not true that those in senior positions do not support me with providing MAS to older people'. Prior to distributing the questionnaire, it should be piloted with a small sample of individuals who are deemed to be similar to the study population. The aim of this is to ensure that all items in the questionnaire are clear and unambiguous and to give an estimate of completion time (Bryman, 2013). Where possible, standardised rating scales should be adopted for example, the most common strategy for measuring attitudes is the use of Likert items and scales (Likert, 1932).

Likert items and Likert sales

The Likert Scale was originally developed in 1932 by Rensis Likert (Likert, 1932). Individual questionnaire items are termed 'Likert items' whereas the combination of multiple Likert items are referred to as 'Likert scales' (Clason and Dormody, 1994; Uebersax, 2006; Boone and Boone, 2012). A Likert item consists of a statement with multiple-response options (e.g. five to seven responses). The most commonly used format is the five response option (strongly agree, agree, neither agree nor disagree, disagree and strongly disagree) (Bryman, 2013). Likert items usually include a middle neutral response (e.g. neither agree nor disagree) to avoid forcing respondents to select a response that they do not truly believe. Responders who choose the neutral response may not hold an opinion or simply do not wish to think about the statement in-depth. Multiple Likert items are often used in questionnaires for consistency in responses. For data analysis purposes, each response to a Likert item can be assigned an integer as a score (e.g. 1 for strongly

agree up to 5 for strongly disagree or vice versa). In some cases, Likert item scores can be combined to produce a summative scale score (e.g. items around a particular trait or personality may be combined into a scale) (Clason and Dormody, 1994).

When combining Likert items into a scale it is important to ensure the items are similar and that the scale has internal consistency; this concept is commonly measured using Cronbach's alpha (α) on a scale of 0 to 1. Internal consistency has been defined as 'the extent to which items on the test or instrument are measuring the same thing' with higher α scores (closer to 1) indicating greater similarities between items (Bolarinwa, 2015). An α value above 0.7 is generally deemed sufficient for scaling multiple Likert items, although some researchers argue that lower values such as 0.6 are sufficient (Bryman, 2013). If a scale has an α value below the ideal cut-off point, it indicates that the items are potentially measuring different concepts (e.g. different theoretical constructs) and it would therefore be inappropriate to combine the items into the proposed scale. Alternatively, the Likert items can be analysed individually as ordinal-type questions (Clason and Dormody, 1994; Boone and Boone, 2012; Sullivan and Artino, 2013).

Reliability and validity

The reliability and validity of a questionnaire are commonly considered in survey research. The reliability (also termed stability) of a questionnaire, is the extent to which the results would be replicated if the study were to be repeated (i.e. whether the questions would be answered in the same way by participants on multiple occasions) (de Vaus, 2014). The most common method for measuring the reliability of a questionnaire is the test-re-test approach, however, due to time restrictions, this was deemed beyond the scope of the current project (Bryman, 2013).

Validity is another important concept in survey research (i.e. whether the questionnaire has truly measured the concept that it was designed to measure). Bryman (2013) indicates that when developing a new questionnaire, as a minimum, face validity should be determined. Face validity is an assessment that the measure appears, albeit on the surface, to reflect the key concepts that it aims to measure. Other more complex methods are available to measure validity (e.g. concurrent validity) but these were deemed to be beyond the scope of this project and are therefore not discussed (Bolarinwa, 2015).

Analysis of survey findings

Researchers most commonly use surveys to describe the phenomenon or behaviour of interest based on data collected at a single point in time (Smith, 1997). Consequently, descriptive analysis is most frequently employed to analyse and present the findings of surveys (e.g. cross-tabulations, measures of central tendencies such as means and medians). In some cases,

collected survey data can be analysed through the use of inferential statistics (e.g. parametric or non-parametric tests, regression analyses—a type of statistical test used to look for associations between dependent and independent variable) (Field, 2013). For instance, responses to Likert items between groups of respondents (e.g. males and females) could be compared or associations between attitudes and self-reported behaviour could be explored using inferential statistics (e.g. regression analysis) (Aparasu, 2011). It is important to note that although cross-sectional research can help to identify possible associations, it cannot prove causality (i.e. it cannot prove that a certain characteristic or attitude causes a behaviour) (Bryman, 2013). In the context of the current study, the target behaviour (provision of MAS by CPs to older adults prescribed polypharmacy) could not be measured discreetly due to its complexity as discussed previously in Section 5.1. Accordingly, it was not possible to perform regression analysis to look for associations between CPs' attitudes (independent variable) and their current MAS behaviour (dependent variable).

5.3.3. Overview of the mixed methods research design

The mixed methods study outlined in this chapter was separated into two sequential phases: in-depth qualitative interviews with CPs (Phase 1), followed by a quantitative survey (Phase 2) to gain a broader overview of the experiences and attitudes of CPs from across the region of NI. Ethical approval for the study was granted by the School of Pharmacy (Queen's University Belfast) research ethics committee (Appendix 5.1). The qualitative aspect of this mixed methods study has been reported in line with the COREQ checklist (see Section 5.5.6) which aims to ensure comprehensive reporting of qualitative methods including interviews (Tong et al. 2007).

TDF1 (12 domains) was selected as the theoretical framework of choice for this mixed methods study (Michie et al. 2005). The decision was made on the basis that this was the theoretical framework used in the development of the previous patient-targeted adherence intervention (ID-MAP intervention; see Chapters 3 and 4). In addition, Huijq et al. (2014b) assessed the distinctiveness of theoretical domains in TDF using a discriminant content validity exercise with 19 experts in behaviour change to assess whether items were assigned to one or multiple domains. Their findings supported 'keeping to the 12 original domains as a basis for the development of TDF questionnaires'. The specific methods employed for Phase 1 (qualitative) and Phase 2 (quantitative) of the study are outlined in more detail below.

5.3.4 Phase 1: Qualitative methods (interviews)

Rationale for the use of semi-structured interviews

TDF-based semi-structured qualitative interviews were selected to gain an initial in-depth understanding of the target behaviour (provision of MAS to older adults prescribed polypharmacy). Interviews were selected over focus groups as they were deemed a more cost-effective approach for the target audience (CPs) in this study. Focus groups would have been more difficult to schedule and more expensive (in comparison with interviews) as it would be necessary to compensate CPs for their time, locum cover and travel expenses to attend.

Sampling and recruitment strategy

To be eligible for inclusion in this study, CPs had to be currently working in a registered community pharmacy in NI. CPs who had previously taken part in the feasibility study (Chapter 4) were not eligible to participate. A purposive (non-probability) sampling strategy was selected to allow for a wide variety of locations and types of pharmacies (independently owned pharmacies and chains). The sampling frame initially included CPs who were part of the School of Pharmacy undergraduate community pharmacy placement Network (QUB). This network included CPs from 164 pharmacies including independently owned pharmacies (n=24), small/medium chains (2-9 pharmacies) (n=64) and large chains (10+ pharmacies) (n=76) from across both urban and rural areas in NI. A 'snowball sampling' approach was also used, whereby recruited participants identified other potentially 'information-rich' individuals (Atkinson and Flint, 2001). Due to the nature of qualitative research, the sample size was determined by data saturation (i.e. the point at which no new themes were emerging) (Fusch and Ness, 2015). Preliminary data analysis ran concurrently with data collection to aid the identification of this point.

Upon identification of CPs using the sampling strategy detailed above, the researcher (DP) made initial contact via telephone to inform them of the research study and invite them to take part. At this stage, CPs who expressed an interest in taking part were e-mailed a formal letter of invitation (Appendix 5.2), along with a study information sheet (Appendix 5.3). CPs were given a minimum of 5 working days to decide if they would like to take part, after which point the researcher followed up with a telephone call.

Interview topic guide

A semi-structured interview topic guide was developed by the research team (Appendix 5.4). Key interview questions were developed based on the 12 theoretical domains in TDF1 (Michie et al. 2005). Examples of questions included:

- What skills do you currently have as a community pharmacist that would enable you to provide medication adherence support to an older adult who is prescribed polypharmacy? [Skills domain]
- To what extent is providing medication adherence support to older adults prescribed polypharmacy a priority for you? [Motivation and goals domain]

Prompts were included in the topic guide to elicit additional information from participants where necessary. The interview topic guide was piloted with two researchers from the Clinical and Practice Research Group (QUB) who were both practising in the community pharmacy setting (on a part-time basis) at the time of the study and had experience of providing MAS to older adults. Minor refinements were made to the topic guide based on feedback from pilot participants, for example, the wording of a small number of questions were slightly altered to improve clarity.

Conduct of interviews

Each interview took place via face-to-face at a time and location that was convenient for both the CP and the researcher (e.g. pharmacy site, CP's own home). The researcher (DP, MPharm, PhD Research Student/practising community pharmacist) had previous experience with qualitative research (focus groups) and had attended relevant training on qualitative research methodologies. Interviews were held between August and November 2016. Prior to the start of the interview, informed consent was collected in-person by the researcher (Appendix 5.5). Demographic details (e.g. job title, years qualified) were obtained at each interview to provide an overview of demographics of study participants. Each participant was offered an honorarium of £50 to account for the time dedicated to this study (funding was provided by the Harold and Marjorie Moss Charitable Trust Fund). Each interviewee was provided a certificate of participation on completion of the interview (Appendix 5.6).

With participants' permission, the interviews were audio-recorded and transcribed verbatim by the researcher. To ensure confidentiality, each participant was allocated a unique identification number (e.g. CP01, CP02 etc.). Transcripts were checked for accuracy prior to importing into a software package (NVivo® QSR 11) for organisation and analysis by the researcher (see Section

5.3.6 for further information on data analysis). All recordings, consent forms and personal contact details were stored either in a locked fire-resistant filing cabinet or on a password protected laptop, to which only the research team had access.

5.3.5 Phase 2: Quantitative methods (survey)

Rationale for the use of self-administered postal survey

Following on from Phase 1 which involved in-depth qualitative interviews with a sample of CPs, Phase 2 aimed to gain a broader overview of the experiences and attitudes of CPs from across NI using a self-administered postal survey. This approach was selected as it allowed information to be obtained from a larger sample of participants within a short period of time and with relatively little cost. A self-administered approach was selected as this helps to avoid the 'interviewer effect' which can otherwise lead to social desirability bias (Bryman, 2013). A postal survey was selected over an electronic survey due to the poor response rates often associated with the latter (Neuman, 2013; Hardigan et al. 2016). In addition, individual email addresses were not available to the researcher, making electronic distribution unfeasible.

Content of questionnaire

The questionnaire (Appendix 5.7) contained three sections as outlined in Figure 5.1 below. The structure and content of the questionnaire was developed based on similar literature (Bright et al. 2009; Mansoor et al. 2014; Mansoor et al. 2015; Clyne et al. 2016), findings from the qualitative interviews (Phase 1), and with respect to the theoretical domains in TDF1 (Michie et al. 2005). Discussions within the research team helped to refine the content of the questionnaire.

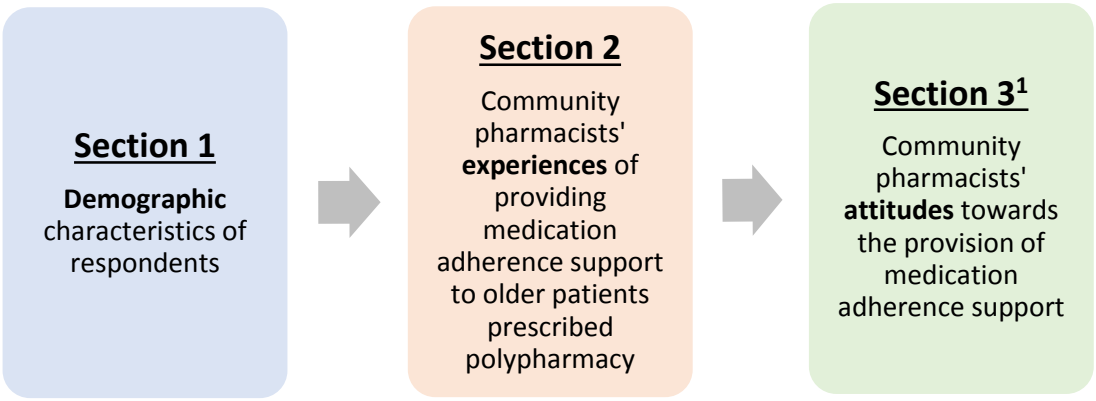


Figure 5.1: An overview of the content of the three sections within the questionnaire

[1]TDF section of the questionnaire

Section 1 of the questionnaire contained demographic questions (n=16) including questions about gender, number of years practising as a CP, type of community pharmacy store they worked in, training undertaken on medication adherence and current service provision (i.e. MUR and MYM provision).

Section 2 of the questionnaire focused on CPs' experience of providing MAS. At the start of this section, a brief overview of the 2009 NICE guidance on MAS provision was provided (National Institute for Health and Clinical Excellence, 2009). This outlined exactly what MAS entailed (i.e. identifying/assessing non-adherence and delivering tailored interventions to improve adherence) and included illustrative examples. It was deemed necessary to include this information for the benefit of those who were unfamiliar with the term 'medication adherence support'. The qualitative aspect of this study (Phase 1) highlighted that some CPs associate the term solely with the provision of MDS (plastic containers which segregate medications into days and times of the week to aid administration), as opposed to the full range of activities that medication adherence can encompass.

Following the overview of NICE guidance, CPs were asked to report how frequently they identified/assessed non-adherence in older patients (e.g. through pharmacy-held records) and how frequently they delivered tailored adherence interventions (e.g. recommended the use of self-monitoring strategies). In total there were 24 items in this section, each based on a five point Likert-type ordinal scale (very frequently, frequently, occasionally, rarely, never/not at all). An open-style question was presented at the end of this section to identify any additional adherence support activities that were not previously covered.

Section 3 of the questionnaire focused on CPs' attitudes (barriers, facilitators) towards the provision of MAS. TDF1 was used as the theoretical framework for this section and 11 out of the 12 domains were assessed. As highlighted previously, the 'Nature of behaviours' domain has been described as slightly different from the other domains in TDF1 in that it represents 'essential characteristics of the behaviour' (dependent variable), rather than a predictor of the behaviour (independent variable) (Cane et al. 2012). The nature of behaviours was assessed as part of Section 2 of the questionnaire which examined CPs' experiences of providing MAS and so was excluded from Section 3.

TDF1 is a comprehensive framework with 12 theoretical domains, each of which includes a range of theoretical constructs, ranging from 4 to 24 constructs per domain (Michie et al. 2005). As it was deemed impractical to measure each individual construct sufficiently as part of the questionnaire, barriers and facilitators to the target behaviour were assessed at the domain

level. Between two to five Likert items (on a 5 point scale; strongly agree to strongly disagree) were assigned to each TDF domain (n=11) using a group consensus approach (37 items in total). This method followed the approaches used in the development of previous TDF-based questionnaires (Amemori et al. 2011; Beenstock et al. 2012; Manikam et al. 2015; McParlin et al. 2016). For example, the item 'I know how to provide medication adherence support to older patients in line with NICE guidance' was assigned to the domain 'Knowledge' and the item 'I am confident that I can address any medication adherence problems that I encounter with older patients' was assigned to the domain 'Beliefs about capabilities'. Likert items within each domain were developed based on barriers and facilitators that had been identified in the qualitative interviews (Phase 1). Where possible, Likert items (n=21) were adapted from previous TDF-based questionnaires (Amemori et al. 2011; Beenstock et al. 2012; Taylor et al. 2013; Huijg et al. 2014a; McParlin et al. 2016). To ensure relevance to the current context, it was necessary to devise a number of new items (n=16) based on the qualitative findings. At the end of this section, CPs were instructed to provide any further comments they felt were relevant to the provision of MAS. This open-style question aimed to identify any additional barriers or facilitators to providing MAS that had not been covered previously.

The approach undertaken in developing the questionnaire aimed to ensure that its content covered the main research questions whilst being relevant to the target audience and as short as possible. This was deemed necessary to reduce 'respondent fatigue' and maximise the response rate (Bryman, 2013).

Face validity and piloting of questionnaire

Face validity of the questionnaire was assessed by three members of the research team (with experience of using the TDF) who assessed whether the items assigned to each theoretical domain, appeared on the surface to measure what they were intended to measure. The questionnaire was also piloted with five pharmacists from the Clinical and Practice Research Group at QUB who had current (n=4) or previous experience (n=1) of working in the community pharmacy setting and experience of providing MAS to older people. The aim of this was to ensure the readability and acceptability of the questionnaire. Following pilot testing, minor amendments were made to questions (e.g. ambiguous items were reworded) prior to the first mailing to CPs. Pilot responses were not included in the final sample.

Sampling and recruitment strategy

The target population for the questionnaire was CPs working in the region of NI, excluding those who had participated in Phase 1 of the current study (qualitative interviews) or in the previous

feasibility study (Chapter 4). The Pharmaceutical Society of Northern Ireland (PSNI) is the regulatory body with which all CPs working in NI are required to register. The PSNI register contains over 2,400 pharmacists working across a range of sectors including community, hospital, industry, and academia. Although it was possible to search for the surnames of pharmacists who were registered with the PSNI, the contact details of individual CPs were confidential and unavailable for research purposes. The PSNI were able to provide addresses for all currently registered pharmacy premises in NI. The list provided by the Society included other types of pharmacy premises such as prison and hospital pharmacies. The list (generated by the PSNI) was hand-searched and pharmacies other than community pharmacies were removed (in addition to pharmacies that participated in Phase 1 and in the feasibility study as discussed above). The final list, which included 521 community pharmacies, was used as the sampling framework for this quantitative study.

Distribution of questionnaires

A short invitation letter (Appendix 5.8), paper copy of the questionnaire and freepost return envelope was posted to the 521 community pharmacies in the sampling framework. As the names of individual CPs working in each pharmacy were not available to the researcher, letters were addressed to the 'pharmacist in charge'. It was anticipated that the questionnaire would most likely be answered by the store manager/proprietor, however, pharmacists in other roles (e.g. support pharmacists) were not prohibited from taking part. A specific date for completion was highlighted in the invitation letter and participants were informed that their anonymity would be guaranteed. The letter provided a brief overview of the research study and included contact details for the research team for those wishing to find out further information or ask any questions.

As a reminder and to encourage completion, a complete re-mailing was carried out four weeks after the first postal mailing. This second mailing included a reminder letter (Appendix 5.9) in addition to another copy of the questionnaire. As the survey was anonymous, it was necessary to post reminder copies to all community pharmacies in the sampling frame (n=521). The reminder letter clearly indicated that those CPs who had already taken the time to complete the questionnaire did not need to complete it again. Participation in the study was voluntary and informed consent was implied on the completion and return of the questionnaire to the research team.

Response rate and non-response bias

As discussed above, to maximise the response rate, a reminder copy of the questionnaire was posted out after four weeks. Efforts were made to restrict the length of the questionnaire and e-signatures of the researchers were included on the cover letter to personalise it. Due to a lack of information about CPs working in each pharmacy, it was not possible to address letters to individual pharmacists. Incentives were not included due to the costs associated with these. Following a low initial response rate, the research protocol was amended and ethical approval was sought to promote the questionnaire via relevant social media outlets (e.g. Twitter) after the second mailing of the questionnaire.

Demographic data were also collected from respondents to allow this to be compared to demographic data from all pharmacists on the PSNI register. The aim of this was to help identify any differences between responders and non-responders so that potential non-response bias could be detected.

Questionnaire data management

Each respondent was assigned a unique identifier number based on the order in which questionnaires were returned (e.g. R01, where R denoted respondent and 01 denoted the questionnaire number). Questionnaire responses were entered by the researcher into IBM's SPSS Version 24.0. Any missing responses were coded according and were subsequently excluded from statistical analyses (see Section 5.3.6 for details of data analysis). To check for inaccuracies in coding, a random 10% sample was generated in SPSS and double-checked. Out of the 1,290 variables that were double-checked, only three inaccuracies were identified (and corrected) giving an inaccuracy rate of 0.23%; this low level was deemed to be acceptable. Qualitative responses from the two open-style questions were entered into Microsoft Word 2016.

5.3.6 Data analysis of interviews and questionnaires

In a similar approach used to develop the patient-targeted intervention (see Chapter 3; qualitative methods only), data analysis for the current study consisted of three key stages. For the current mixed methods study, it was necessary to slightly modify data analysis Stages 1 and 2 (from Figure 3.1 in Chapter 3) to incorporate the additional quantitative methods employed. The three stages have been summarised in Figure 5.2 with further details provided in the subsequent text.

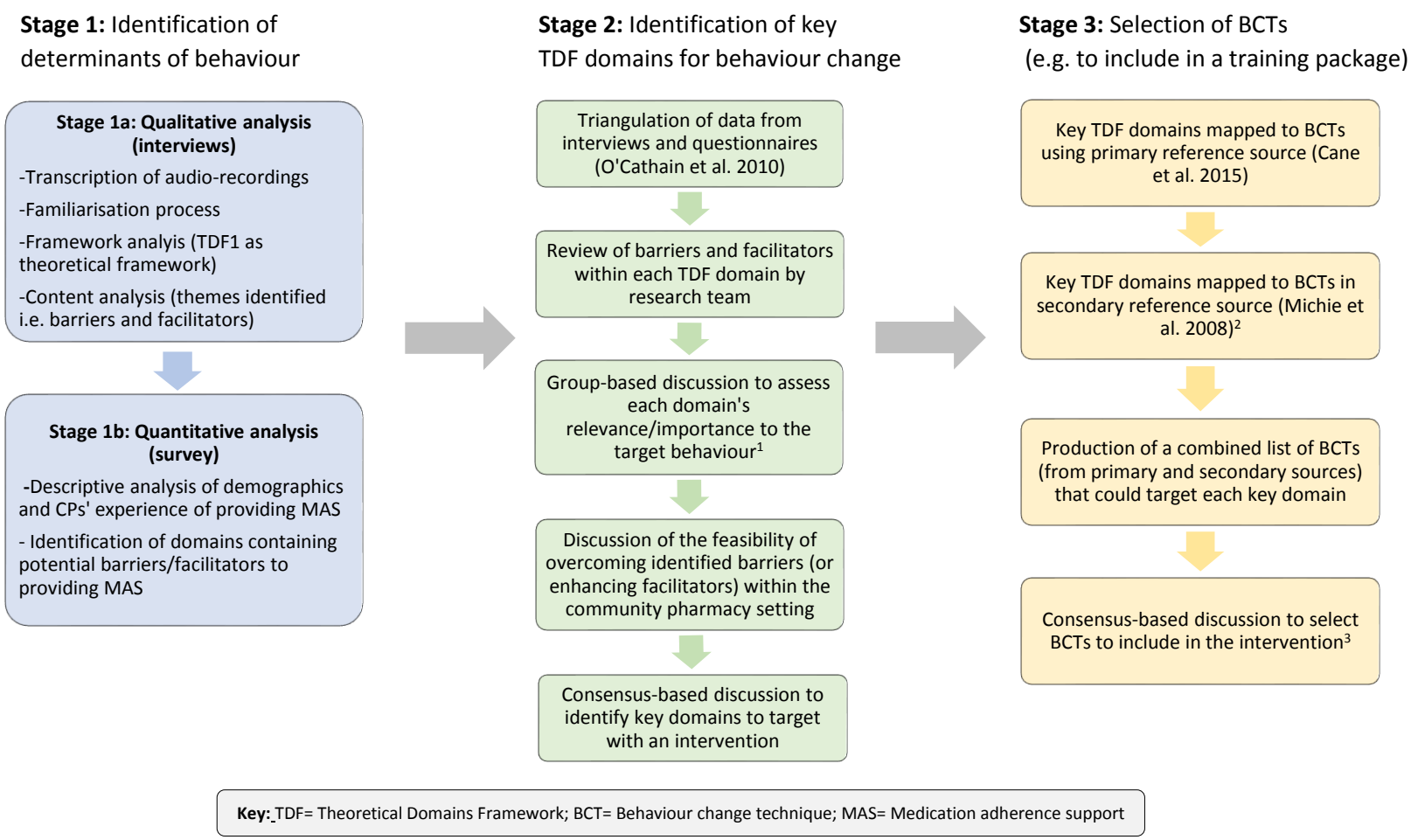


Figure 5.2: An overview of the three stages involved in data analysis

[1] Domain was considered relevant/important if it was frequently coded as part of the qualitative analysis (interviews) and/or it contained items that reflected potential barriers/facilitators to the target behaviour based on the quantitative analysis (survey); [2] No BCTs mapped to 'Memory, attention and decision processes' and 'Social/professional role and identity' domains in the primary reference source hence the secondary reference source was consulted; [3] Selection of BCTs was based on expected feasibility of BCT delivery as part of a CP training package (and/or in a future research study) and applicability to the target behaviour and audience

Data analysis Stage 1a: Identification of determinants of medication adherence support provision by CPs from qualitative interviews

In line with methods outlined previously (Chapter 3), qualitative data analysis consisted of: familiarisation, framework analysis (with TDF1 as the analytical framework) and inductive content analysis to identify emergent themes (i.e. barriers and facilitators) within each TDF domain. Data analysis was undertaken by three independent researchers (two researchers per transcript) and disagreements were resolved through discussion. Refer back to Chapter 3 (Section 3.3.7) for further details of these methods.

Data analysis Stage 1b: Identification of determinants of medication adherence support provision by CPs from the quantitative survey

Descriptive statistical analyses (e.g. frequencies, means, ranges) were conducted for demographic data collected in Section 1 of the questionnaire (e.g. gender, years practising as a CP). Descriptive statistical analyses (frequencies) were also employed for Section 2 of the questionnaire which explored CPs' experience of providing MAS to older adults prescribed pharmacy (e.g. frequency of providing MDS, frequency of recommending the use of reminder strategies). Responses from the open-style questions (n=2) in the questionnaire were qualitatively analysed for emergent themes.

Section 3 of the questionnaire explored CPs' attitudes (i.e. determinants) towards the provision of MAS to older adults prescribed polypharmacy. Descriptive statistical analyses were employed to explore the proportion of CPs in agreement or disagreement with each Likert item in this section (n=37; each Likert item was assigned to one of 11 domains in TDF1). Each individual response to Likert items was assigned an integer (strongly agree=1, agree=2, neither agree nor disagree=3, disagree=4, strongly disagree=5).

The median value for each individual Likert item was then calculated as a measure of central tendency. For ordinal data (e.g. individual Likert items), calculating the median is more appropriate than calculating the mean as the difference between responses cannot be deemed equivalent (Jamieson, 2004). The median is also more appropriate where data are skewed as this measure is not as strongly affected by outliers (Laerd, 2013). Lower median scores for a Likert item (score of 1 or 2) indicated mainly agreement with the Likert statement highlighting that respondents did not deem this to be a barrier to the target behaviour. Higher scores for a Likert item (score of 4 or 5) indicated more disagreement with the Likert statement, highlighting a potential barrier to the target behaviour. For ease of data interpretation some items were reverse-phrased from their original phrasing in the questionnaire so that all items could be analysed in the way described above to identify

potential barriers (see Section 5.4.2) For example, if CPs mainly disagreed with the Likert item 'I know how to provide medication adherence support in line with NICE guidance' (domain: knowledge) then this would produce a high median indicating a potential barrier (i.e. a lack of knowledge). Therefore, when interpreting the quantitative findings, although the term barrier is mainly used, it is recognised that some items are potentially facilitators when reverse worded. TDF domains that contained at least one Likert-item with a high median score of 4 or 5 were identified as possible targets for behaviour change as these contained potential barriers to the target behaviour. For example, if a median score of 4 was calculated for the Likert-item 'I receive sufficient reimbursement for providing MAS to older patients' (domain: 'Motivation and goals'), this would have indicated that pharmacists mainly disagreed with the attitude statement and felt they received insufficient reimbursement, highlighting a potential barrier. Subsequently, the TDF domain 'Motivation and goals' would have been considered as a potential target for behaviour change. One item ['Others (e.g. GPs, carers) decide which adherence support strategies are required by older patients] had the potential to be either a barrier or facilitator depending on the appropriateness of the recommendations made and was therefore excluded from this analysis.

Data collected from Likert items were considered to be ordinal data and therefore not normally distributed (evident from skewed frequency distribution graphs). Consequently, non-parametric tests were deemed more appropriate and used to explore associations between different groups of CPs (e.g. males and females) and their responses to individual Likert items within each TDF domain (n=36). Mann-Whitney U (MWU) was selected for two independent groups (e.g. gender) and Kruskal-Wallis (KW) was selected for three independent groups (type of pharmacy). Where significant differences were identified using KW, post-hoc pairwise comparisons were explored (Dunn's multiple comparisons test) and significance values adjusted using the Bonferroni correction for multiple tests. This adjustment was necessary because the performance of multiple tests on a data set can lead to an increased risk of Type 1 error (i.e. determining that there is a significant difference when one does not truly exist) (Field, 2013). MWU and KW were selected over the Chi (X^2) squared test as the latter does not take into account the ordered nature of the response categories seen with Likert items (Pallant, 2013). A 95% level of probability was set *a priori* with probability (p) values less than 0.05 deemed to be significant.

Previous researchers who have designed TDF-based questionnaires have calculated Cronbach's alpha (α) values for each TDF domain as an indication of how closely items assigned to a domain were related (Amemori et al. 2011; McParlin et al. 2016). As discussed

in Section 5.3.2, a minimum α value of 0.6 has been deemed sufficient for combining individual Likert items into a scale (Bryman, 2013). For the current study, Cronbach alpha values were less than 0.6 for six out of the 11 TDF domains assessed. It was therefore deemed inappropriate to combine median scores from individual Likert-items within each domain to calculate total median domain scores.

To explore alternative underlying structures, researchers have undertaken factor analysis techniques such as Exploratory Factor Analysis (Amemori et al. 2011; Manikam et al. 2015) or Principal Components Analysis (PCA) (Beenstock et al. 2012; Alqubaisi et al. 2016; McParlin et al. 2016). For factor analysis, both Field (2013) and Pallant (2013) recommend that a sample size of 300 is ideally recommended in order to produce a stable factor solution. Others have argued that a minimum sample size of 150 respondents is required (Hutcheson and Sofroniou, 1999). In addition to an adequate sample size, it is recommended that the ratio of respondents to items is ideally 10:1 but again others have argued that a ratio as low as 5:1 is sufficient (Nunnally, 1978; Hutcheson and Sofroniou, 1999; Osborne and Costello, 2004). Factor analysis was not deemed appropriate for the current study as the sample size was below the recommended limit [n=135 when respondents with missing responses for any TDF item were excluded (listwise exclusion) and n=139-142 when respondents were only removed if there was a missing response to a particular item (pairwise exclusion) (Field, 2013)]. In addition, the respondent to item ratio (3.9:1) was also below the lower recommended limit. This decision was made because inappropriate use of factor analysis could result in the incorrect extraction of factors/components and incorrect assignment of items to factors/components which could potentially lead to erroneous conclusions. Accordingly, it was deemed more appropriate to analyse individual Likert items that were assigned to each domain *a priori* using group consensus.

Data analysis Stage 2: Triangulation of findings and identification of key TDF domains

Data from qualitative and quantitative methods were integrated at the point of data interpretation (O'Cathain et al. 2010). Key findings from both methods were listed together to allow the research team to explore similarities and differences (Farmer et al. 2006). The research team discussed potential barriers identified within each domain and used the frequency of interview coding as a crude measure of the domains relevance/importance. The findings from the quantitative analysis (i.e. domains containing items with high medians and therefore potential barriers) were also considered when assessing the relevance/importance of each TDF domain in the context of the target behaviour. A domain was subsequently deemed relevant/important in the context of the target behaviour if it was frequently coded

in the qualitative analysis and/or the findings from the quantitative analysis indicated that there was a potential barrier (or multiple barriers) within the domain (highlighted by the presence of TDF Likert items with high medians of either 4 or 5).

As discussed previously (Chapter 3), a domain can be deemed relevant/important to the behaviour but it may not be feasible to target the barriers (or enhance the facilitators further) with an intervention. The research team therefore used a group consensus approach to select domains containing barriers that could feasibly be overcome (or facilitators that could be enhanced) using strategies delivered either as part of a CP training package and/or as part of a future research study (e.g. incentives, reminders). Domains that could be feasibly targeted were termed 'key domains'.

Data analysis Stage 3: Mapping of Key TDF domains to BCTs

Key domains were then mapped across to BCTs using methods developed by Michie et al. (2008) and updated by Cane et al. (2015). The methods for this mapping approach have previously been discussed at length in Chapter 3 (Section 3.3.7). BCTs were selected using a group consensus approach and decisions were informed by the triangulated findings from the qualitative (Phase 1) and quantitative analyses (Phase 2). The research team considered the applicability of each BCT to the target behaviour (provision of MAS to older adults prescribed polypharmacy) and the target audience (CPs). Potential difficulties with delivering BCTs, as part of a training workshop and/or in a future research study, were taken into consideration at this stage. For example, delivery of the BCT 'Motivational interviewing' would require specialised training for research staff which may not be feasible. This approach follows recommendations made by WIDER that recommends reporting on the '…change techniques used in the intervention' (e.g. the CP training package) and 'the causal processes targeted by these change techniques' (Albrecht et al. 2013).

5.4 Results

5.4.1 Summary of findings from qualitative interviews (Phase 1)

Interview participant characteristics

Fifteen CPs took part in qualitative interviews between August and November 2016. More than half of CPs (56.6%) who were contacted by the researcher (total n=27) agreed to take part. The most common reasons stated for refusal were a lack of time or previous participation in research. Participants had been registered with the PSNI for an average of 14.1 years (range 1-31 years). A small minority of CPs (20%; n=3) had additional pharmacy qualifications including a Clinical Diploma/Masters in Community Pharmacy (n=2) or a PhD (n=1). Less than half of CPs (40%; n=6) had received training on medication adherence and only a minority of CPs (13.3%; n=2) had participated in previous research on medication adherence (including service evaluations). Further demographic details are provided in Table 5.1. Interviews ranged in duration from 30 to 72 minutes (average 46 minutes). Data saturation was reached by the fifteenth interview as no new themes were emerging.

Table 5.1: Demographics of CP interview participants

Demographic	Number of respondents in each category (%)
Gender	**Female:** 7 (46.7) **Male:** 8 (53.3)
Type of pharmacy	**Independently owned:** 7 (46.7) **Small/medium chain (2-9 stores):** 3 (20) **Large chain (10+ stores):** 5 (33.3)
Location of pharmacy	**Rural area:** 7 (46.7) **Urban area:** 8 (53.3)
Current job title	**Proprietor (i.e. owner):** 3 (20) **Managerial role (but not owner):** 8 (53.3) **Non-managerial role (e.g. support pharmacist):** 4 (26.7)

Identification of determinants of medication adherence support provision (data analysis stage 1a findings: interviews)

CPs reported a wide range of determinants (i.e. barriers and facilitators) that influenced the provision of MAS to older adults prescribed polypharmacy. The barriers and facilitators identified within each TDF domain are summarised in Table 5.2 together with illustrative quotes.

Table 5.2: Determinants (barriers, facilitators) of CPs' provision of MAS identified within each TDF domain and illustrative quotes (interviews)

Domain	Determinants (barriers, facilitator) of CPs' provision of MAS to older adults prescribed polypharmacy	Illustrative quotes
Knowledge	• Knowledge of medications/products/medical conditions *(facilitator)* • Lack of in-depth knowledge about medications/products/medical conditions/ (e.g. insulin products, diabetes) *(barrier)* • Knowledge of importance of adherence and consequences of non-adherence *(facilitator)* • Knowledge of patients (e.g. social background, medical history) *(facilitator)* • Knowledge of adherence problems/solutions *(facilitator)* • Lack of up-to-date knowledge on adherence problems and solutions *(barrier)*	"*So there's the pharmaceutical knowledge and then I think just the community knowledge and background knowledge of knowing the patients and knowing their family set-up and, em, knowing their level of education…"* (CP13) *"I think we're, we're fairly aware of the… issues that are out there in terms of adherence."* (CP03) "*…And giving them* (CPs), *sort of, even ideas that, that they could use within the pharmacy to help, help with the patients. And not just the simple Mediboxes… which are so time-consuming.*" (CP07) *"…you're not going to give someone medication adherence sup– advice if you don't really know— if, you know, that you don't have obviously that, like, em, knowledge."* (CP05)
Skills	• Communication skills (e.g. listening, empathy, questioning skills) *(facilitator)* • Skills required to motivate/persuade older patients to adhere *(facilitator)* • Lack of skills required to motivate/persuade older patients to adhere *(barrier)* • Interpersonal skills (relationship-building, team-working) *(facilitator)* • Time management and problem solving skills (delegation, organisational skills) *(facilitator)* • Computer/technology skills *(facilitator)* • Lack of consultation skills (e.g. reviews, follow-ups) *(barrier)*	*"…communication skills is one of the most important ones to be able to converse with the patient. Em, and, eh, ask, sorry questions, so questioning skills, listening skills, everything within communication."* (CP13) *"…any type of training where you're, sort of, giving people ideas of how, how to approach people and just what way to speak with them, it's– I think it would be good."* (CP07) *"There's a skill that would be needed, is how to actually instigate a review, how to, you know, get something happening, but then to actually come back and review it…"* (CP09) *Aw we try… are my persuasion skills that good? Sometimes yes but it can–… you do in ways with different people, and it's back to the some of the people some of the time..."* (CP11)

Table 5.2 (cont'd): Determinants (barriers, facilitators) of CPs' provision of MAS identified within each TDF domain and illustrative quotes (interviews)

Domain	Determinants (barriers, facilitator) of CPs' provision of MAS to old adults prescribed polypharmacy	Illustrative quotes
Social, professional role and identity	• Important role to play in providing MAS including referral, liaison and social care roles *(facilitator)* • Not seen as major part of current role *(barrier)* • Unable to prescribe as part of current role *(barrier)* • Professional responsibility to support adherence *(facilitator)* • Isolated role/not integrated into primary care team *(barrier)* • Role unrecognised by others (e.g. patients, commissioners, GPs) *(barrier)* • Roles of pharmacy support staff (e.g. preparing MDS, identifying non-adherent patients) *(facilitator)*	*"In terms of their adherence with medication you are the last person in that chain before the medicine arrives with the patient. Em, so you— I suppose you have ultimate responsibility for understanding why they're taking their medicines and how they should be taken."* (CP15) *"…if there was something that I thought it wasn't— it was beyond my responsibility I would still try and refer them to whoever… it was. Em, obviously like I can't change their tablets over to something else but I, I can refer them on to the GP who can…"* (CP01) *"…the only potential problem I see is one, perception… of the public that this is our role."* (CP09)
Beliefs about capabilities	• Professional confidence *(facilitator)* • Lack of confidence in certain circumstances (e.g. unfamiliarity with medical conditions/medications) *(barrier)* • Lack of control over situations/difficult to change older patients' adherence behaviours *(barrier)*	*"..when you say confident you, you, yeah you'd be confident to carry out the role…"* (CP01) *"…perhaps if it is some— you would even, medication itself, if you're not overly familiar with it, maybe could make you feel maybe a bit less confident about, em, dealing with any issues."* (CP03) *"I would like more training in, in engaging patients, you know, em, but I think a lot of it is down to confidence, you know, and em, but the MURs* [Medicine Use Review Service] *have definitely helped with that…"* (CP15) *"Trying to break their determination down* (laughs) *'cause once they have an idea in their head, it's very difficult to get them to move."* (CP04)
Beliefs about consequences	• Beliefs about potential positive outcomes (e.g. improved clinical outcomes, cost savings, fewer GP visits and hospital admissions) *(facilitator)* • Beliefs about personal gain (e.g. job satisfaction, increased respect) *(facilitator)*	*"I think there could be a financial benefit but also I think just a health benefit for people, em, and just ensuring that they're getting the best out of their medication."* (CP02)

Table 5.2 (cont'd): Determinants (barriers, facilitators) of CPs' provision of MAS identified within each TDF domain and illustrative quotes (interviews)

Domain	Determinants (barriers, facilitator) of CPs' provision of MAS to older adults prescribed polypharmacy	Illustrative quotes
Beliefs about consequences (cont'd)	• Beliefs that providing MAS improves the profile of community pharmacy (e.g. increased patient satisfaction, confidence) *(facilitator)* • Beliefs about potential costs and impact on time (i.e. negative impact on other services) *(barrier)* • Concerns about potential adverse events (e.g. side effects) when adherence improves *(barrier)*	*"…just personal gain in, like, eh, more— increased respect and maybe, like, that would come probably with more opportunities…"* (CP05) *"…You'd definitely— if you get a positive outcome it makes you feel good about your job."* (CP10) *" 'cause once someone is non-adherent and then becomes adherent, potential is there that they could actually get really unwell. Because they're not taking them as directed as before, then suddenly they're taking them and… somethings too strong…"* (CP12)
Motivation and goals	• High intrinsic motivation (i.e. high personal priority) *(facilitator)* • Motivated by potential benefits to patients (e.g. improved clinical outcomes) *(facilitator)* • Lower priority than other pharmacy activities (e.g. dispensing, other paid services) *(barrier)* • Conflicting priorities (professional responsibility verses commercial priorities) *(barrier)* • Proprietors/owners largely motivated by financial rewards *(barrier)* • Employees less motivated by financial rewards *(facilitator)* • Prioritising high risk patients/medications (e.g. those with limited social support, patients taking warfarin) *(facilitator)/(barrier)*	*"Very high priority yeah, very important, very important."* (CP08) *"Em, no I think it comes down to more than money. I think it's a service we have to provide, whether we get paid for it or not…"* (CP04) *"I wouldn't say it's a priority at the minute… the priority would be patients who you look at and you see them going downhill or they're not coping with their medication…"* (CP02) *"…we've a delicate balance between the commercial realities of having to keep customers happy and telling people this is what's good for you, you have to do it, you don't want to alienate people."* (CP06) *"…the contractors, you would probably want some sort of a remuneration for it."* (CP14) *"…directly I'm not a contractor so I don't get paid per MUR* [Medicine Use Review]… *I get paid to go in and do a day's work, what that– a day's work entails… it doesn't really make a difference to me.* (CP15)

Table 5.2 (cont'd): Determinants (barriers, facilitators) of CPs' provision of MAS identified within each TDF domain and illustrative quotes (interviews)

Domain	Determinants (barriers, facilitator) of CPs' provision of MAS to older adults prescribed polypharmacy	Illustrative quotes
Memory, attention and decision processes	• Difficult to remember *(barrier)* • Decisions tailored to individual patients *(facilitator)* • Involvement of patients, carers and other HCPs in decisions *(facilitator)* • Lack of structured approach to aid decisions *(barrier)*	*"…without a formal assessment tool at the minute, em, it's done very much on an individual basis…"* (CP06) *"Well the patient's response to the questions or to the proposed interventions, em… so whether they would– whether a change would make any difference. Em, whether the GP buys into the change as well or the prescriber…"* (CP15) *"I think, you need some system that will highlight it, otherwise you see so many people, so many things that yeah some you might remember but no you wouldn't consistently remember."* (CP02) *"…we can put like notes on PMRs* [Patient medication records] *but sometimes they get overlooked."* (CP07)
Environmental context and resources	• Time constraints due to heavy workload *(barrier)* • Currently funded services (MUR, MYM) *(facilitator)* • No service focusing specifically on adherence *(barrier)* • Accessibility of community pharmacy *(facilitator)* • Presence of multiple pharmacists *(facilitator)* • Inadequate pharmacist staff levels *(barrier)* • Adequate pharmacy support staff (levels, competency) *(facilitator)* • Technology (PMR, internet access, websites such as patient.co.uk) *(facilitator)* • Physical resources (e.g. reminder charts) *(facilitator)* • Inadequate space *(barrier)* • Lack of integration in primary healthcare team *(barrier)* • Lack of access to full medication history (ECR) *(barrier)*	"*But pharmacies like to say time is a problem–we don't have time to do anything.* (Laughs) *No I think time is the only one but you would just fit it in– just one of those things.*" (CP04) *"….the only thing that puts me off is time, you know, pharmacy's got busier and busier…"* (CP15) *"…well I suppose just MURs* [Medicine Use Review Service] *and medicines management* [Managing Your Medicines Service] *would help, you know, would help identify the problems."* (CP01) *"So if I'm not integrated within a team, then there's, there's only so much I can actually do..."* (CP09) *"So I think, em, even having access to maybe the ECR* [Electronic Care Record] *or something like that where we could see exactly what sort of prescriptions have been… processed and, and that kind of thing would help to sort of establish if there was any issues."* (CP03)

Table 5.2 (cont'd): Determinants (barriers, facilitators) of CPs' provision of MAS identified within each TDF domain and illustrative quotes (interviews)

Domain	Determinants (barriers, facilitator) of CPs' provision of MAS to older adults prescribed polypharmacy	Illustrative quotes
Social influences	• Positive influences from patients, relatives, pharmacy support staff and other HCPS (e.g. GP, nurse, formal carers) *(facilitator)* • Resistance from patients *(barrier)* • Resistance/lack of support from GPs and surgery staff *(barrier)* • Pressure from others to provide solutions (e.g. pressure from formal carers, hospital staff to provide MDS) *(barrier)* • Others make decisions about solutions *(barrier/facilitator)* • Influence from colleagues in senior positions to focus on business priorities (e.g. proprietor, management) *(barrier)*	*"All of our patients have either been referred by doctors, by carers, by relatives."* (CP11) *"Some patients, no matter what you say to them or how much you try and you try to talk to them about something, just don't want to know."* (CP01) *"…for whatever reason the powers that be, be it the family, the doctors, the carers– 'cause the carers completely refuse to deal with medication if it's not in a blister pack* [Monitored Dosage System]" (CP04) *"Sometimes you can, you can, reach a bit of a, not loggerheads but you're kind of having problems with maybe getting onto a surgery, trying to get stuff sorted and you're getting resistance there."* (CP12) *"…obviously, like, you're working for a company— would be, like, patients but your other, like, staff obviously, like, my, like, manager would have like a huge say in that and, em, like, what… we need to focus on, like in any kind of business…"* (CP05)
Emotion	• Positive affect (i.e. encouraged)*(facilitator)* • Worried about providing incorrect advice *(barrier)* • Stress due to time constraints *(barrier)*	*"You feel like you're helping somebody so you feel like you're, you're doing good so yeah it does make you feel good, if it, if it works out." (CP01)* *"It makes you feel good, that you're actually doing something of benefit… and that they're getting the best… that they can get."* (CP04) *"I suppose a bit of a fear thing isn't it like? Where, you're afraid of saying the wrong thing…"* (CP12)

Table 5.2 (cont'd): Determinants (barriers, facilitators) of CPs' provision of MAS identified within each TDF domain and illustrative quotes (interviews)

Domain	Determinants (barriers, facilitator) of CPs' provision of MAS to older adults prescribed polypharmacy	Illustrative quotes
Behavioural regulation	• Reactive behaviour (i.e. not proactive in identifying and supporting patients) *(barrier)* • Lack of formalised procedures (i.e. no standard operating procedures or framework currently in use) *(barrier)* • Record keeping (e.g. on PMR) *(facilitator)* • Positive feedback from patients *(facilitator)* • Reminder systems as moderators of intention- behaviour gap (e.g. diary, notes on PMR) *(facilitator)* • Monitoring patients' adherence behaviour (e.g. frequency of dispensing using PMR)	*"Speaking to the patient would probably be one of the main ones, seeing are they happier, you know. Do they feel like things have improved?"* (CP01) *"I suppose with their PMRs* [Patient Medication Records] *we've an opportunity to highlight sort of things on it… and throw up messages that maybe, you know, you can check back with them the next time…"* (CP02) *"…you'd like to assume that people's following the directions and taking their medication as is, until that problem is identified. So maybe, potentially it might be something more proactive that we could do."* (CP12)
Nature of the behaviours	• Direct experience through provision of funded services (e.g. MUR, MYM services) *(facilitator)* • Identification of non-adherent patients is not routine *(barrier)* • Most routine activity is the supply of MDS *(barrier)*	*"Em… there's nothing that I'd routinely do I suppose it would be coming from, like, the patient themselves."* (CP05) *"I think the current trend would be medidose boxes* [Monitored Dosage System]… *you know, if somebody's having difficulty taking their tablets, put it in a medidose box but I've seen people do strange things with medidose boxes once they get them (Laughs)."* (CP15) *"… we're kind of already doing it with our smoking cessation and our MURs* [Medicine Use Review service], *you know, Medicines Management* [Managing Your Medicines Service]*, things like that."* (CP12)

Key: ECR= Electronic summary of care record; HCP= Healthcare professional; MDS= Monitored Dosage System; MUR= Medicine Use Review; MYM= Managing Your Medicines service; PMR= Patient medication record

5.4.2 Summary of findings from the quantitative survey (Phase 2)

Survey participant characteristics

Seventy seven responses were received after the first mailing of the paper-based questionnaire and a further 66 responses were received after the second mailing. In total, 143 questionnaires were returned giving a response rate of 27.4% (143/521).

Demographic data for CPs who responded have been summarised in Table 5.3. Where available, data collected from survey participants were compared with demographic details of all pharmacists who are currently listed on the pharmaceutical register in NI (Fay, personal communication, 2017). As noted previously, demographics provided by the PSNI were not restricted to community pharmacists (i.e. data provided included pharmacists employed in other settings such as hospital, industry, academia). Information that was not made available to the researcher from the PSNI is marked with an asterisk in Table 5.3.

Eighty-two respondents were female (57.3%), which, when compared to the PSNI register was marginally under-representative of females (68.1%). In relation to age categories, the PSNI provided a breakdown in different age groups to those that were used in the questionnaire, making direct comparison somewhat difficult. However, it appears that the age distribution of respondents is somewhat similar to those registered with the PSNI. Ninety-one (63.7%) survey respondents were aged 44 years or under, whereas in 2016, 68.1% of all PSNI pharmacist registrants were aged 40 years or under. Forty-nine survey respondents (34.3%) were aged 45 years or older, whereas in 2016, 31.9% of PSNI registrants were aged 41 years or older.

CP respondents had been practising an average of 15.3 (SD: $\pm$11.2) years. Nineteen respondents (13.3%) had a postgraduate qualification (e.g. Independent Prescriber, Clinical Diploma). The PSNI was able to provide details of those with supplementary or independent prescribing qualifications (13.1%) and so this compared favourably with survey respondents who had a postgraduate qualification. Fifty-nine respondents (41.3%) worked for a large chain (10+ stores), 40 respondents (28.0%) worked for a small/medium chain (2-9 stores) and 41 respondents (28.7%) worked at an independently-owned pharmacy. CPs also reported working across a range of locations: rural (n=43; 30.1%), suburban (n=32; 22.4%) and urban (n=65; 45.5%). Comparable data were not available from the PSNI on types of pharmacies and locations but the survey provided a wide range of views from across the spectrum of pharmacy types and locations in NI.

The majority of respondents reported working in a managerial role (n=114; 79.7%) such as superintendent pharmacist, proprietor or store manager. Less than a fifth of respondents reported working in non-managerial roles (n=25; 17.5%) such as a support pharmacist. Sixty-four respondents (44.8%) reported being the only pharmacist during the working week, whereas 75 respondents (52.4%) reported having multiple pharmacists working in the store, ranging from additional part-time pharmacist staff (e.g. working only one day per week) up to four additional pharmacists daily. CPs reported having a mean of 3.84 (±1.83) non-pharmacist support staff employed in their store (range: 1 to 10).

The number of prescription items dispensed in pharmacies on an average weekday varied with the largest frequencies reported in the 200-299 items range (n=34; 23.8%) and 100-199 items range (n=31; 21.7%). Twenty-two respondents (15.4%) worked in pharmacies that dispensed 500 items or more on an average weekday. A large proportion of respondents (n=90; 62.9%) estimated that over half of all patients who attended their community pharmacy were older adults. A large majority of respondents (n=113; 79.1%) estimated that at least half of all older patients who attended their pharmacy were prescribed four or more medications (i.e. polypharmacy).

Most respondents (n=133; 93.0%) reported providing the MUR service in their clinical practice, whereas less than half of all respondents (n=61; 42.7%) reported providing the more comprehensive MYM review service. From those who provided the MUR service (n=133), 75.2% of respondents documented the number of patients for whom they provided this service to in the last year [range: 0 to 120; mean: 70.2 (±42.7) patients]. From those who provided the MYM service (n=66), 72.7% documented the number of patients for whom they provided this service to in the last year [range: 0 to 30; mean: 8.08 (± 8.35) patients]. The majority of respondents (n=139; 97.3%) provided MDS to older patients with 11.9% (n=17) reporting that they supplied MDS to more than 100 older patients every month.

Just over half of all respondents (n=75; 52.4%) reported that they had received some form of training on medication adherence in the previous five years, but only a small minority (n=13; 9.1%) had participated in research, audits or service evaluations specifically related to medication adherence in the previous 5 years.

Table 5.3: Demographic profile of community pharmacist survey respondents

	Number of survey respondents (%)	**Number of registrants on PSNI register (%)**	
Gender			
Male	58 (40.6)	768 (31.9)	
Female	82 (57.3)	1637 (68.1)	
Missing	3 (2.1)	N/A	
Age (years)			
<25	11 (7.7)	20-30[1]	773 (32.1)
25-34	56 (39.2)	31-40	835 (34.7)
35-44	24 (16.8)	41-50	474 (19.7)
45-54	37 (25.9)	51-60	256 (10.6)
55-64	11 (7.7)	61-70	59 (2.5)
65+	1 (0.7)	70+	8 (0.3)
Missing	3 (2.1)	N/A	N/A
Years practising as a community pharmacist			
< 5	35 (24.5)	*	
6-11	35 (24.5)	*	
12-17	11 (7.7)	*	
18-23	14 (9.8)	*	
24-29	29 (20.3)	*	
30-35	12 (8.4)	*	
> 36	4 (2.8)	*	
Missing	3 (2.1)	*	
Postgraduate qualification (e.g. Independent Prescriber)			
Yes	19 (13.3)	315 (13.1)[2]	
No	121 (84.6)	2090 (86.9)	
Missing	3 (2.1)	N/A	
Type of community pharmacy			
Large chain (10+ stores)	59 (41.3)	*	
Small/medium chain (2-9 stores)	40 (28.0)	*	
Independently-owned	41 (28.7)	*	
Missing	3 (2.1)	*	
Location of community pharmacy			
Rural	43 (30.1)	*	
Suburban	32 (22.4)	*	
Urban	65 (45.5)	*	
Missing	3 (2.1)	*	
Current job role in community pharmacy			
Managerial	114 (79.7)	*	
Non-managerial	25 (17.5)	*	
Missing	4 (2.8)	*	
Number of additional pharmacists working in store			
None	64 (44.8)	*	
Part-time basis *(e.g. 1 day per week)*	5 (3.5)	*	
One to two every week day	60 (42)	*	
Three to four every week day	9 (6.3)	*	
Missing	5 (3.5)	*	

Table 5.3 (cont'd): Demographic profile of community pharmacist survey respondents

	Number of survey respondents (%)	Number of registrants on PSNI register (%)
Number of support staff working in store		
1-2	37 (25.9)	*
3-4	54 (37.8)	*
5-6	38 (26.6)	*
7+	11 (7.7)	*
Missing	3 (2.1)	*
Average number of prescription items dispensed on weekdays		
< 100	7 (4.9)	*
100-199	31 (21.7)	*
200-299	34 (23.8)	*
300-399	27 (18.9)	*
400-499	19 (13.3)	*
500-599	13 (9.1)	*
600+	9 (6.3)	*
Missing	3 (2.1)	*
Percentage[3] of patients aged 65 years+ who attend their pharmacy		
< 25%	2 (1.4)	*
25-49%	47 (32.9)	*
50-74%	84 (58.7)	*
75%+	6 (4.2)	*
Missing	4 (2.8)	*
Percentage[3] of older patients prescribed polypharmacy who attend their pharmacy		
< 25%	2 (1.4)	*
25-49%	25 (17.5)	*
50-74%	69 (48.3)	*
75%+	44 (30.8)	*
Missing	3 (2.1)	*
Number of older patients supplied with a MDS in previous month		
None	1 (0.7)	*
1-25	17 (11.9)	*
26-50	38 (26.6)	*
51-75	35 (24.5)	*
76-100	32 (22.4)	*
>100	17 (11.9)	*
Missing	3 (2.1)	*
Provision of Managing Your Medicines service		
Yes	61 (42.7)	*
No	74 (51.7)	*
Missing	8 (5.6)	*
Provision of Medicine Use Review service		
Yes	133 (93.0)	*
No	7 (4.9)	*
Missing	3 (2.1)	*
Training on adherence in previous 5 years		
Yes	75 (52.4)	*
No	64 (44.8)	*
Missing	4 (2.8)	*
Participation in research, audits or service evaluations on adherence in previous 5 years		
Yes	13 (9.1)	*
No	126 (88.1)	*
Missing	4 (2.8)	*

Key: MDS= Monitored dosage system; N/A= Not applicable; PSNI= Pharmaceutical Society of Northern Ireland

[1] Different age range to the survey; [2]Only included Supplementary and Independent Prescribers; [3]Estimated percentage

Survey participants' experiences of providing medication adherence support

In Section 2 of the questionnaire, CPs were asked about their experiences of providing MAS to older patients prescribed polypharmacy. Less than half of CPs reported very frequent or frequent use of pharmacy held-records (n=64; 44.8%) or return of unused medications (n= 59; 41.3%) as methods for identifying non-adherent older patients. Only a third of CPs (n=48; 33.6%) reported very frequently or frequently asking older patients (in a non-judgemental manor) about missed doses of medications. Less than a third of CPs (n=43; 30.1%) reported very frequently or frequently exploring the underlying reasons for older patients' non-adherence (see Figure 5.3).

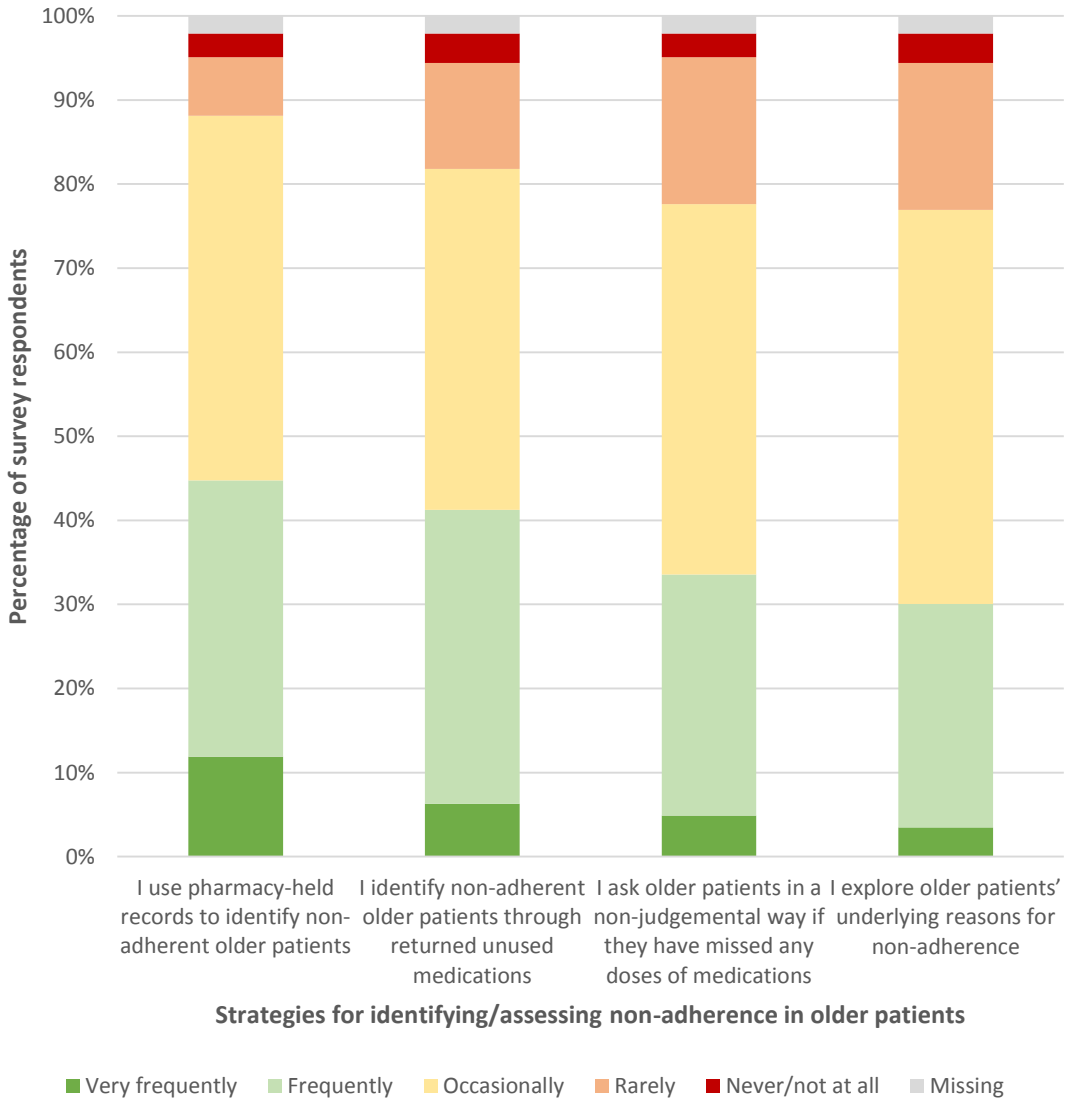


Figure 5.3: Identification and assessment of non-adherence in older adults prescribed polypharmacy by community pharmacist survey respondents

Just over half of the respondents (n=79; 55.3%) reported that they very frequently or frequently considered options to improve adherence in discussion with older patients. Just over a third of CPs (n=55; 38.5%) reported very frequently or frequently tailoring adherence support strategies to the underlying reasons for non-adherence.

Adherence solutions that were most frequently employed (i.e. more than 70% of CPs reported very frequent or frequent provision) included: prescription collection services (n= 134; 93.7%), supply of MDS at the request of others (n=126; 88.1%), support/reassurance/encouragement (n=114; 79.7%), prescription ordering services (n=109; 76.2%) and deliveries to patients' homes (n=101; 70.6%). Adherence solutions that were delivered least frequently (i.e. less than 30% of CPs reported very frequent or frequent provision) included: techniques to increase motivation such as goal-setting or action plans (n=18; 12.6%), requesting changes to medications/regimens (n=30; 21%), provision of alternative packaging (n=39; 27.3%), recommendations to purchase adherence aids (n=39; 27.3%) and recommendation of self-monitoring strategies (e.g. diary, calendar) (n=42; 29.4%) (see Figure 5.4).

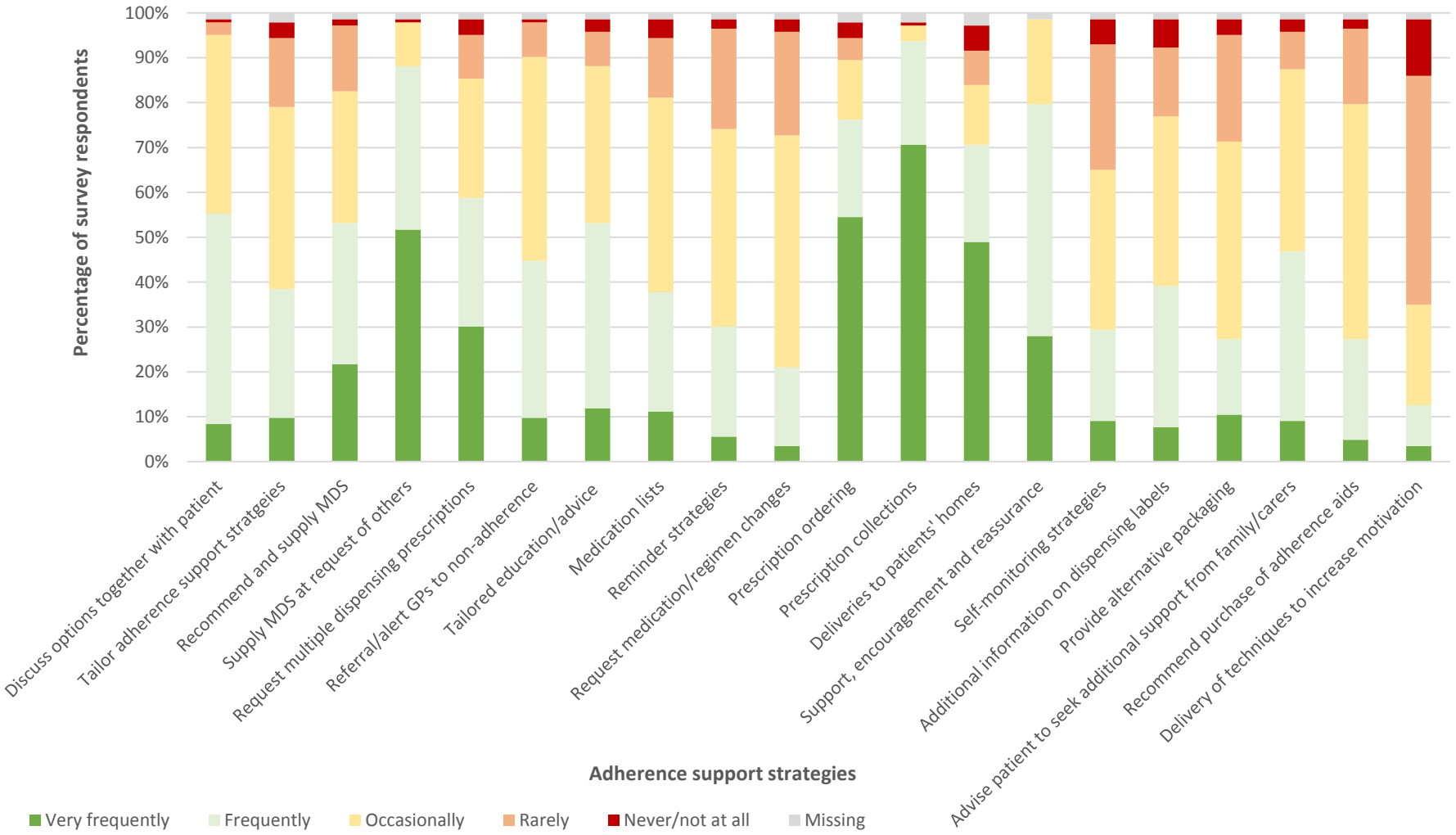


Figure 5.4: Frequency of delivery of adherence strategies to older adults prescribed polypharmacy

Only a few additional adherence strategies were reported by respondents in the open-style question at the end of Section 2. These included: synchronising medications so that they could all be ordered at one time (n=3), home visits (n=1), colour coding time slots on MDS (n=1) and asking patients to return MDS packaging before providing a new supply (n=1).

Identification of determinants of medication adherence support provision (data analysis stage 1b findings: questionnaire)

Section 3 of the questionnaire included 37 Likert items that were assigned to 11 of the 12 domains of TDF1 (2-5 items per domain). The proportion of CPs that agreed or disagreed with each Likert item is displayed in Table 5.4. As discussed previously in Section 5.3.5, for ease of data interpretation, some of the items in the table have been reverse-phrased (from their original phrasing in the questionnaire). The reason for this was to allow a median of either 4 (mainly disagreement) or 5 (mainly strong disagreement) to signify a potential barrier to the target behaviour. As noted earlier, one item was excluded from this analysis as it could be either a barrier or a facilitator depending on individual circumstances (see Section 5.3.5). Six out of the 36 items analysed had high medians (of 4 or 5) highlighting potential barriers and therefore targets for behaviour change. These items had been assigned *a priori* to four TDF domains: 'Skills', 'Environmental context and resources', 'Memory, attention and decision processes' and 'Motivation and goals'. High medians for Likert items are highlighted in bold text in Table 5.4.

Within the 'Skills' domain, only 10.6% (n=15) of CPs expressed agreement with the item, 'I do not require additional training on techniques that can be used to increase older patients' motivation to adherence' (item reverse-phrased in the questionnaire). Within the 'Environmental context and resources' domain: only 14% (n=20) of CPs expressed agreement with the item, 'I have enough time to provide MAS to older patients' (item reverse phrased in questionnaire), just under one third of CPs (n=45; 31.5%) expressed agreement with the item, 'I have sufficient pharmacist staff levels to allow me to provide MAS to older patients' and a minority of CPs (n=13; 9.1%) expressed agreement with the item, 'Lack of access to patients' medical notes is not a barrier to providing MAS' (reverse phrased in questionnaire). Within the 'Motivation and goals' domain, only a very small minority of CPs (n=8; 5.6%) expressed agreement with the item, 'I receive sufficient reimbursement for providing MAS to older patients'. In the 'Memory, attention and decision processes' domain, less than one tenth of CPs (n=13; 9.1%) reported agreement with the item, 'Deciding on the best adherence support strategy for older patients is easy' (reverse-phrased in questionnaire).

Table 5.4: Community pharmacists' responses to Likert items within each TDF domain

TDF domain	Likert-items assigned to each TDF domain	Strongly agree N (%) (score:1)	Agree N (%) (score:2)	Neither agree nor disagree N (%) (Score:3)	Disagree N (%) (Score:4)	Strongly disagree N (%) (score:5)	Missing responses N (%)	Median score for item (IQR)[1]	Potential target for behaviour change
Knowledge	I know how to provide MAS to older patients in line with NICE guidance	14 (9.8)	77 (53.8)	36 (25.2)	12 (8.4)	3 (2.1)	1 (0.7)	2.0 (2.0-3.0)	No (no items with high medians in this domain)
	I know the appropriate questions to ask older patients to determine underlying reasons for non-adherence	16 (11.2)	87 (60.8)	26 (18.2)	12 (8.4)	1 (0.7)	1 (0.7)	2.0 (2.0-3.0)	
	I have sufficient knowledge of the range of adherence strategies that are available to support older patients	14 (9.8)	67 (46.9)	32 (22.4)	27 (18.9)	2 (1.4)	1 (0.7)	2.0 (2.0-3.0)	
Skills	I have been trained to provide MAS to older patients in line with NICE guidance	11 (7.7)	33 (23.1)	45 (31.5)	44 (30.8)	9 (6.3)	1 (0.7)	3.0 (2.0-4.0)	Yes (domain contains an item with high median)
	I have the communication skills required to provide MAS to older patients	38 (26.6)	89 (62.2)	13 (9.1)	1 (0.7)	0 (0)	2 (1.4)	2.0 (1.0-2.0)	
	I <u>do not</u> require additional training on techniques that can be used to increase older patients' motivation to adherence[2]	3 (2.1)	12 (8.5)	31 (21.7)	71 (49.7)	24 (16.8)	2 (1.4)	**4.0 (3.0-4.0)[1]**	
Social, professional role and identity	Providing MAS to older patients is part of my current role as a community pharmacist	34 (23.8)	86 (60.1)	17 (11.9)	2 (1.4)	2 (1.4)	2 (1.4)	2.0 (2.0-2.0)	No (no items with high medians in this domain)
	It is my responsibility to provide MAS to older patients	22 (15.4)	83 (58.0)	29 (20.3)	7 (4.9)	1 (0.7)	1 (0.7)	2.0 (2.0-3.0)	
	Older patients consider the provision of MAS to be part of my role as a community pharmacist	10 (7.0)	52 (36.4)	56 (39.2)	22 (15.4)	1 (0.7)	2 (1.4)	3.0 (2.0-3.0)	
Beliefs about capabilities	I find it easy to discuss medication adherence with older patients[2]	15 (10.5)	88 (61.5)	27 (18.9)	9 (6.3)	3 (2.1)	1 (0.7)	2.0 (2.0-3.0)	No (no items with high medians in this domain)
	I am confident that I can address any medication adherence problems that I encounter with older patients	20 (14.0)	96 (67.1)	20 (14.0)	6 (4.2)	0 (0)	1 (0.7)	2.0 (2.0-2.0)	
	I am confident that I can provide MAS to older patients even when they are not motivated	13 (9.1)	82 (57.3)	28 (19.6)	19 (13.3)	0 (0)	1 (0.7)	2.0 (2.0-3.0)	
	I am confident that I can provide MAS to older patients even when I am unfamiliar with their medical conditions	10 (7.0)	58 (40.6)	37 (25.9)	34 (23.8)	3 (2.1)	1 (0.7)	3.0 (2.0-4.0)	

Table 5.4 (cont'd): Community pharmacists' responses to Likert items within each TDF domain

TDF domain	Likert-items assigned to each TDF domain	Strongly agree N (%) (score:1)	Agree N (%) (score:2)	Neither agree nor disagree N (%) (Score:3)	Disagree N (%) (Score:4)	Strongly disagree N (%) (score:5)	Missing responses N (%)	Median score for item (IQR)[1]	Potential target for behaviour change
Beliefs about consequences	Providing MAS to older patients improves the profile of community pharmacy	53 (37.1)	75 (52.4)	11 (7.7)	1 (0.7)	1 (0.7)	2 (1.4)	2.0 (1.0-2.0)	No (no items with high medians in this domain)
	Providing MAS to older patients leads to health benefits for patients and cost-savings for the NHS	65 (45.5)	67 (46.9)	6 (4.2)	0 (0)	1 (0.7)	4 (2.8)	2.0 (1.0-2.0)	
	Providing MAS to older patients gives me job satisfaction	51 (35.7)	80 (55.9)	10 (7.0)	1 (0.7)	0 (0)	1 (0.7)	2.0 (1.0-2.0)	
Motivation and goals	Seeing the benefits of providing MAS to older patients helps me to overcome barriers such as lack of time and reimbursement	16 (11.2)	46 (32.2)	53 (37.1)	20 (14.0)	7 (4.9)	1 (0.7)	3.0 (2-3.0)	Yes (domain contains an item with a high median)
	Providing MAS to older patients is a high priority for me in my daily practice[1]	13 (9.1)	66 (46.2)	43 (30.1)	18 (12.6)	2 (1.4)	1 (0.7)	2.0 (2.0-3.0)	
	I want to support more older patients with medication adherence in the future	41 (28.7)	90 (62.9)	8 (1.4)	2 (1.4)	1 (0.7)	1 (0.7)	2.0 (1.0-2.0)	
	It is important to always offer MAS to older patients	39 (27.3)	85 (59.4)	17 (11.9)	1 (0.7)	0 (0)	1 (0.7)	2.0 (1.0-2.0)	
	I receive sufficient reimbursement for providing MAS to older patients	2 (1.4)	6 (4.2)	25 (17.5)	53 (37.1)	56 (39.2)	1 (0.7)	**4.0**[1] (4.0-5.0)	
Memory, attention and decision processes	Providing MAS is easy for me to remember	4 (2.8)	35 (24.5)	72 (50.3)	29 (20.3)	2 (1.4)	1 (0.7)	3.0 (2.0-3.0)	Yes (domain contains an item with high median)
	Deciding on the best adherence support strategy for older patients is easy[2]	2 (1.4)	11 (7.7)	30 (21.0)	92 (64.3)	6 (4.2)	2 (1.4)	**4.0**[1] (3.0-4.0)	
Environmental context and resources	**I have sufficient pharmacist staff levels to allow me to provide MAS to older patients**	10 (7.0)	35 (24.5)	18 (12.6)	53 (37.1)	26 (18.2)	1 (0.7)	**4.0**[1] (2.0-4.0)	Yes (domain contains items with high medians)
	I have sufficient non-pharmacist staff levels to allow me to provide MAS to older patients	8 (5.6)	47 (32.9)	26 (18.2)	40 (28.0)	21 (14.7)	1 (0.7)	3.0 (2.0-4.0)	
	I have sufficient space in the pharmacy to allow me to provide MAS to older patients	29 (20.3)	57 (39.9)	22 (15.4)	20 (14.0)	14 (9.8)	1 (0.7)	2.0 (2.0-3.0)	
	I have enough time to provide MAS to older patients[2]	5 (3.5)	15 (10.5)	36 (25.2)	59 (41.3)	26 (18.2)	2 (1.4)	**4.0**[1] (3.0-4.0)	
	Lack of access to patients medical notes is <u>not</u> a barrier to providing MAS[2]	2 (1.4)	11 (7.7)	20 (14.0)	62 (43.4)	47 (32.9)	1 (0.7)	**4.0**[1] (4.0-5.0)	

Table 5.4 (cont'd): Community pharmacists' responses to Likert items within each TDF domain

TDF domain	Likert-items assigned to each TDF domain	Strongly agree N (%) (score:1)	Agree N (%) (score:2)	Neither agree nor disagree N (%) (Score:3)	Disagree N (%) (Score:4)	Strongly disagree N (%) (score:5)	Missing responses N (%)	Median score for item (IQR)	Potential target for behaviour change
Social influences	Colleagues in senior positions support me in providing adherence support to older patients	5 (3.5)	31 (21.7)	47 (32.9)	44 (30.8)	14 (9.8)	1 (0.7)	3.0 (2-0-4.0)	No (no items with high medians in this domain)
	I do not face resistance from GPs when trying to provide MAS[2]	9 (6.3)	54 (37.8)	33 (23.1)	35 (24.5)	11 (7.7)	1 (0.7)	3.0 (2.0-3.0)	
	I do not face resistance from patients when trying to provide MAS[2]	8 (5.6)	60 (42.0)	43 (30.1)	31 (21.7)	0 (0)	1 (0.7)	3.0 (2.0-3.0	
	Others (e.g. GPs, carers) decide which adherence support strategies are required by older patients[3]	19 (13.3)	63 (44.1)	38 (26.6)	19 (13.3)	2 (1.4)	2 (1.4)	2.0 (2.0-3.0)[2]	
Emotion	I do not worry about giving the wrong advice to older patients when providing MAS[2]	14 (9.8)	65 (45.5)	39 (27.3)	23 (16.1)	1 (0.7)	1 (0.7)	2.0 (2.0-3.0)	No (no items with high medians in this domain)
	I am comfortable talking to older patients about medication adherence[2]	32 (22.4)	88 (61.5)	18 (12.6)	3 (2.1)	1 (0.7)	1 (0.7)	2.0 (2.0-2.0)	
Behavioural regulation	I try to be proactive by planning how I can identify and support older patients with medication adherence	7 (4.9)	48 (33.6)	42 (29.4)	40 (28.0)	5 (3.5)	1 (0.7)	2.0 (2.0-4.0)	No (no items with high medians in this domain)
	I monitor and record the type of MAS that I provide to older patients	6 (4.2)	43 (30.1)	34 (23.8)	52 (36.4)	6 (4.2)	2 (1.4)	3.0 (2.0-4.0)	
	Receiving negative feedback from a patient regarding adherence support advice would not prevent me from offering this advice to others[2]	15 (10.5)	82 (57.3)	25 (17.5)	18 (12.6)	1 (0.7)	2 (1.4)	2.0 (2.0-3.0)	

Key: IQR= Interquartile range; MAS= Medication adherence support; MDS= Monitored dosage system; NICE= National Institute for Health and Care Excellence; N= Number of survey respondents; TDF= Theoretical Domains Framework

[1]A high median of 4 or 5 signified a potential barrier to the provision of MAS; [2] Item reverse worded in questionnaire and rephrased/recoded for data analysis purposes; [3] This item could be either a barrier or facilitator depending on the appropriateness of the solutions recommended by others. For this reason this item was excluded from further statistical analysis.

MWU and KW tests identified some significant differences between different groups of pharmacists. Differences in responses to Likert items were explored across gender, number of years practising (≤10 years verses > 10 years), previous training (on medication adherence in last five years verses no training), number of pharmacists working in the store (only pharmacist verses two or more pharmacists) and the type of pharmacy (independently owned, small/medium chain, large chain). The results are presented in Table 5.5, Table 5.6, Table 5.7, Table 5.8 and Table 5.9, respectively. High medians are highlighted in bold text as these indicated potential barriers that could be targeted for behaviour change. Items with high medians (highlighted in bold) were identified in five domains in the subgroup analysis: 'Motivation and goals', 'Environmental context and resources', 'Skills', 'Behavioural regulation' and 'Social influences'.

Table 5.5: Statistically significant differences in responses to TDF Likert items between male and female pharmacists

TDF Likert Item (domain)	Males				Females				Probability (p) value[4]
	Total N	N (%) who agreed[1]	N (%) who disagreed[2]	Median[3] (mean rank)	Total N	N (%) who agreed[1]	N (%) who disagreed[2]	Median[3] (mean rank)	
Providing MAS to older patients is part of my current role as a community pharmacist *(social professional role and identity)*	58	53 (91.4)	1 (1.7)	2.0 (60.7)	82	65 (79.3)	3 (3.6)	2.0 (76.7)	p=0.008* **Females expressed significantly less agreement than males*
Older patients consider the provision of MAS to be part of my role as a community pharmacist *(social professional role and identity)*	57	31 (53.4)	6 (10.3)	2.0 (60.9)	82	29 (35.4)	17 (20.7)	3.0 (75.6)	p= 0.024* **Females expressed significantly less agreement than males*
I find it easy to discuss medication adherence with older patients[5] *(Beliefs about capabilities)*	58	46 (79.3)	3 (5.1)	2.0 (62.0)	82	56 (68.3)	9 (11.0)	2.0 (75.8)	p=0.022* **Females expressed significantly less agreement than males*
Providing MAS to older patients is a high priority for me in my daily practice[5] *(Motivation and goals)*	58	39 (67.2)	7 (12.0)	2.0 (61.3)	82	38 (46.3)	13 (15.8)	3.0 (76.2)	p=0.02* **Females expressed significantly less agreement than males*
I receive sufficient reimbursement for providing MAS to older patients *(Motivation and goals)*	58	2 (3.4)	51 (87.9)	**5.0[3]** (84.0)	82	6 (7.3)	55 (67.0)	**4.0[3]** (60.0)	p<0.001* **Males expressed less significantly agreement than females*
I do not face resistance from GPs when trying to provide MAS[4] *(Social influences)*	58	31 (53.4)	11 (18.9)	2.0 (60.9)	82	31 (37.8)	33 (40.3)	3.0 (76.9)	p=0.013* **Females expressed significantly less agreement than males*
I do not face resistance from patients when trying to provide MAS[5] *(Social influences)*	58	34 (58.6)	7 (12.1)	2.0 (60.0)	82	32 (39.1)	23 (28)	3.0 (77.2)	p=0.008* **Females expressed significantly less agreement than males*

[1] Includes those who strongly agreed or agreed; [2] Includes those who strongly disagreed or disagreed; [3] A high median of 4 or 5 signified a potential barrier to the provision of MAS; [4] Mann-Whitney U test; [5] Item was reverse worded in questionnaire (reverse phrased and recoded for data analysis purposes)

Table 5.6: Statistically significant differences in responses to TDF Likert items between pharmacists practising 10 years or less and pharmacists practising more than 10 years

TDF Likert Item (domain)	Practising 10 years or less				Practising more than 10 years				Probability (p) value[4]
	Total N	N (%) who agreed[1]	N (%) who disagreed[2]	Median[3] (mean rank)	Total N	N (%) who agreed[1]	N (%) who disagreed[2]	Median[3] (mean rank)	
I know how to provide MAS to older patients in line with NICE guidance *(Knowledge)*	68	48 (70.6)	5 (7.4)	2.0 (63.7)	71	40 (55.5)	10 (13.9)	2.0 (76.0)	p=0.049* **CPs practising >10 years expressed significantly less agreement*
It is my responsibility to provide MAS to older patients *(Social, professional role and identity)*	68	59 (86.7)	0 (0)	3.0 (60.7)	71	45 (62.5)	8 (11.1)	2.0 (78.8)	p=0.003* **CPs practising >10 years expressed significantly less agreement*
Lack of access to patients medical notes is <u>not</u> a barrier to providing MAS[5] *(Environmental context and resources)*	68	3 (4.4)	61 (89.7)	**4.0[3]** (78.2)	71	10 (13.9)	45 (62.5)	**4.0** (62.2)	p=0.012* **CPs practising ≤ 10 years expressed significantly less agreement*
I <u>do not</u> face resistance from <u>GPs</u> when trying to provide MAS[5] *(Social influences)*	68	27 (39.7)	29 (39.7)	**4.0[3]** (76.8)	70	35 (48.6)	15 (20.9)	3.0 (63.5)	p=0.043* **CPs practising ≤ 10 years expressed significantly less agreement*
I <u>do not</u> face resistance from <u>patients</u> when trying to provide MAS[5] *(Social influences)*	68	27 (39.7)	20 (29.4)	2.0 (76.7)	70	39 (54.2)	10 (13.9)	2.0 (63.5)	p=0.040* **CPs practising ≤ 10 years expressed significantly less agreement*

[1] Includes those who strongly agreed or agreed; [2] Includes those who strongly disagreed or disagreed; [3] A high median of 4 or 5 signified a potential barrier to the provision of MAS; [4] Mann-Whitney U test; [5] Item was reverse worded in questionnaire (reverse phrased and recoded for data analysis purposes)

Table 5.7: Statistically significant differences in responses to TDF Likert items between CPs who had undertaken training on medication adherence in the past five years and those who had not

TDF Likert Item (domain)	Pharmacists with training on MAS in past five years				Pharmacists with no training on MAS in past five years				Probability (p) value[4]
	Total N	N (%) who agreed[1]	N (%) who disagreed[2]	Median[3] (mean rank)	Total N	N (%) who agreed[1]	N (%) who disagreed[2]	Median[3] (mean rank)	
I know how to provide MAS to older patients in line with NICE guidance *(knowledge)*	75	55 (73.3)	3 (4.0)	2.0 (61.3)	64	33 (51.6)	12 (18.8)	2.0 (80.2)	p=0.002* **Those who had no training in previous 5 years expressed significantly less agreement*
I know the appropriate questions to ask older patients to determine underlying reasons for non-adherence *(knowledge)*	75	62 (82.7)	2 (2.7)	2.0 (61.0)	64	39 (61.0)	10 (15.7)	2.0 (80.5)	p=0.001* **Those who had no training in previous 5 years expressed significantly less agreement*
I have sufficient knowledge of the range of adherence strategies that are available to support older patients *(knowledge)*	75	52 (69.4)	11 (14.7)	2.0 (60.2)	64	27 (42.2)	18 (28.1)	3.0 (81.5)	p=0.001* **Those who had no training in previous 5 years expressed significantly less agreement*
I have been trained to provide MAS to older patients in line with NICE guidance *(skills)*	75	32 (42.7)	17 (22.7)	3.0 (55.4)	64	10 (15.6)	36 (56.2)	**4.0[3]** (87.1)	p<0.001* **Those who had no training in previous 5 years expressed significantly less agreement*
It is my responsibility to provide MAS to older patients *(Social, professional role and identity)*	75	61 (81.4)	3 (4)	2.0 (64.4)	64	42 (65.6)	4 (6.3)	2.0 (76.6)	p=0.046* **Those who had no training in previous 5 years expressed significantly less agreement*
It is important to always offer MAS to older patients *(Motivation and goals)*	75	70 (93.4)	0 (0)	2.0 (60.4)	64	51 (79.7)	1 (1.6)	2.0 (81.2)	p=0.001* **Those who had no training in previous 5 years expressed significantly less agreement*
I monitor and record the type of MAS that I provide to older patients *(Behavioural regulation)*	75	33 (44.0)	24 (32.0)	3.0 (61.7)	64	15 (23.5)	32 (50.1)	**4.0[3]** (79.4)	p=0.05* **Those who had no training in previous 5 years expressed significantly less agreement*

[1] Includes those who strongly agreed or agreed; [2] Includes those who strongly disagreed or disagreed; [3] A high median of 4 or 5 signified a potential barrier to the provision of MAS; [4] Mann-Whitney U test

Table 5.8: Statistically significant differences in responses to TDF Likert items between stores with an individual pharmacist and stores with multiple pharmacists[1]

TDF Likert Item (domain)	Individual pharmacist				Multiple pharmacists[1]				Probability (p) value[5]
	Total N	N (%) who agreed[2]	N (%) who disagreed[3]	Median[4] (Mean rank)	Total N	N (%) who agreed[2]	N (%) who disagreed[3]	Median[4] (Mean rank)	
I have sufficient pharmacist staff levels to allow me to provide MAS to older patients *(Environmental context and resources)*	64	10 (15.6)	47 (73.5)	**4.0**[4] (82.4)	74	32 (42.6)	32 (42.7)	3.0 (58.4)	P<0.001* **individual pharmacists expressed significantly less agreement*
I have sufficient non-pharmacist staff levels to allow me to provide MAS to older patients *(Environmental context and resources)*	64	19 (29.7)	35 (54.7)	**4.0**[4] (76.9)	74	34 (45.4)	25 (33.3)	3.0 (63.0)	p=0.033* **individual pharmacists expressed significantly less agreement*
Colleagues in senior positions support me in providing adherence support to older patients *(Social influences)*	64	7(10.9)	38 (59.4)	**4.0**[4] (84.2)	74	29 (38.7)	20 (26.7)	3.0 (65.8)	p<0.001* **individual pharmacists expressed significantly less agreement*

[1] Stores which had two or more CPs working on at least one day of the week; [2] Includes those who strongly agreed or agreed; [3] Includes those who strongly disagreed or disagreed; [4] A high median of 4 or 5 signified a potential barrier to the provision of MAS; [5] Mann-Whitney U test

Table 5.9: Statistically significant differences in responses to TDF Likert items between pharmacists working at independently owned pharmacies, small/medium chains and large chains

TDF Likert Item (domain)	Independently owned pharmacy (IND)				Small/medium chain (S/M= 2-9 stores)				Large chain (LG= 10+ stores)				Overall Probability (p) value[4]	Post hoc pair wise comparison: probability (p) values[5]
	Total N	N (%) who agreed[1]	N (%) who dis-agreed[2]	Median[3] (Mean rank in KW)	Total N	N (%) who agreed[1]	N (%) who dis-agreed[2]	Median[3] (Mean rank in KW)	Total N	N (%) who agreed[1]	N (%) who dis-agreed[2]	Median[3] (Mean rank in KW)		
I have been trained to provide MAS to older patients in line with NICE guidance *(skills)*	41	14 (34.1)	14 (24.2)	3 (67.01)	39	17 (42.5)	8 (20)	3.0 (58.2)	59	12 (20.4)	30 (50.9)	**4.0[3]** (79.8)	p=0.022	IND verses S/M: p=0.919 S/M verses LG: p=0.021* IND verses LG: p=0.316 **CPs in large chains expressed significantly less agreement than CPs in small/medium chains*
Providing MAS to older patients is a high priority for me in my daily practice[6] *(Motivation and goals)*	41	22 (56.3)	5 (12.2)	2 (70.9)	39	28 (70)	4 (10)	2.0 (56.9)	59	27 (45.8)	11 (18.6)	3.0 (78.1)	p=0.024	IND verses S/M: p= 0.286 S/M verses LG: p=0.019* IND verses LG: p= 1.000 **CPs in large chains expressed significantly less agreement than CPs in small/medium chains*
I have sufficient pharmacist staff levels to allow me to provide MAS to older patients *(Environmental context and resources)*	41	17 (41.4)	19 (46.3)	3.0 (61.9)	39	15 (37.5)	18 (45)	3.0 (62.1)	59	10 (17.0)	42 (71.2)	**4.0[3]** (80.9)	p=0.17	IND verses S/M: p= 1.000 S/M verses LG: p= 0.057 IND verses LG: p= 0.046* **CPs in large chains expressed significantly less agreement than CPs in independent pharmacies*
Colleagues in senior positions support me in providing adherence support to older patients *(Social influences)*	41	17 (41.4)	11 (26.8)	3.0 (58.1)	39 39	14 (35.0)	13 (32.5)	3.0 (62.0)	59	5 (8.5)	24 (57.7)	**4.0[3]** (83.6)	p=0.002	IND verses S/M: p=1.000 S/M verses LG: p=0.020* IND verses LG: p=0.004* **CPs in large chains expressed significantly less agreement than CPs in both independent pharmacies and small/medium chains*

[1]Includes those who strongly agreed or agreed; [2]Includes those who strongly disagreed or disagreed; [3]A high median of 4 or 5 signified a potential barrier to the provision of MAS; [4]Kruskal-wallis test; [5]Post-hoc pairwise comparisons (Dunn's multiple comparisons test) were adjusted using the Bonferroni correction for multiple tests; [6]Item was reverse worded in questionnaire (reverse phrased and recoded for data analysis purposes)

A quarter of CPs (n=35; 24.5%) took the opportunity to comment at the end of the questionnaire, with comments re-emphasising barriers and facilitators that had previously been addressed within Section 3 of the questionnaire. Although MAS provision was seen as a valuable service, the majority of comments focused on insufficient levels of reimbursement (n=17), followed by the lack of time in current practice to provide such support (n=7).

> *"MAS* [Medication Adherence Support] *is an important service but remuneration warrants it unfeasible. We do it when it is required but do not offer it freely—the payment— what payment!"* (R95)

> *"Much, much work has to be carried out to convince GPs and HSCB* [Health and Social Care Board] *how vital this service is. At present the service is not sustainable without a fair contract and appropriate remuneration."* (R115)

> *"The service must be appropriately remunerated to allow a quality service— unlike the current provision of blister packs– grossly underfunded and supported. This service has grown as an ad-hoc* [sticking] *plaster service."* (R141)

> *"Although an important service and part of my practice I feel that time constraints sometimes make it difficult to provide comprehensive support for <u>all</u> patients."* (R03)

A large number of participants' (n=17) comments focused specifically on the provision of MDS as an adherence enhancing strategy (e.g. rising demand, safety issues/adverse events, mixed benefits, pressure from other HCPs to supply MDS, inadequate reimbursement, time constraints).

> *"I feel we are pressured by social care and GPs to provide 'mediboxes'* [Monitored Dosage System] *which in my experience have mixed results in terms of adherence…"* (R57)

> *"Safety is priority so we have to limit the number of patients we supply dossette boxes* [Monitored Dosage System] *to make sure there is sufficient time/staff to make them safely. Unfortunately demand for dossette boxes is higher than what we can physically cope with."* (R101)

A few CPs emphasised the potential benefits of having access to the ECR (n=3) and access to additional training (n=2).

> *"More integrated software solutions with PMR* [Patient medication record]*, ECR* [Electronic Care Record summary] *would be extremely beneficial."* (R86)

> *"Any further training would be welcomed. Delivery of medication adherence support is currently only touching the tip of the iceberg. Lack of funding and a limit of MUR* [Medicine Use Review Service] *and MYM* [Managing Your Medicines Service] *thresholds is a limiting factor."* (R07)

Other CPs emphasised that they would need additional pharmacist staffing levels to allow this type of support to be provided more routinely (n=2).

> *"There needs to be an adherence support service with training, goals, guidelines, remuneration. When I get sufficient proper services then I can consider employing a second pharmacist leaving me uninterrupted time to discuss medication issues."* (R01)

> *"The main factor which determines how much time I can spend on adherence issues depends on the availability of a second* pharmacist*."* (R131)

Some CPs emphasised a perceived lack of support from GP colleagues (n=4).

> *"Very little support from GPs regarding issues."* (R38)

> *"Time is a massive factor—I don't have it and GPs are unwilling to help."* (R73)

Other comments highlighted that the provision of MAS was opportunistic (n=1), conflicting demands, such as remunerated services, took priority (n=1) and that MAS should be prioritised to those with a lack of family support (n=1).

5.4.3 Triangulation of findings and identification of key TDF domains (data analysis stage 2 findings)

Following comparison of the summary of findings from the qualitative data analysis (Phase 1) and quantitative data analysis (Phase 2), and discussion among members of the research team, eight out of 12 domains were identified as relevant/important in the context of the target behaviour: 'Knowledge', 'Skills', 'Social, professional role and identity', 'Motivation and goals', 'Memory, attention and decision processes', 'Environmental context and resources', Social influences' and 'Behavioural regulation'. Four domains were not seen relevant/important in the context of the target behaviour: 'Beliefs about capabilities', 'Beliefs about consequences', 'Emotion', 'Nature of the behaviours'. The reasons for this are discussed later in Section 5.5.3.

Out of the eight domains deemed relevant/important in the context of the target behaviour, seven of these were considered to be key domains for targeting for behaviour change with a

training package for CPs and/or as part of a future research study. The domain 'Social, professional role and identity' was not selected for targeting; the reason for this is discussed later in Section 5.5.3.

5.4.4 Mapping of key TDF domains to BCTs (data analysis Stage 3 findings)

The seven key domains identified in Stage 2 were mapped across to BCTs using the two reference sources discussed previously in Chapter 3 (Section 3.3.7) (Michie et al. 2008; Cane et al. 2015). Thirty nine potential BCTs were identified using this mapping approach and were subsequently considered by the research team for inclusion in a CP training package to accompany the ID-MAP intervention and/or to be delivered as part of a future research study. Using group consensus, 18 BCTs were selected: 'Information about health consequences (and behaviour)', 'Antecedents', 'Feedback on behaviour', 'Graded tasks', 'Behavioural rehearsal/practice', 'Self-monitoring', 'Rewards/incentives', 'Increasing skills (e.g. decision making, problem solving)', 'Modelling or demonstrating the behaviour', 'Homework', 'Behavioural contract', 'Action planning', 'Social support (unspecified)', 'Credible source', 'Prompts/cues', 'Restructuring the social environment', 'Social reward' and 'Use of imagery'. Table 5.10 outlines the BCTs that mapped to each key domain as well as reasons for selection (or non-selection). Table 5.11 provides definitions for each selected BCT (n=18) and an indication of whether the BCT could be delivered as part of a training package and/or as part of a future research study to improve the implementation of the patient-targeted (ID-MAP) intervention.

Table 5.10: Mapping of key domains to behaviour change techniques (BCTs) for inclusion in a future training package for community pharmacists and/or to deliver as part of a future research study to improve implementation of the patient intervention

Key TDF domain	**BCTs** [a]=Primary reference source (Cane et al. 2015) [b]=Secondary reference source (Michie et al. 2008)	**BCT selected** ✓ = YES X = NO	**Rationale for selection (or non-selection) of BCT(s) to include in a training package and/or to deliver as part of a future research study**
Knowledge	• Information about health consequences[a] /Information regarding behaviour, outcome[b]	✓	Information about the behaviour and potential positive outcomes for patients could be presented to CPs at a training workshop. This BCT also mapped to the 'Motivation and goals' domain—see below. *Note: The BCT 'information regarding behaviour, outcome' encapsulates the BCT 'information about health consequences'.*
	• Feedback on behaviour[a]	✓	CPs could be given verbal feedback on their performance of providing MAS during a training workshop, after having the opportunity to practice the behaviour. Feedback on behavioural performance could also be given as part of a future research study.
	• Antecedents[a] (i.e. preceding factors)	✓	CPs could be provided information about the factors that can positively or negatively affect the performance of the behaviour such as time, skills training etc.
	• Biofeedback[a]	X	This BCT was not deemed relevant in the context of the target behaviour (provision of MAS).
Skills	• Graded tasks[a]/Graded tasks, starting with easy tasks[b]	✓	CPs could be set tasks to perform in a training workshop, ranging in complexity from easy to difficult. This BCT also mapped to the 'Motivation and goals' domain—see below. *Note: These BCTs were deemed to be equivalent.*
	• Behavioural rehearsal/practice[a]/rehearsal of relevant skills[b]	✓	CPs could practice performing the behaviour with patient actors as part of a training workshop using role play scenarios. *Note: These BCTs were deemed to be equivalent.*
	• Habit reversal[a] • Body changes[a] • Habit formation[a] • Perform behaviour in different settings[b]	X	These BCTs were not deemed relevant in the context of the target behaviour (provision of MAS).
	• Goal/target specified: behaviour or outcome[b]	X	This BCT was not deemed appropriate to deliver in the context of a future study as recruitment targets would likely be pre-specified.

Table 5.10 (cont'd): Mapping of key domains to behaviour change techniques (BCTs) for inclusion in a future training package for community pharmacists and/or to deliver as part of a future research study to improve implementation of the patient intervention

Key TDF domain	**BCTs** [a]=Primary reference source (Cane et al. 2015) [b]=Secondary reference source (Michie et al. 2008)	**BCT selected** ✓ = YES X = NO	**Rationale for selection (or non-selection) of BCT(s) to include in a training package and/or to deliver as part of a future research study**
Skills (cont'd)	• Self-monitoring[b]	✓	CPs could record the number of patients they provided MAS to during future research studies in a daily pharmacy tasks diary. This BCT also mapped to 'Memory, attention and decision processes' domain—see below.
	• Monitoring (i.e. feedback on behaviour)[b]	✓	Equivalent to 'Feedback on behaviour' from BCTTv1. This BCT also mapped to the 'Knowledge' domain—see above.
	• Rewards; incentives[b]	✓	Small monetary incentives could be provided to encourage CPs to perform the target behaviour as part of future research studies. This BCT also mapped to the 'Motivation and goals' domain—see below.
	• Increasing skills e.g. decision making, problem solving[b]	✓	CPs could be trained on how to decide on the best adherence solutions for older patients during a training workshop. This could be facilitated by a decision-making tool (e.g. a mobile application on a hand-held tablet device) that maps adherence problems across to potential adherence solutions.
	• Modelling/demonstration of behaviour by others[b]	✓	The target behaviour (provision of MAS) could be demonstrated as part of the training workshop. This could be video-recorded in advance with a patient actor.
	• Homework[b]	✓	CPs could be given reading material on the target behaviour to review at home in advance of the workshop or given additional example patient scenarios following the training workshop.
Motivation and goals	• Behavioural contract[a]/contract[b]	✓	CPs could be asked to sign a written contract, agreeing to carry out the target behaviour in their own clinical practice as instructed in the training workshop. *Note: These BCTs were deemed to be equivalent.*
	• Commitment[a]	X	This BCT was not deemed relevant in the context of the target audience (CPs).
	• Goal setting (outcome)[a] • Goal setting (behaviour)[a] • Review of outcome goal(s)[a] • Review behaviour goal(s)[a] • Goal/target specified: behaviour or outcome[b]	X	Goal/target specified: behaviour/outcome also mapped to 'Skills' domain— see reason for non-selection above. *Note: The BCT 'Goal/target specified: behaviour/outcome' encompasses the four goal-based BCTs identified from Cane et al. (2012).*

Table 5.10 (cont'd): Mapping of key domains to behaviour change techniques (BCTs) for inclusion in a future training package for community pharmacists and/or to deliver as part of a future research study to improve implementation of the patient intervention

Key TDF domain	**BCTs** [a]=Primary reference source (Cane et al. 2015) [b]=Secondary reference source (Michie et al. 2008)	**BCT selected** ✓ = YES X = NO	**Rationale for selection (or non-selection) of BCT(s) to include in a training package and/or to deliver as part of a future research study**
Motivation and goals (cont'd)	• Action planning (including implementation intentions)[a]	✓	As part of a training workshop, CPs could be instructed to develop advance plans for how they will identify and provide MAS to older patients in their clinical practice.
	• Rewards; incentives	✓	These BCTs also mapped to the 'Skills' domain—see above.
	• Graded tasks, starting with easy task[b]	✓	
	• Increasing skills e.g. decision making, problem solving [b]	✓	
	• Social processes of encouragement, pressure, support[b]	✓	The research team could provide encouragement/support as part of a future research study. Group support could also be encouraged as part of the training workshops. This BCT also mapped to 'Social influences'— see below.
	• Persuasive communication i.e. credible source[b]	✓	A credible source (defined as an expert or leader in the field) could present arguments in favour of performing the behaviour to CPs at a training workshop.
	• Information regarding behaviour/outcome [b]	✓	This BCT also maps to the domain 'Knowledge'—see above.
	• Motivational interviewing[b]	X	This BCT would not be feasible to deliver as part of a future study as it would likely require comprehensive training of research staff and delivery over multiple sessions.
Memory, attention and decision processes	• Self-monitoring [b]	✓	This BCT also mapped to the 'Skills' domain— see above.
	• Planning, implementation	✓	Equivalent to 'Action planning' in BCTTv1. This BCT also mapped to the 'Motivation and goals' and 'Behavioural regulation' domains— see reason for selection above.
	• Prompts, triggers, cues[b]	✓	Prompts could be included as part of the decision-making tool on a mobile application using a hand-held tablet device. In addition, pharmacy support staff could help prompt CPs to provide MAS to older people. This BCT also mapped to the domains 'Environmental context and resources' and 'Behavioural regulation'—see below.

Table 5.10 (cont'd): Mapping of key domains to behaviour change techniques (BCTs) for inclusion in a future training package for community pharmacists and/or to deliver as part of a future research study to improve implementation of the patient intervention

Key TDF domain	**BCTs** [a]=Primary reference source (Cane et al. 2015) [b]=Secondary reference source (Michie et al. 2008)	**BCT selected** ✓ = YES X = NO	**Rationale for selection (or non-selection) of BCT(s) to include in a training package and/or to deliver as part of a future research study**
Environmental context and resources	• Restructuring the social environment	✓	CPs could be advised to restructure their social working environment by involving pharmacy support staff in the process of identifying potentially non-adherent older patients.
	• Avoidance/ changing exposure to cues for the behaviour[a] • Discriminative (learned) cue[a] • Restructuring the physical environment[a]/environmental changes[b]	X	These BCTs were not deemed relevant to the target behaviour (provision of MAS).
	• Prompts/cues[a]	✓	This BCT also mapped to 'Memory, attention and decision processes' and 'Behavioural regulation' domains—see reason for selection above.
Social influences	• Social comparison[a] • Information about others' approval[a]	X	These BCTs would not be feasible to deliver as part of a training package or in the context of future research studies.
	• Social support (unspecified)[a]/Social processes of encouragement, pressure, support[b]	✓	This BCT mapped to the 'Motivation and goals' domain—see above. *Note: These BCTs were deemed to be equivalent.*
	• Social support (practical)[a] • Social support (emotional)[a]	X	These BCTs are encompassed by the BCT 'Social support (unspecified)'—see above.
	• Vicarious reinforcement[a] • Identification of self as role model[a]	X	These BCTs were not deemed relevant in the context of the target behaviour (provision of MAS).
	• Restructuring the social environment[a]	✓	This BCT also mapped to the domain 'Environmental context and resources'—see above.
	• Modelling or demonstrating the behaviour[a]/ modelling/demonstration of behaviour by others[b]	✓	This BCT also mapped to the domain 'Skills'—see above. *Note: These BCTs were deemed to be equivalent.*
	• Social reward	✓	CPs could be given verbal rewards if there has been sufficient effort/progress in performing the behaviour during the context of a future research study.

Table 5.10 (cont'd): Mapping of key domains to behaviour change techniques (BCTs) for inclusion in a future training package for community pharmacists and/or to deliver as part of a future research study to improve implementation of the patient intervention

Key TDF domain	**BCTs** [a]=Primary reference source (Cane et al. 2015) [b]=Secondary reference source (Michie et al. 2008)	**BCT selected** ✓ = YES X = NO	**Rationale for selection (or non-selection) of BCT(s) to include in a training package and/or to deliver as part of a future research study**
Behavioural regulation	Goal/target specified: behaviour or outcome	X	This BCT also mapped to the 'Motivation and goals' domain—see reason for non-selection above.
	Contract	✓	This BCT also mapped to the 'Motivation and goals' domain—see reason for selection above.
	Planning, implementation	✓	This BCT also mapped to 'Motivation and goals' and 'Memory, attention and decision processes' domains— see reason for selection above.
	Prompts, triggers, cues	✓	This BCT also mapped to 'Memory, attention and decision processes' and 'Environmental context and resources' domains—see reason for selection above.
	Use of imagery	✓	Visuals (e.g. videos) could be used to deliver other selected BCTs such as demonstration of the behaviour.

Table 5.11: Proposed delivery of BCTs as part of a training package for CPs and/or as part of a future research study to support the delivery of the ID-MAP intervention

Behaviour change technique (BCT)	Definition from BCTTv1 (Michie et al. 2013)	How might the BCT be delivered?	
		As part of a training package for CPs (e.g. a one day group-based workshop)	As part of a future research study (e.g. pilot study)
Information on health consequences (and behaviour)	'Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour.' Also includes provision of information about the behaviour (Michie et al. 2008)	✓	
Antecedents	'Provide information about antecedents (e.g. social and environmental situations and events, emotions, cognitions) that reliably predict performance of the behaviour.'	✓	
Feedback on behaviour	'Monitor and provide informative or evaluative feedback on performance of the behaviour (e.g. form, frequency, duration, intensity).'	✓	✓
Graded tasks	'Set easy-to-perform tasks, making them increasingly difficult, but achievable, until behaviour is performed.'	✓	
Behavioural rehearsal/practice	'Prompt practice or rehearsal of the performance of the behaviour one or more times in a context or at a time when the performance may not be necessary, in order to increase habit and skill.'	✓	
Self-monitoring	'Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy'		✓
Rewards; incentives	'Arrange for the delivery of money, vouchers or other valued objects if and only if there has been effort and/or progress in performing the behavior'		✓
Increasing skills (e.g. decision making, problem solving)	Not included in BCTTv1: no definition provided in either Cane et al. (2015) or Michie et al. (2008)	✓	✓
Modelling or demonstrating the behaviour	'Provide an observable sample of the performance of the behaviour, directly in person or indirectly e.g. via film, pictures, for the person to aspire to or imitate…'	✓	
Homework	Not included in BCTTv1: no definition provided in either Cane et al. (2015) or Michie et al. (2008)	✓	

Table 5.11 (cont'd): Proposed delivery of BCTs as part of a training package for CPs and/or as part of a future research study to support the delivery of the ID-MAP intervention

Behaviour change technique (BCT)	Definition from BCTTv1 (Michie et al. 2013)	How might the BCT be delivered?	
		As part of a training package for CPs (e.g. one day group workshop)	As part of a future research study (e.g. pilot study)
Behavioural contract	'Create a written specification of the behaviour to be performed, agreed on by the person, and witnessed by another.'	✓	
Action planning	'Prompt detailed planning of performance of the behaviour (must include at least one of context, frequency, duration and intensity). Context may be environmental (physical or social) or internal (physical, emotional or cognitive).'	✓	
Social support (unspecified)	'Advise on, arrange or provide social support (e.g. from friends, relatives, colleagues,' buddies' or staff) or non-contingent praise or reward for performance of the behaviour. It includes encouragement and counselling, but only when it is directed at the behaviour.'	✓	✓
Persuasive communication/credible source	'Present verbal or visual communication from a credible source (e.g. celebrities or words used to indicate expertise or leader in field) in favour of or against the behavior.'	✓	
Prompts/cues	'Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance.'		✓
Restructuring the social environment	'Change, or advise to change the social environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour (other than prompts/cues, rewards and punishments).'		✓
Social reward	'Arrange verbal or non-verbal reward if and only if there has been effort and/or progress in performing the behaviour.'	✓	✓
Use of imagery	Not included in BCTTv1. Defined in Michie et al. (2008) as 'Use planned images (visual, motor, sensory) to implement behaviour change techniques (inc. mental rehearsal)'	✓	

5.5 Discussion

The current chapter has outlined key findings from a mixed methods study that sought to identify key determinants influencing the provision of MAS by CPs to older adults prescribed polypharmacy. In a similar approach used to develop the content of the patient-targeted intervention (outlined in Chapter 3), the TDF was used as a 'theoretical lens' in the current study to explore the clinical behaviour of CPs. This study has extended the methods used previously in this thesis by incorporating a quantitative phase and triangulating findings with findings from the qualitative phase. Following identification of key TDF domains to target for behaviour change (using the triangulated data), these domains (n=7) were mapped across to BCTs (n=18) using established methods (Michie et al. 2008; Cane et al. 2015). As part of future research the identified BCTs will be delivered to CPs as part of a theory-based training package (e.g. 'Demonstration of the behaviour') that will accompany the patient-targeted intervention and/or as part of a future research study (e.g. 'Rewards; incentives') to improve the provision of MAS by CPs and subsequent implementation of the patient intervention.

5.5.1 Current provision of medication adherence support by community pharmacists in Northern Ireland

As part of this mixed methods study it was also deemed important to explore what CPs in NI were doing in their daily practice to support older patients prescribed polypharmacy with medication adherence. The quantitative phase of this study (Phase 2) highlighted that less than half of surveyed CPs reported frequent use of methods (e.g. PMR computer systems) to identify non-adherent older patients who may require adherence support. For example, only a third of surveyed CPs (33.6%) reported frequently asking older patients if they had missed any doses of medication. This reflects findings from an EU-wide survey of 3,196 HCPs (pharmacists, doctors and nurses) that found only half of HCPs regularly asked patients about missed doses (Clyne et al. 2016). Pharmacists in the EU-wide survey were five times less likely to ask patients about missed doses (OR: 0.2; 95% CI: 0.17-0.27) in comparison with doctors. Given the scale of the problem of non-adherence, this represents a missed opportunity in the community pharmacy setting, as CPs have frequent contact with these patients when they collect prescriptions for repeat medications. CPs have a significant role to play in identifying non-adherent patients and delivering strategies to improve this, but to do this effectively CPs require access to specific training on managing medication adherence and systems (e.g. adequate reimbursement levels) that support this (Sabate, 2003). Despite the provision of services such as MURs and MYM, the current study has shown that only half of

surveyed CPs in NI have undertaken training on medication adherence in the previous five years, highlighting that more widespread training is necessary.

The provision of MURs in recent years in NI has provided the opportunity for CPs to identify non-adherent patients. The majority of surveyed pharmacists offered this service (93.0%) to an average of 70 (±42.7) patients each year. In comparison, the MYM service, which is a more comprehensive medication review service available in NI, was only offered by less than half of surveyed CPs (42.7%) and to a very small minority of patients [8.08 (± 8.35)] each year. As indicated previously, neither service incorporates a structured adherence support component which could be limiting their usefulness in the context of improving adherence. In addition, their effectiveness and cost-effectiveness remains unknown (Wright, 2016)

Despite research emphasising the importance of tailored approaches to addressing medication non-adherence, under two fifths of CPs (38.5%) reported frequently tailoring adherence solutions to the underlying reasons for older patients' non-adherence. One of the most frequently offered adherence solutions was the provision of MDS which was most commonly supplied at the request of others (e.g. carers). This finding is similar to findings reported by Mansoor et al. (2014), whereby 95% of Australian CPs who were surveyed reported that MDS was the most common adherence strategy they offered. Some CPs who were interviewed in Phase 1 of the current study emphasised purposefully avoiding offering this solution to patients due to pressures they faced in terms of capacity (i.e. limited staff members to prepare MDS), safety concerns (potential increased risk of dispensing errors) and a lack of funding for the provision of this adherence solution.

The UK Royal Pharmaceutical Society has recently published guidance on the best use of MDS, indicating that this solution is commonly selected without giving full consideration to the range of alternative adherence solutions (Royal Pharmaceutical Society, 2013). The reason for this may be due to the convenience this solution offers for patients on complex regimens. The RPS guidance indicates that MDS should be selected out a range of solutions taking into consideration any risks and potential benefits. It has been recognised both in this study and similar research that focused specially on MDS provision in the community pharmacy setting (Stewart et al. 2017) that CPs do not consider MDS to be the most suitable solution for all non-adherent patients. The decision to supply MDS is often influenced by others (e.g. other HCPs, carers) and research has shown that they are commonly issued without first discussing the best option with patients (Nunney et al. 2011; Stewart et al. 2017). This approach does not align with patient-centred care that has been advocated by NICE (National Institute for Health and Clinical Excellence, 2009).

Although MDS are widely used, there is limited evidence to support this, with systematic reviews that have explored their effectiveness reporting mixed findings (Mahtani et al. 2011; Boeni et al. 2014; Watson et al. 2016). The evidence in relation to the effectiveness of MDS is also limited by high risk of bias and poor quality studies and so more research in this area is urgently needed. In the UK, research is underway to explore the effectiveness/cost-effectiveness of MDS, although a definitive RCT has yet to be completed (Bhattacharya et al. 2016). There are a number of problems associated with MDS such as the stability of medications, potential to cause adverse events if medications are inappropriately prescribed and safety considerations (e.g. dispensing errors) (Royal Pharmaceutical Society, 2013). Although MDS are potentially beneficial for those who are unintentionally non-adherent (e.g. due to forgetfulness), this adherence solution does not address intentional non-adherence. Alternative solutions relevant for all patients or packages of solutions that can be individually tailored to each patient's need require investigation. Self-monitoring of the behaviour through the use of a medication diary is an example of a solution that could be relevant for a wide range of non-adherent patients, by acting both as a reminder for unintentionally non-adherent patients and forcing intentionally non-adherent patients to reflect on their behaviour (Snyder, 1979). Self-monitoring also offers the opportunity for HCPs to provide feedback to patients (based on a review of the patients' diary) and a platform for discussing the potential health consequences of non-adherence.

5.5.2 Determinants of providing medication adherence support to older adults prescribed polypharmacy

This study has highlighted multiple determinants potentially influencing CPs' behaviour in terms of providing MAS to older adults who are prescribed polypharmacy. Although the vast majority of surveyed CPs in Phase 2 of this study agreed that the provision of MAS was their responsibility (73.4%) and part of their current role as a community pharmacist (83.9%), it appears that this has not been translated into action in clinical practice. It was unsurprising that a lack of time, insufficient pharmacist staff levels (domain: 'Environmental context and resources') and insufficient reimbursement (domain: 'Motivation and goals') were identified as potential barriers to the target behaviour. These findings reflect the most commonly identified barriers to the provision of clinical services in the community setting (Dunlop and Shaw, 2002; Roberts et al. 2008; Lounsbery et al. 2009; Osborne et al. 2011) and are also consistent with findings from similar research on the provision on MAS that was recently conducted in Australia (Mansoor et al. 2014).

A lack of time was the most frequently mentioned barrier in the qualitative phase of this study (Phase 1) but this was not the greatest potential barrier in the quantitative phase (Phase 2). Just over half of CPs (59.5%) in the quantitative survey indicated they did not have enough time to provide MAS to older people, whereas a lack of reimbursement appeared to be the greatest potential barrier with just over three-quarters of CPs (76.3%) indicating they did not receive sufficient reimbursement for this clinical activity. A qualitative study conducted in Scotland (Bacci et al. 2014) has also reported that a lack of time was not seen as the greatest barrier to implementing an adherence intervention, which was in contrast with previously conducted research (Osborne et al. 2011). A lack of reimbursement has also been cited as the most important facilitator of practice change from the viewpoint of CPs in a study conducted in Spain (Gastelurrutia et al. 2009).

The use of a comprehensive theoretical model of behaviour change in this study has however, helped go beyond identifying the barriers most commonly considered in the delivery of any new community pharmacy service, such as a lack of time, insufficient staff resources or reimbursement (Dunlop and Shaw, 2002; Roberts et al. 2008; Lounsbery et al. 2009; Osborne et al. 2011; Huston, 2015). This theory-based approach has allowed for an exploration of other important areas such as CPs' knowledge, skills and confidence in relation to the target behaviour. Although CPs were mainly confident in this area and reported having good communication skills, two thirds of CPs (66.5%) indicated that they required additional training on techniques that can be used to increase older patients' motivation to adhere, such as goal-setting techniques and action planning (domain: 'Skills'). This is an important finding as these types of skills would be essential for the future implementation of the patient (ID-MAP) intervention.

The qualitative component of this study (Phase 1) also highlighted that there may be differences in perceived barriers across different groups of CPs, for example, between those working at independently-owned pharmacies versus those working for pharmacy chains. To explore this further, subgroup analysis was undertaken as part of Phase 2 (quantitative component) of this study which revealed some interesting findings. Interestingly, more CPs working at independently-owned pharmacies (41.5%) and small/medium chains (2-9 pharmacies) (35.0%) felt supported by colleagues working in senior positions in comparison with CPs working at larger chains (10+ pharmacies) (8.5%; p=0.002). In addition, only 17% of CPs working at large chains agreed they had sufficient pharmacist staff levels in comparison with 41.4% of CPs at independently-owned pharmacies (p=0.046) (domain: Environmental context and resources). Another interesting finding was that CPs who had undertaken

training on medication adherence in the previous five years were more likely to monitor and record their behaviour (44%) in comparison with those who had not undertaken training (23.5%; p=0.05) (domain: 'Behavioural regulation'). Self-monitoring of behaviour could help CPs to reflect on what they are currently doing in practice and encourage them to improve on this in the future.

5.5.3 Selection of key TDF domains to target for behaviour change

Following triangulation of data from Phases 1 and 2 and discussions between members of the research group (DP, CH, CR), consensus was reached and eight domains were identified as relevant/important in the context of the target behaviour. Six of these domains were selected because they were frequently coded in the qualitative analysis (listed in order of frequency): 'Environmental context and resources', 'Motivation and goals', 'Social, professional role and identity', 'Social influences' 'Skills' and 'Knowledge'. All but two of these domains ('Knowledge', 'Social, professional role and identity') also had had potential barriers identified in the quantitative analysis (Phase 2). The following two domains, although not as frequently coded in Phase 1, were selected because the quantitative analysis (Phase 2) revealed potential barriers to the target behaviour within these domains: 'Memory, attention and decision processes' and 'Behavioural regulation'. For example, under the 'Memory, attention and decision processes' domain, over two-thirds of CPs (68.5%) reported that they found it difficult to decide on the best adherence solutions to offer older patients. The 2003 WHO report recognised this difficulty and highlighted that clinical decision-making process needs to be covered as part of training alongside the development of 'behavioural tools' for HCPs (Sabate, 2003). A decision making tool, such as that developed for the feasibility study outlined in Chapter 4 (ID-MAP Tool), may assist CPs in this complex decision process.

Four domains ('Beliefs about capabilities', 'Beliefs about consequences', 'Emotion', 'Nature of the behaviours') were not selected as relevant/important in the context of the target behaviour. This was because they were not frequently coded in the qualitative analysis (Phase 1) and the quantitative analysis (Phase 2) did not highlight potential barriers/facilitators to the target behaviour within these domains. In relation to CPs' confidence (domain: 'Beliefs about capabilities'), the qualitative findings suggest that this stems from their level of skills training and so focusing on the latter is of greater importance. The quantitative component of this study confirmed that the majority of CPs were confident in providing adherence support to older patients but lacked the skills required to motivate older patients to change their behaviour. Emotions were rarely discussed in the context of the target behaviour and no barriers were identified under the 'Emotion' domain in the

quantitative analysis which confirmed this finding. In relation to CPs' 'Beliefs about the consequences', these were discussed less frequently than other domains in the qualitative analysis and CPs reported having awareness of the positive consequences of providing MAS to older adults prescribed polypharmacy. In addition, no barriers were identified under this domain in the quantitative analysis. Although it was noted that certain adherence support activities were already routine (e.g. provision of MDS) or could become more routine (e.g. asking patients about missed doses), the overall behaviour was not seen as automatic and instead requires planning and consideration. Consequently, the 'Nature of the behaviours' domain was not deemed relevant/important in this context.

The current study has highlighted the usefulness of a mixed methods approach in selecting domains that are relevant/important in the context of the target behaviour. The majority of studies that have previously employed the TDF have relied on qualitative data from interviews and used frequency counts as a crude measure of a domain's relevance/importance (Atkins et al. 2017). This study takes this a step further by providing quantitative data to support the qualitative findings and also identify domains which are likely to be important but are infrequently coded in qualitative research (e.g. 'Behavioural regulation' in the current study).

Although the domain 'Social, professional role and identity' was identified as important/relevant in this context, it was not selected as a key target domain for behaviour change. CPs largely considered the target behaviour to be part of their role, although they recognised that an inability to prescribe and lack of integration in the primary healthcare team were potential barriers to the provision of MAS. Changing the role of CPs in the primary care setting would require major policy and organisational changes which was deemed to be beyond the scope of a future research study (e.g. pilot study).

5.5.4 Selection of BCTs to bring about behaviour change

Out of the 39 BCTs identified using the mapping approaches developed by Michie et al. (2008) and updated by Cane et al. (2015), 18 BCTs were selected. These were selected because it was agreed that these would be feasible to deliver either as part of a training package for CPs to accompany the ID-MAP intervention or in a future research study. As discussed previously in Chapter 3, some BCTs in the two reference sources have overlapping characteristics and similar names. The research team opted for the most up-to-date terminology, as reported by Cane et al. (2015), as these are consistent with the BCTTv1 (Michie et al. 2013).

It was proposed that 10 BCTs could be delivered during a training workshop (e.g. 'Demonstration of the behaviour'), four BCTs could be solely delivered as part of a future research study (e.g. 'Reminders; incentives') and four BCTs could be delivered as part of both. For example, the BCT 'Social support (unspecified)' could be delivered both at a training workshop through group activities and also as part of a future research study through encouragement from the research team or by creating opportunities for CPs to communicate with each other for support (e.g. using social messaging platforms).

Ten out of the 18 BCTs that were selected in this mapping process mapped to multiple key target TDF domains and collectively covered all seven key domains. For example, the BCT 'Prompts and cues' mapped to three domains ('Memory, attention and decision processes', 'Environmental context and resources' and 'Behavioural regulation'). For the patient-targeted intervention (Chapter 3), the time constraints in the community pharmacy setting dictated the selection of BCTs as CPs would have only limited time to spend with individual patients in which to deliver BCTs. Therefore, BCTs that targeted multiple domains were selected over those that did not in the patient-targeted intervention. For the current study, the issue of time was not deemed a major consideration as a larger number of BCTs could be delivered to CPs during a one day workshop (e.g. 'Demonstration of the behaviour', 'Graded tasks') or as part of a future study (e.g. 'Rewards; incentives').

5.5.5 Methodological advancements

The current study involved a mixed methods approach using both qualitative and quantitative methods to guide the selection of key domains to target for behaviour change. To the best of our knowledge, this is the first study to outline, in detail, the processes undertaken to select key TDF domains to target by triangulating findings from both qualitative and quantitative approaches. Guidance on the use of the TDF was published shortly after the completion of this study (Atkins et al. 2017). This guidance focuses on qualitative approaches, although the authors recognised that TDF-based methodology is evolving to include quantitative approaches. The current study contributes to the growing literature on the use of mixed methods TDF-based approaches. The qualitative methods employed in both the current study and in Chapter 3 (patient focus groups) reflect the methods advocated in this recently published guidance on how to use the TDF.

5.5.6 Study strengths and limitations

To the author's best knowledge, this is the first study to make use of the TDF as a theoretical lens to explore the provision of MAS by CPs to older adults prescribed polypharmacy. A key

strength of this study was the triangulation of data from both qualitative and quantitative approaches which helps to increase the generalisability of findings. The study followed guidance from the MRC which recommends incorporating a theoretical base when developing interventions designed to change behaviours, such as training packages for HCPs (Medical Research Council, 2008). By explicitly outlining the techniques that will be used to change CPs' behaviours (and the hypothesised causal processes), the current study follows recommendations in WIDER guidelines (Albrecht et al. 2013). The qualitative component of this study has also been reported in line with the COREQ checklist (see completed checklist in Appendix 5.10).

As a limitation of this study, the low response rate (27.4%) achieved for the survey (Phase 2) should be noted. This response rate was comparable to the response rate (27.6%) obtained in a survey on MAS that was mailed to 500 CPs in New South Wales, Australia (Mansoor et al. 2014). Both surveys focused on CPs' experiences of, and barriers to, providing MAS, although only the current study was informed by a theoretical framework (TDF). Despite two reminders in the study by Mansoor et al. (2014) and one reminder in the current study, response rates remained low. This may be due to a number of factors such as a lack of time to complete the survey, the time of mailing (which in the current study coincided with public holidays), a lack of interest in the topic or a current lack of provision of MAS.

Nonetheless, as discussed in Section 5.3.2, the response rate alone is not indicative of a poor quality study and instead researchers should seek to identify non-response bias (Davern, 2013; Halbesleben and Whitman, 2013). Attempts were therefore made to compare the survey sample characteristics with those of the entire population of CPs in NI. Despite challenges in doing so due to a lack of data focusing solely on CPs, similarities in terms of gender, age groups and post-graduate qualifications were observed between the sample of survey respondents and all pharmacists who were registered with the PSNI at the time of the study. However, it is important to note that there was a slight underrepresentation of females in the survey sample of CPs and over-representation of those in managerial positions which may impact on the generalisability of findings. Nonetheless, the findings reported in this study included the views and opinions of CPs from across different areas (rural, suburban, urban) and working in different types of pharmacies (independently-owned pharmacies, small/medium chains and large chains). This variation helps to increase the generalisability of findings, to a certain extent, to the population of CPs practising in NI. The potential for social desirability bias must also be noted, as CPs (in both the interviews and the survey) were made aware of the latest guidance on supporting patients with medication

adherence that had been published by NICE (National Institute for Health and Clinical Excellence, 2009). By using an anonymous self-administered questionnaire which included both positive and negatively phrased items it is hoped that the level of social desirability bias in the survey was minimal.

As indicated in Section 5.3.2, due to the complexity of the target behaviour (i.e. provision of MAS), it was not possible to discreetly measure this using a cross-sectional survey. Other studies of HCPs' behaviour have been able to measure their target behaviour. For example, a study by McParlin et al (2016) measured how frequently midwives advised pregnant women to undertake exercise and used this in regression analysis to explore which attitudes had the most significant influence on midwives' behaviour. In the current study, it was not feasible to carry out regression analysis which requires a specific target behaviour (i.e. dependent variable) and so statistical analyses were limited to descriptive statistics and non-parametric group comparison tests (MWU, KW).

As discussed in Section 5.3.6, it was not possible to combine scores for individual Likert items in each TDF domain due to low Cronbach's alpha values. As stated by Tavakol and Dennick (2011), 'A low value of alpha could be due to a low number of questions, poor interrelatedness between items or heterogeneous constructs'. Items for the current questionnaire were developed at the domain level which may help to explain the low α values (Huijg et al. 2014a). This findings is consistent with other TDF-based questionnaires that have sought to explore HCPs' behaviours and also reported low α values for domains (Amemori et al. 2011; Beenstock et al. 2012; Manikam et al. 2015). It was also not possible to carry out factor analysis (e.g. principle components analysis), to explore alternative underlying structures as has been done in previous TDF-based survey research, for the reasons stated previously (see Section 5.3.6). Alternatively, to aid the selection of TDF-domains to target for behaviour change, Likert items were individually assessed to identify potential barriers to the target behaviour within each domain. Triangulated qualitative and quantitative data aided decisions about the barriers that were most likely to influence the target behaviour. This represents a novel approach to selecting important/relevant domains that can be targeted for behaviour change.

5.6 Conclusion

This study involved a mixed methods approach to explore CPs' clinical behaviour, in terms of providing MAS to older adults prescribed polypharmacy. A range of determinants (barriers, facilitators) were perceived to influence the target behaviour including insufficient reimbursement, lack of relevant skills, and social support from colleagues and other HCPs. Triangulation of qualitative and quantitative findings facilitated the selection of seven key theoretical domains that could be targeted for behaviour change. Established methods were employed to map key TDF domains to BCTs, and using group consensus methods, multiple BCTs (n=18) were identified as applicable to the target audience and behaviour. As part of future research these BCTs will be delivered as part of a training package for CPs that will accompany the ID-MAP intervention and/or as part of a research study to improve the provision of MAS by CPs.

Chapter 6

General discussion and conclusion

6.1 General discussion

The research presented in this thesis has focused on improving medication adherence in older adults prescribed polypharmacy. Older patients commonly suffer from multimorbidity and it is widely accepted that polypharmacy is unavoidable and in many cases can be of therapeutic benefit. As stated by Duerden et al. (2013), 'Polypharmacy is likely to be futile if medicines are not taken as the prescriber intends'. Although a plethora of interventions have been tested over the last four decades to improve patients' medication adherence behaviours, there is a lack of strong evidence to support any particular strategy to bring about behaviour change. As a result, the problem of non-adherence continues to be a significant global challenge (Bosworth et al. 2011; Nieuwlaat et al. 2014).

It has been recognised that complex interventions containing multiple interacting components are likely to be the only possible answer to a multi-faceted problem such as adherence, although there are major challenges associated with developing and evaluating such interventions (Medical Research Council, 2008; Nieuwlaat et al. 2014). The role of theory in developing and evaluating complex adherence interventions has become a major topic in recent years, due to its potential to advance the field by going beyond simply identifying what works, and what does not, and more importantly, helping to explain the reasons why (Ruppar, 2010b).

The research presented in this thesis has therefore focused on the development and feasibility testing of a novel complex theory-based intervention (ID-MAP intervention) to improve medication adherence in older adults prescribed polypharmacy and managed in primary care. This intervention was designed for delivery by CPs in the community pharmacy setting for reasons stated previously (Nieuwlaat et al. 2014; Ryan et al. 2014). The methods adopted throughout the thesis have followed recommendations from the UK MRC with a focus on development and feasibility testing, as well as future implementation and training of intervention providers (Medical Research Council, 2008).

Chapter 2 of this thesis outlined findings from a systematic review that aimed to address a gap in the literature by exploring exactly how theory had been used previously to develop adherence interventions delivered to older adults prescribed polypharmacy. Chapter 3 involved the use of a comprehensive theoretical framework of behaviour change (TDF1), to guide the selection of components of a novel complex intervention aimed at improving older patients' adherence to multiple medications (i.e. polypharmacy). The work presented in Chapter 4 combined components identified in Chapter 3 into a complex intervention package

(ID-MAP intervention) and tested whether it was feasible to deliver this in the community pharmacy setting. Finally, Chapter 5 involved further development work to explore how the CP training package that accompanied the patient-targeted intervention could be enhanced by incorporating a theoretical basis (also using TDF1). This final study also identified strategies that could be used to enhance the future implementation of the intervention by exploring CPs' clinical behaviour in terms of providing MAS to older patients. The key findings from the work presented in this thesis are discussed below in more detail in the context of the wider literature, along with recommendations for future research, practice and policy considerations in this area.

6.1.1 Theory-based adherence interventions for older adults prescribed polypharmacy: an evidence gap

Previous systematic reviews of adherence interventions for older patients have not focused on how psychological theory has informed intervention development and evaluation (Banning, 2008; George et al. 2008; Ruppar et al. 2008). The research presented in Chapter 2 of this thesis addressed this gap in the literature by examining the effectiveness of theory-based adherence interventions that had been delivered to older adults prescribed polypharmacy and through an exploration of exactly how theory was used. The conduct of this review was in line with the development phase of the MRC framework, which recommends that researchers explore existing evidence in relation to the topic of interest and address any noted gaps in the literature.

An important finding from the review was that all of the studies focused on patients with a single long-term medical condition (or comorbidity) instead of including older patients with a range of LTCs (i.e. multimorbidity). This finding was not surprising given that the structure of healthcare provision globally focuses on a single-disease framework (Barnett et al. 2012). With an ageing population and growing number of older patients with multi-morbidity, adherence research needs to focus on developing interventions that can be tailored to multimorbid older patients irrespective of their underlying LTCs. This approach is necessary to meet the needs of both current and future populations of older people and is consistent with guidance published by NICE in 2016 on multimorbidity, which advocates for a tailored approach to healthcare (National Institute for Health and Care Excellence, 2016). The findings from the systematic review supported the need for further research in this area and the subsequent need for the remainder of the work presented in this thesis.

The findings from the review have also added to the literature by highlighting that only a limited number of interventions in this area have reported using psychological theory in their

development. As a result, there is a lack of robust evidence on their effectiveness and therefore more research is needed. Although authors from studies in the review cited theory, it was evident that the selection of intervention components was not always guided by theory, or at least was not reported as such. This may help to explain findings recently reported in a large meta-analysis of adherence interventions (delivered to all types of patients) that found effect sizes were greater for theory-based interventions (0.302) than non-theory based interventions (0.289), but this difference was not statistically significant (p=0.727) (Conn and Ruppar, 2017). The authors of this meta-analysis did not explore theory use in great detail as has been done in the review presented in this thesis. It is, therefore, hypothesised that this non-significant finding could be due to insufficient use of theory in intervention development.

Authors of studies included in our review rarely reported using theory to explore the underlying mechanism of action of the intervention (e.g. in a process evaluation). This is an important aspect of theory that could be better utilised to advance the field of adherence research by exploring not just 'if' interventions are effective but also 'how'. Furthermore, there was insufficient evidence available to support the use of any individual psychological theory in future intervention development. This reinforced the decision to use a comprehensive theoretical framework as a lens to explore the target behaviour in detail. Hence, the next chapter of the thesis presented how TDF1 was used as a theoretical lens to explore older patients' adherence behaviours, in the context of polypharmacy.

6.1.2 Selection of components for a complex intervention to improve medication adherence in older adults prescribed polypharmacy

In line with the development stage of the MRC framework, the work presented in Chapter 3 of this thesis described how TDF1 was used as part of a qualitative focus group study to explore the target behaviour of medication adherence in the target audience of older adults prescribed polypharmacy. Although determinants of adherence have been studied in previous research, to the best of our knowledge, determinants most relevant to older patients prescribed polypharmacy had not yet been explored using the TDF (Sabate, 2003; Clifford et al. 2008; Demonceau et al. 2013).

The findings from this TDF-based focus group study led to the identification of a wide range of determinants (barriers, facilitators) that were perceived to be influencing older patients' adherence behaviour. Examples of determinants included prioritising medications, social support from family, beliefs that medications are unnecessary, forgetfulness and difficulty opening medication packaging. The habitual nature of the behaviour was also emphasised as

important by participants. Identified determinants were assigned to domains within TDF1 (12 domains) and all 12 domains were deemed to be relevant in the context of older patients' adherence behaviours based on group consensus. Some of the determinants reported in this qualitative study (such as physical difficulties, forgetfulness, concerns about side effects), and also the importance of routines, reflect findings from previous qualitative research conducted with older people (Thompson and Stewart, 2001; Granås and Bates, 2005; Tordoff et al. 2010a; Sanders and Van Oss, 2013; Notenboom et al. 2014) and also quantitative research (Barat et al. 2001; Tordoff et al. 2010b; Ben-Natan and Noselozich, 2011). However, the qualitative research presented in Chapter 3 of this thesis has added to the literature by using a comprehensive theoretical framework of behaviour change to better understand and categorise determinants.

The study outlined in Chapter 3 also aimed to identify which theoretical domains could feasibly be targeted for behaviour change as part of a community pharmacy-based intervention. This was because, although all 12 domains were deemed relevant to the target behaviour, it was recognised that determinants assigned to some theoretical domains could not be easily modified (e.g. ability to open medication packaging identified under the 'Skills' domain). Eight domains (e.g. 'Beliefs about consequences, 'Motivation and goals', 'Social influences') were therefore identified as key domains that could feasibly be targeted. These domains were then mapped to 11 intervention components (BCTs such as 'Information about health consequences' 'Self-monitoring of behaviour', 'Social support-unspecified') using established mapping methods (Michie et al. 2008; Cane et al. 2015).

This theory-based approach also facilitated the identification of intervention components (BCTs) that have been infrequently used in adherence interventions directed at older patients prescribed multiple medications. This included the BCTs 'Goal-setting-behaviour' and 'Feedback on behaviour' which may otherwise have been overlooked (George et al. 2008; Nieuwlaat et al. 2014; Allemann et al. 2016). Focusing on patients' goals and priorities adopts a similar approach to that recommended for prescribing physicians when managing patients with multimorbidity, known as the Ariadne principles (Muth et al. 2014). These principles have been suggested to aid decision-making for multimorbid patients and centre on selecting treatment goals that are relevant and realistic for patients. Focusing on what is important to patients may help to improve motivation and willingness to change their adherence behaviours.

Although the key target domain 'Nature of the behaviours' did not map to any specific intervention components (BCTs) in the mapping exercise, the routine nature of medication-

taking was deemed essential to take into consideration. Recent evidence from a meta-analysis has found that habit-based interventions are more effective than other types of interventions and so this further supports our decision to consider this (Conn and Ruppar, 2017). The BCTs 'Self-monitoring of the behaviour' (medication diary) and 'Prompts and cues' (e.g. situational cues such as meals) were selected to include in the intervention, as they could also serve to help patients establish effective medication-taking routines.

Another study (Allemann et al. 2016) published after the conduct of the study that has been presented in Chapter 3, has linked determinants of adherence and also intervention components to domains in TDF2 (Version 2: 14 domains) (Cane et al. 2012). This study by Alleman et al. (2016) did not focus specifically on any patient group and it adopted a different approach by undertaking a review of the literature to identify determinants and intervention components. The determinants and components linked to each TDF domain by Alleman et al. (2016) largely corresponded with the findings of our study but there were some differences noted including perceptual differences (i.e. differences in the way information was interpreted or understood). For example, in our study the relationship between patients and HCPs was assigned to the 'Social influences' domain, whereas this was assigned to 'Social, professional role and identity' domain by Alleman et al. (2016). The TDF guide recently published by Atkins et al. (2017) has recognised that assigning behavioural determinants to TDF domains requires a level of interpretation of theoretical constructs. Hence, they recommend that an expert (with experience in the application of the TDF) should be consulted to clarify any uncertainties, where possible. For the current study, one of the original developers of the TDF (Prof. Jill Francis) provided advice and guidance where there were uncertainties.

By explicitly stating the key target theoretical domains and links to intervention components (i.e. BCTs) in published reports, this will aid replication of the intervention by others and future process evaluations to explore the underlying mechanism of action. The next stage of this research, in line with the MRC approach, involved testing the feasibility of delivering the identified components (BCTs) as part of a complex intervention in the proposed setting of community pharmacies. Therefore the next chapter of the thesis outlined the design process and findings from a small-scale feasibility study.

6.1.3 Design and feasibility testing of a theory-based complex patient-targeted intervention

Design of a complex intervention package

The first phase of the study outlined in Chapter 4 reported on how the ID-MAP intervention was designed for delivery by CPs to older patients prescribed polypharmacy. This involved combining the 11 BCTs identified in Chapter 3 into a complex package and required development of intervention materials (e.g. leaflets, medication diary to aid delivery of BCTs) and a brief training package for CPs. At this early stage of testing, a brief training session was deemed sufficient as a starting point for exploring the intensity and type of training required by CPs.

A key consideration when designing the intervention was how the intervention could be tailored to each older patient's needs. Previous research (Chapter 3) indicated that older patients prescribed polypharmacy are often non-adherent for a range of different reasons and these can vary both between and within patients (i.e. different reasons for different medications). However, to the best of the author's knowledge there is no guidance available in the literature that outlines exactly how complex interventions should be tailored. In order for a tailored intervention to be replicable, it was agreed that the process needed to be systematic and outlined in detail in any published reports. Thus, the study presented in Chapter 4 sought to explicitly outline exactly how the intervention was designed to be tailored based on an adherence assessment using a novel assessment tool (ID-MAP tool). This assessment tool was developed using findings from the previous qualitative research with older patients (Chapter 3) and it included a range of open style questions to help CPs explore the underlying nature of adherence problems faced. Each type of adherence problem was then linked to at least one intervention component (BCT) and this aimed to guide CPs in consistently tailoring the intervention content to older patients' needs.

Research undertaken by Easthall et al. (2014) which explored medication adherence in adults (18 years+) with CVD, led to the development of a 30-item questionnaire for patients to complete to help identify barriers to adherence. This was subsequently refined to a 10-item version as the previous version was deemed to be too lengthy for practice (Unpublished work available at: http://www.uea.ac.uk/pharmacy/research/imab-q). For older patients, who were the focus of the current project, a more informal conversational style approach to barrier (and potential facilitator) identification was deemed most suitable. This decision was made based on findings from the previous qualitative research (Chapter 3) in which patients emphasised the importance of conversations with HCPs in establishing/maintaining

relationships and addressing any issues they faced. In our study, a short validated questionnaire (MMAS-8) was deemed appropriate for measuring adherence and as a screening tool to identify non-adherent patients who required support. However, this method was not considered the best approach for exploring, in-depth, factors (barriers, facilitators) influencing older people's adherence behaviours and mapping these across to potential adherence solutions (i.e. BCTs).

Tailoring of adherence interventions in the literature is uncommon. This has been illustrated in a meta-analysis of 771 adherence interventions delivered to adult patients (18 years+) which found only nine studies that reported individual-level tailoring (Conn and Ruppar, 2017). Therefore, this part of the study will add to the literature by outlining exactly how a complex adherence intervention was designed so that it could be tailored at an individual-level. Following design of the intervention package, the next phase of this study was to test the feasibility of delivering this in the community pharmacy setting.

Feasibility testing in the community pharmacy setting

The second phase of the study outlined in Chapter 4, reported findings from a small-scale feasibility study which took place in two community pharmacy sites and included three CPs and 10 older patients who were prescribed polypharmacy. The decision to select CPs as the intervention provider in the primary care setting has been further supported by findings from a large meta-analysis that found that interventions delivered by pharmacists produced significantly (p=0.031) larger effect sizes (0.337) in comparison with those delivered by other HCPs such as nurses and physicians (0.279) (Conn and Ruppar, 2017).

The feasibility study findings presented in Chapter 4 demonstrated the usability and acceptability of the ID-MAP intervention from the viewpoint of both intervention recipients (older adults) and providers (CPs) with a patient retention rate of 90%. Although many of the findings from the feasibility study were positive, this research demonstrated that modifications are required to optimise both the intervention content and future study procedures. This highlights the benefits of conducting feasibility studies prior to pilot testing and larger evaluation studies (e.g. RCTs). Qualitative feedback from CPs and patients in this study has helped to identify where such modifications could be beneficial. This includes minor changes to the patient medication diary, changes to how intervention components are tailored and changes to key study procedures (e.g. screening and data collection). This feasibility study has also indicated that a strict appointment system may not be optimal for this group of patients as adherence problems can range in severity and therefore patients

require varying levels of support and contact with HCPs. This finding reflects guidance from NICE discussed previously that advocates a tailored approach to healthcare for individuals with multimorbidity (National Institute for Health and Care Excellence, 2016). Due to the high acceptability and usability levels reported, the ID-MAP intervention warrants further testing in a larger sample of community pharmacies and patients.

Another key finding from this study was the need for additional training for CPs to enhance delivery of the intervention in accordance with the intervention manual (i.e. intervention fidelity). For example, CPs did not always deliver goal-based BCTs with high fidelity which was thought to be due to a lack of experience and only limited training provided in these techniques. Consequently, the research presented in the next chapter of the thesis sought to examine CPs' behaviour (provision of MAS) in more detail. The aim of this was to identify how the training package could be modified and identify any additional strategies needed to improve the future implementation of the patient-targeted intervention.

6.1.4 Selection of components to include in a theory-based community pharmacist training package and strategies to improve the provision of medication adherence support

It has been recognised that in order to elicit behaviour change in one group of individuals, the behaviours of another group of individuals may need to be targeted (Huston, 2015). In the feasibility study (Chapter 4), CPs were selected as the intervention provider and therefore the study outlined in Chapter 5 sought to explore CPs' clinical behaviour, in terms of providing MAS to older adults prescribed polypharmacy. The overall aim of this study was to help select components to include in an enhanced CP training package and also explore strategies to improve the future implementation of the patient-targeted intervention (e.g. in future research studies).

In line with methods used previously in this thesis for exploring older patients' adherence behaviours (Chapter 3), the TDF was selected as a theoretical lens to explore CPs' clinical behaviour. The use of such a framework can help researchers explore a wide range of potential influences on behaviour that may otherwise be overlooked and help integrate a theoretical basis into the design of complex interventions such as training packages. At the time of this study, the research team noted that TDF-based methods were rapidly evolving with more researchers using quantitative methods as an alternative to, or alongside, qualitative methods. Therefore, this chapter used a mixed methods approach to explore CPs' behaviour and extended the methods used previously in this package of research.

Despite the low response rate for the quantitative aspect of the study (survey), the mixed methods approach undertaken allowed this information to be triangulated with qualitative research. Findings from this study highlighted a range of behavioural determinants that were perceived to be influencing the provision of MAS to older patients in current practice. For example, some CPs appeared to lack knowledge of the full range of adherence solutions that were available to address adherence problems. MDS were one of the most frequently offered adherence solutions, despite evidence indicating that these are not always the most appropriate solution (Raynor and Nunney, 2002; Royal Pharmaceutical Society, 2013; Stewart et al. 2017)**.** An Australian study also found that MDS were the most commonly provided adherence support strategy, indicating that this issue is not isolated to the UK (Mansoor et al. 2015). Our mixed methods study also found that CPs could benefit from additional skills training on techniques that can be used to increase older patients' motivation to adhere to prescribed regimens. This mirrored findings from the feasibility study (Chapter 4) whereby CPs experienced difficulties with delivering motivational-based techniques such as the BCT 'Goal-setting (outcome)'. Other key determinants (barriers) to providing MAS to older adults included a lack of reimbursement and time. Although it was noted that these barriers cannot be addressed as part of a training package, these are important behavioural influences to consider for future implementation.

Triangulation of findings from the qualitative and quantitative aspects of this study aided the selection of seven theoretical domains (e.g. 'Knowledge', 'Skills', 'Motivation and goals') that could be targeted to change CPs' behaviour. These domains were then mapped across to 18 BCTs that could be incorporated as components of a future training package (e.g. 'Demonstration of the behaviour', 'Behaviour rehearsal/practice') and/or delivered as part of future research studies (e.g. 'Rewards/incentives', 'Prompts/cues') to improve the implementation of the ID-MAP intervention by CPs.

Although the TDF provided a useful framework for the current study, other frameworks have been developed for use in implementation research and developing behaviour change interventions (May et al. 2009; Stewart and Klein, 2016; Kok et al. 2016). One example is the Normalization Process Theory which can help researchers explain '…how new technologies, ways of acting, and ways of working become routinely embedded in everyday practice…' (May et al. 2009). Nonetheless, the TDF was selected for the study presented in Chapter 5 for consistency as it was used as the theoretical framework for developing the patient-targeted intervention (Chapter 3).

6.1.5 Recommendations for future research, practice and policy

Effectiveness of theory-based interventions

Further research needs to be conducted to establish whether or not this theory-based approach to developing complex interventions using the TDF is effective. To the best of the author's knowledge, only two TDF-based studies have reached the evaluation stage of intervention testing in a RCT (French et al. 2013; Nathan et al. 2016). A study by Nathan et al (2016) which focused on the implementation of a healthy school canteen policy showed statistically significant effects, whereas a study by French et al. (2013), which aimed to improve GPs' management of low back pain, despite showing improvements, did not produce statistically significant effects. These findings highlight that whilst using this systematic theory-based approach has potential benefits, it does not automatically guarantee effectiveness. Instead, this type of approach is useful in that it can aid understanding of why an intervention has worked or failed to work through the use of theory testing and process evaluations. A process evaluation of the ID-MAP intervention should therefore be undertaken in future research to explore the proposed mechanism of action.

Identifying non-adherent patients

The feasibility study (Chapter 4) provided the opportunity to test whether a short validated questionnaire (MMAS-8) could be used to identify older patients who were non-adherent, as previous research has shown that including all patients who are willing to take part often results in high baseline adherence levels (Ruppar, 2010a). The MMAS-8 questionnaire was largely acceptable to participants as a screening tool, however it is recognised that self-report methods are limited by social desirability bias and therefore a combination of methods for identifying non-adherent patients may be more useful (Lam and Fresco, 2015). In Australia, electronic pharmacy-held record systems have been used to flag non-adherent patients who could benefit from an adherence assessment using an algorithm developed by MIRIXA® (https://www.mirixa.com/payers/mirixa-solutions). Future research could explore whether it is possible for this type of system to be developed for use in the UK and for patients taking multiple medications.

Tailoring adherence interventions

The qualitative findings presented in Chapter 3 have illustrated that knowledge is just one of many potential determinants of older patients' adherence behaviours. This supports claims made by other researchers that patient education alone is insufficient in changing patients' adherence behaviour (Nieuwlaat et al. 2014; Allemann et al. 2016; Kahwati et al. 2016).

Consequently, CPs should move away from focusing solely on patient education strategies to improve knowledge and instead should try to explore the underlying reasons for each older patients' non-adherence. Until more evidence on the most effective combination of adherence solutions becomes available, it seems reasonable to recommend that CPs should adopt a tailored approach in practice when deciding on the best adherence solutions.

In addition to tailoring adherence solutions, future research should focus on how best to tailor the number of intervention appointments to each older patient's needs. To be replicable by others, this tailoring process needs be systematic and involve decision rules to guide CPs. As an alternative to face-to-face appointments, short telephone calls could be made at pre-specified intervals where adherence could be reassessed (e.g. using validated self-report measures). If adherence has not been maintained, patients could then be re-invited to attend additional face-to-face appointments in the pharmacy to identify ongoing challenges. It is likely that ongoing contact with HCPs is necessary to maintain the effects of the intervention and therefore future research should explore how this type of ongoing support can be best achieved.

Important outcomes to measure in future studies

The feasibility study outlined in Chapter 4 only assessed adherence as an outcome measure at baseline and three months post-intervention (i.e. medium-term) due to time restrictions. Future research should attempt to assess changes in adherence after at least six months to measure longer-term effects of the intervention (Cross et al. 2016). Although adverse drug events (ADEs) were not recorded as part of our feasibility study, ADEs were reported in a feasibility study conducted by Bhattacharya et al. (2016) that aimed to explore the effectiveness of MDS on unintentional medication adherence. This emphasises the importance of follow-up appointments/telephone calls for all patients as these provide opportunities to detect unwanted side effects which may result from improved adherence. It will be prudent to collect outcome data on ADEs and hospitalisations as part of future testing of the ID-MAP intervention. In addition, Wright (2016) recommends that a risk assessment should be carried out prior to the adherence assessment. This could include checking whether the patient's medical conditions are already controlled on the prescribed regimen despite non-adherence (e.g. BP already at optimal level), as improving adherence could result in ADEs (e.g. hypotension). However, conducting such risk assessments poses a challenge for CPs in current practice as this may require direct contact with GPs to access this information. Having access to this type of information as part of the Electronic Care Record would help with this process but this is not currently available to CPs in NI.

Enhancing the reach of the intervention

The feasibility study presented in this thesis only explored delivery of the ID-MAP intervention at the community pharmacy site which may restrict the reach of the intervention. Additional research is required to explore how this type of intervention could be adapted for delivery in the domiciliary setting to support older patients who are housebound. One of the key purposes of the Responsible Pharmacist Regulations (introduced in 2008) was to allow CPs to be absent from the pharmacy to carry out these types of roles (Pharmaceutical Society of Northern Ireland, 2016). However, the qualitative research conducted with CPs in this thesis (Chapter 5) suggests that this has not translated into practice, with some CPs, particularly those working as the sole pharmacist, reporting that it is not feasible for them to leave the pharmacy to conduct these type of domiciliary reviews. In 2016, significant funding was announced by the Department of Health (NI) in an attempt to relieve the pressure currently faced by GPs in the primary care setting. Funding was allocated to allow for the development of 300 (full-time equivalent) GP practice-based pharmacist posts in NI by 2020 (Strategic Leadership Group for Pharmacy, 2016). GP practice-based pharmacists may have a future role to play in improving medication adherence, particularly in the context of frail housebound older patients through the provision of domiciliary adherence support.

Future integration into community pharmacy practice

The patient-targeted intervention outlined in this thesis was developed as a stand-alone intervention for ease of development and testing but future research could focus on how this type of intervention could be integrated with services already in place in community pharmacies (e.g. as an extension to MURs) or as a replacement for these. In NI, a new adherence service (Medication Adherence Support Service) has recently undergone a service evaluation in two administrative (HSCT) areas, although the findings of this have yet to be reported (http://www.hscbusiness.hscni.net/pdf/Service_Guidance_Version_2.pdf). It is unclear how the components of this service were selected and without a link to theory, it will be difficult to explore its mechanism of action. In addition, without undertaking comprehensive intervention development, feasibility and pilot testing followed by a robust evaluation (e.g. RCT along with a process and economic evaluation), it will be unclear whether this service is effective or cost-effective. As recommended by Wright (2016) 'New [community pharmacy] services should always be feasibility tested and piloted first with a focus at this stage on training, implementation and delivery rather than outcomes.'

Funding models in community pharmacy

As a first step to providing MAS, CPs need to be more pro-active in identifying non-adherent older patients in their daily practice. The research findings in Chapter 5 have highlighted that less than half of surveyed CPs frequently reported using strategies to identify non-adherent older patients. The qualitative findings indicated that a lack of reimbursement and time constraints are major barriers to this. The current funding model in community pharmacies in the UK focuses on volume of activity (i.e. 'volume-based' services contract) whereby CPs are paid based on the number of patients to whom they provide services (Wright, 2016). This is a potential barrier to implementation of the ID-MAP intervention in future practice as this could lead to suboptimal delivery in an attempt to increase efficiency and maximise profits, as has been reported with other volume-based services (Smith et al. 2017). Suggestions have been made to move towards a 'value-based' services community pharmacy contract by focusing more on outcomes in relation to payment, for example, CPs could be paid a higher fee if improvements in adherence are evidenced (e.g. through a post-service questionnaire) (Wright, 2016). Until such a policy change is made, it is likely that CPs will need to be incentivised to deliver this type of adherence intervention in practice.

The role of improving adherence as part of medicines optimisation

Although improving medication adherence is vital to improving clinical outcomes, it is recognised that this is only one aspect of 'medicines optimisation' ('…a person-centred approach to safe and effective medicines use, to ensure people obtain the best possible outcomes from their medicines'*)* (National Institute for Health and Care Excellence, 2015). Evidence suggests that around 30 to 34% of older adults in the UK and NI are prescribed at least one unnecessary/inappropriate medication (e.g. duplication of therapies) (Bradley et al. 2012; Bradley et al. 2014). As outlined previously, the current adherence project outlined in this thesis was part of a larger project on polypharmacy that sought to improve the use of multiple medications in older patients. In this larger project, a complex intervention has been developed (Cadogan et al. 2015; Cadogan et al. 2016a) to improve the appropriateness of polypharmacy by targeting GPs' prescribing behaviours and this has undergone feasibility testing (Cadogan et al. 2017).

A comprehensive medication review was not undertaken by CPs as part of the feasibility study (Chapter 4) in this thesis as this was not the focus of the current project. Nonetheless, CPs in the feasibility study were instructed to prepare a list of each patient's medications in advance of delivering the ID-MAP adherence intervention. CPs were advised to contact the

prescriber (GP) if they had any concerns regarding prescribed regimens (e.g. duplication of therapy, interactions) and were instructed to ask patients about side effects during the adherence assessment. The latter also provided an opportunity to explore how each patient managed their medication regimen and the opportunity to refer patients onto the prescriber (GP) if the pill burden or regimen complexity was affecting adherence. These activities were included in the feasibility study to help identify medications/regimens that required modifications prior to attempting to improve adherence. Despite this, it is recognised that CPs could likely benefit from further training on recognising and dealing with inappropriate polypharmacy. Future research could focus on integrating a comprehensive medication review, conducted by a prescriber (e.g. GP, GP practice-based pharmacist), with the ID-MAP adherence intervention, in a sequential manner. This stepwise approach has been advocated by other researchers to ensure the regimen is the most appropriate one prior to addressing problems of non-adherence (George et al. 2008; Marcum and Gellad, 2012)**.** Nevertheless, due to the complexity of these interventions (prescriber-targeted and patient/CP-targeted), in terms of the number and types of behaviours being targeted, individually optimising each intervention first is warranted prior to combining these into a step-wise approach.

To reduce medication waste and harm to patients and improve clinical outcomes, healthcare systems need to be re-organised in a way that facilitates the optimal use of medicines, particularly in the context of polypharmacy and older multi-morbid patients (Duerden et al. 2013). A large EU-funded research project (Stimulating Innovation Management of Oolypharmacy and Adherence In The Elderly; SIMPATHY) has placed emphasis on working together to address key challenges faced in relation to polypharmacy. SIMPATHY's vision is that by '…2030 European healthcare will be widely characterised by effective policies for the management of polypharmacy implemented through multi-disciplinary teams.' (Mair et al. 2017). The research presented in this thesis has added to the literature on polypharmacy and medication adherence in older people. In line with the MRC approach adopted in this package of research, the next stage will involve testing the patient-targeted intervention and enhanced CP training package in a pilot study with a larger sample of patients and pharmacies and across another region in the UK to explore if the findings are transferable.

6.2 General conclusion

The work presented in this thesis has addressed an identified gap in the literature by developing a complex theory-based intervention to improve medication adherence in older adults prescribed polypharmacy. In line with guidance from the MRC, the patient-targeted

intervention was developed based on a theoretical exploration of older patients' adherence behaviour using a TDF-based qualitative study. Multiple determinants (barriers, facilitators) were identified and assigned to theoretical domains in TDF1. Key domains for targeting were selected and mapped across to intervention components (BCTs) that could be included in a complex intervention package. The feasibility of tailoring the components of this complex intervention package to older patients' needs in the community pharmacy setting was then explored in a small-scale feasibility study. Although findings demonstrated that this intervention was highly acceptable and useful for both older patients and CPs, some recommendations were made to further enhance this, including more comprehensive training for CPs. As a result, a TDF-based mixed methods (qualitative, quantitative) study was used to explore CPs' behaviour in terms of supporting older patients with adherence to help enhance the training package. A range of determinants (barriers, facilitators) were identified and assigned to domains in TDF1 in a similar approach used to develop the patient-targeted intervention. Key target domains were selected and linked to multiple strategies (BCTs) that could be delivered as part of an enhanced CP training package and/or in future research studies to facilitate the implementation of the patient-targeted intervention. Future research will involve the conduct of a pilot study to test a modified version of the patient-targeted intervention and CP training package in a larger sample of participants.

This research adds to the broader literature on medication adherence, a field that has attracted significant attention in the last few decades. It is widely accepted that medications will only be effective if taken as prescribed and finding an effective solution to non-adherence could bring greater health outcomes than any individual advances in therapeutics (Sabate, 2003). With an ageing population and predicted rise in the number of patients with multimorbidity, the issue of non-adherence will continue to be of concern in the coming years. Therefore, it of vital importance that research into finding effective adherence interventions continues and most importantly, identifies strategies to address this behaviour.

Before providing a new drug to patients, an in-depth systematic exploration of both how and if the drug works is undertaken (Jacobsen and Wertheimer, 2010). To advance the field of adherence research, a similar systematic approach to intervention development is essential. Future research should dedicate sufficient time to developing and optimising adherence interventions before embarking on sufficiently powered evaluation studies (e.g. RCTs) to explore their effectiveness.

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Appendices

List of appendices

Appendix 2.1: Completed PRISMA checklist

Section/ topic	#	Checklist item	Page in thesis
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	30
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	Not relevant
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	31-33
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	34-35
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	34
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	34-36
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	35-36
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	265
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	36
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	36
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	266-267
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	36
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Not relevant (meta-analysis not conducted)
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	

Appendix 2.2: MEDLINE search string

1. Medication adherence (MeSH)
2. 'Patient adherence' (keyword)
3. 'Medication compliance' (keyword)
4. 'Patient compliance' (MeSH)
5. 'Non complian$' (keyword)
6. 'Non-complian$' (keyword)
7. 'Concordan$' (keyword)
8. 'Treatment adj3 persistence' (keyword)
9. 'Treatment adj3 refusal' (keyword)
10. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9
11. Polypharmacy (MeSH)
12. Drug therapy (MeSH)
13. Drug therapy, combination (MeSH)
14. 'Multiple adj3 medicat$' (keyword)
15. 'Multidrug$' (keyword)
16. 'Drug polytherapy' (keyword)
17. 'Polymedicine' (keyword)
18. 'Multiple drug regimen' (keyword)
19. 'Combination therapy' (keyword)
20. 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21. 'Theor$' (keyword)
22. 'Theoretical' (keyword)
23. 'Model$' (keyword)
24. 'Principle' (keyword)
25. 'Behavio$r$' (keyword)
26. 'Psycho$social' (keyword)
27. Psychological theory (MeSH)
28. 'Construct$' (keyword)
29. 'Framework' (keyword)
30. 'Cognitive' (keyword)
31. Concept formation (MeSH)
32. 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31
33. 'Older adj3 adult$' (keyword)
34. 'Older adj3 patient$' (keyword)
35. Aged (MeSH)
36. 'Senior' (keyword)
37. Geriatrics (MeSH)
38. Veterans (MeSH)
39. 'Elderly' (keyword)
40. 33 or 34 or 35 or 36 or 37 or 38 or 39
41. 10 and 20 and 32 and 40

Appendix 2.3: Other sources that were hand-searched

- National Institute for Health and Care Excellence (NICE) guidelines
- NHS evidence Turning Research into Practice (TRIP) database
- World Health Organisation (WHO) International database
- International Clinical Trials Registry Platform (ICTRP)
- Google and Google Scholar
- The Database of Abstracts of Effects (DARE)
- ClinicalTrials.gov

Appendix 2.4: Data extraction form

REF ID	Characteristics of study									
	Paper Title	Author(s)	Publication year	Study dates	Country of study origin	Clinical setting (Primary/ secondary/other)	Study aims and hypotheses	Inclusion criteria	Exclusion criteria	Follow-up duration

REF ID	Participant characteristics					
	Mean/median age of participants (intervention and control)	% male/% female (intervention and control)	Mean/median no. of medications (intervention and control)	Mean/median no. of conditions (intervention and control)	Number of patients recruited (intervention and control)	Number of drop outs (%) (intervention and control)

Appendix 2.4 (cont'd): Data extraction form

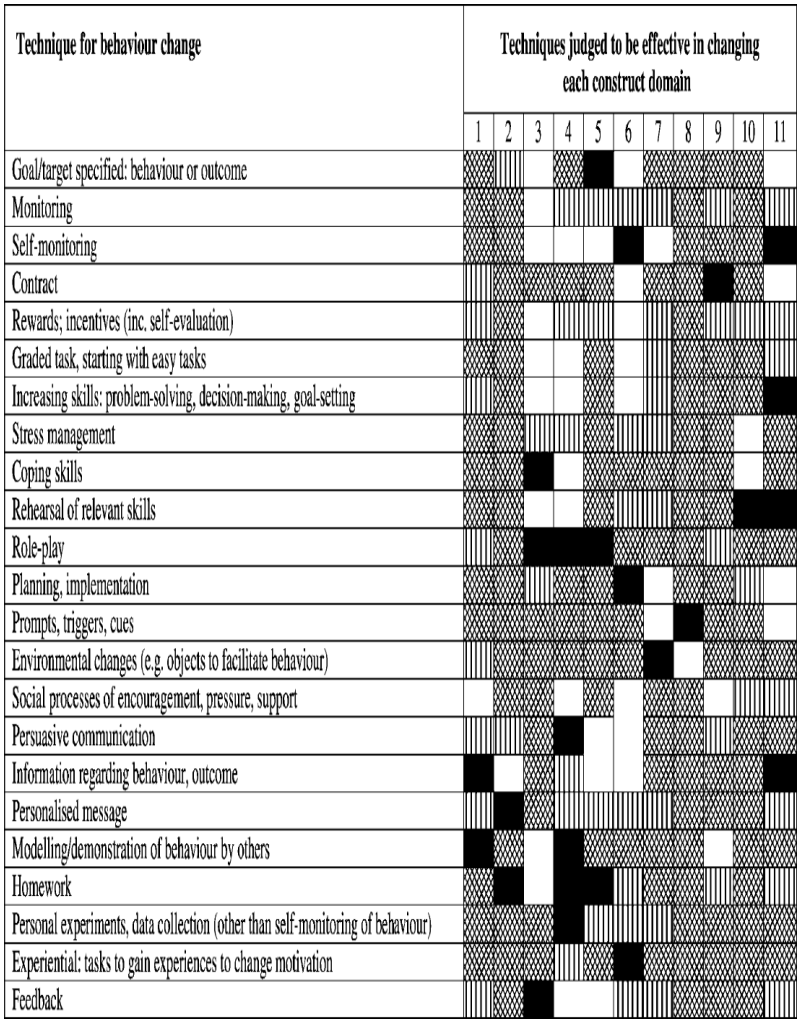
REF ID	Intervention design and delivery						
	Study type (e.g. RCT, ITS)	Number of intervention sites/control sites	Description of intervention/ Intervention content (i.e. techniques used)	Description of control/usual care group	Intervention setting (e.g. patients' own home)	Mode of delivery (e.g. face-to-face)	Provider (Who delivered the intervention)

REF ID	Intervention design and delivery (cont'd)					
	Intensity (number of sessions delivered over the given time period)	Intervention duration (length of sessions)	Adherence outcome measurement (e.g. self-report)	Definition of extent of adherence (or non-adherence)	Clinical outcome(s)	Timing of outcome measurements

REF ID	Intervention design and delivery (cont'd)					
	Intensity (number of sessions delivered over the given time period)	Intervention duration (length of sessions)	Adherence outcome measurement (e.g. self-report)	Definition of extent of adherence (or non-adherence)	Clinical outcome(s)	Timing of outcome measurements

REF ID	Risk of bias assessment						
	Sequence Generation	Allocation Concealment	Blinding of participants, personnel and outcome assessors	Incomplete outcome data (attrition bias)	Selective outcome reporting	Other potential threats to validity	Overall impression

Appendix 3.1: TDF to BCT mapping table taken from Michie et al. (2008)



Technique for behaviour change	Techniques judged to be effective in changing each construct domain										
	1	2	3	4	5	6	7	8	9	10	11
Goal/target specified: behaviour or outcome											
Monitoring											
Self-monitoring											
Contract											
Rewards; incentives (inc. self-evaluation)											
Graded task, starting with easy tasks											
Increasing skills: problem-solving, decision-making, goal-setting											
Stress management											
Coping skills											
Rehearsal of relevant skills											
Role-play											
Planning, implementation											
Prompts, triggers, cues											
Environmental changes (e.g. objects to facilitate behaviour)											
Social processes of encouragement, pressure, support											
Persuasive communication											
Information regarding behaviour, outcome											
Personalised message											
Modelling/demonstration of behaviour by others											
Homework											
Personal experiments, data collection (other than self-monitoring of behaviour)											
Experiential: tasks to gain experiences to change motivation											
Feedback											
Self talk											
Use of imagery											
Perform behaviour in different settings											
Shaping of behaviour											
Motivational interviewing											
Relapse prevention											
Cognitive restructuring											
Relaxation											
Desensitisation											
Problem-solving											
Time management											
Identify/prepare for difficult situation/problems											

KEY[a]:

	Agreed use
	Uncertain
	Disagreement
	Agreed non-use

Techniques judged to be effective in changing each construct domain

1 Social/Professional role and identity
2 Knowledge
3 Skills
4 Beliefs about capabilities
5 Beliefs about consequences
6 Motivation and goals
7 Memory, attention, decision processes
8 Environmental context and resources
9 Social influences
10 Emotion
11 Action planning

NB: *Four independent experts were asked 'Which techniques would you use as part of an intervention to change each construct domain?' and responded within each cell of table with one of four options (possibly=1; probably=2; definitely=3; No=blank). The key indicates the combined responses for the four experts who took part (agreed use, uncertain, disagreement or agreed non-use).*

Appendix 3.2: TDF to BCT mapping table adapted from Cane et al. (2015)

Domain	BCT	BCT Definition from BCTTV1 (Michie et al. 2013)
Knowledge	Information about health consequences[1]	*'Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour.'*
	Biofeedback	*'Provide feedback about the body (e.g. physiological or biochemical state) using an external monitoring device as part of a behaviour change strategy.'*
	Antecedents	*'Provide information about antecedents (e.g. social and environmental situations and events, emotions, cognitions) that reliably predict performance of the behaviour.'*
	Feedback on behaviour[1]	'Monitor and provide informative or evaluative feedback on performance of the behaviour *(e.g. form, frequency, duration, intensity).'*
Skills	Graded tasks	*'Set easy-to-perform tasks, making them increasingly difficult, but achievable, until behaviour is performed.'*
	Behavioural rehearsal/ practice[1]	*'Prompt practice or rehearsal of the performance of the behaviour one or more times in a context or at a time when the performance may not be necessary, in order to increase habit and skill.'*
	Habit reversal	*'Prompt rehearsal and repetition of an alternative behaviour to replace an unwanted habitual behaviour.'*
	Body changes	*'Alter body structure, functioning or support directly to facilitate behaviour change.'*
	Habit formation	*'Prompt rehearsal and repetition of the behaviour in the same context repeatedly so that the context elicits the behaviour'*
Social/ professional role and identity	No BCTs mapped to this domain in Cane 2015 paper	N/A
Beliefs about Capabilities	Verbal persuasion to boost self-efficacy	*'Tell the person that they can successfully perform the wanted behaviour, arguing against self-doubts and asserting that they can and will succeed'*
	Focus on past success	*'Advise to think about or list previous successes in performing the behaviour (or parts of it).'*
Optimism	Verbal persuasion to boost self-efficacy	See above under 'Beliefs about capabilities' domain.
Beliefs about Consequences	Emotional consequences	*'Provide information (e.g. written, verbal, visual) about emotional consequences of performing the behaviour.'*
	Salience of consequences	*'Use methods specifically designed to emphasise the consequences of performing the behaviour with the aim of making them more memorable (goes beyond informing about consequences).'*
	Covert sensitization	Part of the BCT 'Imaginary punishment' which is defined as: *'Advise to imagine performing the unwanted behaviour in a real-life situation followed by imagining an unpleasant consequence…'*
	Anticipated regret	*'Induce or raise awareness of expectations of future regret about performance of the unwanted behaviour.'*
	Social and environmental consequences	*'Provide information (e.g. written, verbal, visual) about social and environmental consequences of performing the behaviour.'*
	Comparative imagining of future outcomes	*'Prompt or advise the imagining and comparing of future outcomes of changed versus unchanged behaviour.'*
	Vicarious reinforcement	*'Prompt observation of the consequences (including rewards and punishments) for others when they perform the behaviour.'*
	Threat	Part of the BCT 'Future punishment' which is defined as: *'Inform that future punishment or removal of reward will be a consequence of performance of an unwanted behaviour (may include fear arousal)…'*
	Pros and cons	*'Advise the person to identify and compare reasons for wanting (pros) and not wanting to (cons) change the behaviour.'*
	Covert conditioning	Part of 'Imaginary reward' which is defined as: *'Advise to imagine performing the wanted behaviour in a real-life situation followed by imagining a pleasant consequence…'*

Appendix 3.2 (cont'd): TDF to BCT mapping table adapted from Cane et al. (2015)

Domain	BCT	BCT Definition from BCTTV1 (Michie et al. 2013)
Reinforcement	Threat	See above under 'Beliefs about consequences' domain.
	Self-reward	*'Prompt self-praise or self-reward if and only if there has been effort and/or progress in performing the behaviour.'*
	Differential reinforcement	Part of BCT: '*Reward alternative behaviour*' which is defined as: *'Arrange reward for performance of an alternative to the unwanted behaviour.'*
	Shaping	Part of BCT *'Reward approximation'* which is defined as: *'Arrange for reward following any approximation to the target behaviour, gradually rewarding only performance closer to the wanted behaviour…'*
	Thinning	Part of BCT 'Reduce reward frequency' which is defined as: *'Arrange for rewards to be made contingent on increasing duration or frequency of the behaviour…'*
	Negative reinforcement	Part of BCT *'Remove punishment'* which is defined as: *'Arrange for removal of an unpleasant consequence contingent on performance of the wanted behaviour…'*
	Incentive[1]	*'Inform that money, vouchers or other valued objects will be delivered if and only if there has been effort and/or progress in performing the behaviour.'*
	Counter conditioning	Part of BCT *'Reward incompatible behaviour'* which is defined as: *'Arrange reward for responding in a manner that is incompatible with a previous response to that situation…'*
	Discrimination training	Part of BCT '*Situation-specific reward*' which is defined as: *'Arrange for reward following the behaviour in one situation but not in another.'*
	Material reward[1]	*'Arrange for the delivery of money, vouchers or other valued objects if and only if there has been effort and/or progress in performing the behaviour.'*
	Social reward	*'Arrange verbal or non-verbal reward if and only if there has been effort and/or progress in performing the behaviour.'*
	Non-specific reward	*'Inform that a reward will be delivered if and only if there has been effort and/or progress in performing the behaviour.'*
	Response cost	Part of BCT *'Behaviour cost'* which is defined as: *'Arrange for withdrawal of something valued if and only if an unwanted behaviour is performed…'*
	Anticipation of future rewards or removal of punishment	No definition provided in BCTTV1.
	Punishment	*'Arrange for aversive consequence contingent on the performance of the unwanted behaviour.'*
Reinforcement (cont'd)	Extinction	Part of *'Remove reward'* which is defined as: *'Arrange for discontinuation of contingent reward following performance of the unwanted behaviour.'*
	Classical conditioning	Part of BCT 'Associative learning' which is defined as: *'Present a neutral stimulus jointly with a stimulus that already elicits the behaviour repeatedly until the neutral stimulus elicits that behaviour'*
Intentions	Commitment	*'Ask the person to affirm or reaffirm statements indicating commitment to change the behaviour.'*
	Behavioural contract	*'Create a written specification of the behaviour to be performed, agreed on by the person, and witnessed by another.'*
Goals	Goal setting (outcome)[1]	*'Set or agree on a goal defined in terms of a positive outcome of wanted behaviour.'*
	Goal setting (behaviour)[1]	*'Set or agree on a goal defined in terms of the behaviour to be achieved.'*
	Review of outcome goal(s)[1]	*'Review outcome goal(s) jointly with the person and consider modifying goal(s) in light of achievement. This may lead to resetting the same goal, a small change in that goal or setting a new goal instead of, or in addition to the first.'*
	Review behaviour goals[1]	*'Review behaviour goal(s) jointly with the person and consider modifying goal(s) or behaviour change strategy in light of achievement. This may lead to re-setting the same goal, a small change in that goal or setting a new goal instead of (or in addition to) the first, or no change.'*
	Action planning (including implementation intentions)[1]	*'Prompt detailed planning of performance of the behaviour (must include at least one of context, frequency, duration and intensity). Context may be environmental (physical or social) or internal (physical, emotional or cognitive).'*
Memory, Attention, and Decision Processes	No BCTs mapped to this domain in Cane 2015 paper	N/A

Appendix 3.2 (cont'd): TDF to BCT mapping table adapted from Cane et al. (2015)

Domain	BCT	BCT Definition from BCTTV1 (Michie et al. 2013)
Environmental Context and Resources	Restructuring the physical environment[1]	*'Change, or advise to change the physical environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour…'*
	Discriminative (learned) cue	Part of BCT *'Cue signalling reward'* which is defined as: *'Identify an environmental stimulus that reliably predicts that reward will follow the behaviour.'*
	Prompts/cues[1]	*'Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance.'*
	Restructuring the social environment	*'Change, or advise to change the social environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour (other than prompts/cues, rewards and punishments).'*
	Avoidance/ changing exposure to cues for the behaviour	*'Advise on how to avoid exposure to specific social and contextual/physical cues for the behaviour, including changing daily or weekly routines.'*
Social Influences	Social comparison[1]	*'Draw attention to others' performance to allow comparison with the person's own performance'*
	Social support (unspecified)[1]	*'Advise on, arrange or provide social support (e.g. from friends, relatives, colleagues,' buddies' or staff) or non-contingent praise or reward for performance of the behaviour. It includes encouragement and counselling, but only when it is directed at the behaviour.'*
	Information about others' approval	*'Provide information about what other people think about the behaviour. The information clarifies whether others will like, approve or disapprove of what the person is doing or will do.'*
	Social support (emotional)	*'Advise on, arrange, or provide emotional social support (e.g. from friends, relatives, colleagues, 'buddies' or staff) for performance of the behaviour.'*
Social influences (cont'd)	Social support (practical)[1]	*'Advise on, arrange, or provide practical help (e.g. from friends, relatives, colleagues, 'buddies' or staff) for performance of the behaviour.'*
	Vicarious reinforcement	See above under 'Beliefs about consequences' domain.
	Restructuring the social environment	See above under 'Environmental Context and Resources' domain.
	Modelling or demonstrating the behaviour[1]	*'Provide an observable sample of the performance of the behaviour, directly in person or indirectly e.g. via film, pictures, for the person to aspire to or imitate…'*
	Identification of self as role model	*'Inform that one's own behaviour may be an example to others.'*
	Social reward	See above under 'Reinforcement' domain.
Emotion	Reduce negative emotions	*'Advise on ways of reducing negative emotions to facilitate performance of the behaviour (includes 'Stress Management').'*
	Emotional consequences	See above under 'Beliefs about Consequences' domain.
	Self-assessment of affective consequences	No definition provided in BCTTV1.
	Social support (emotional)	See above under 'Social influences' domain.
Behavioural Regulation	Self-monitoring of behaviour[1]	*'Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy'*

[1] *commonly identified BCTs*

Appendix 3.3: Patient invitation letter (focus groups)

Patient participant invitation letter

ON GENERAL PRACTICES' HEADED NOTEPAPER

Date

Dear Patient,

I am writing to invite you to take part in a research project. We would like to hear your views about your medicines, and how you feel your General Practitioner and Community pharmacist help you with your medicines. Please find enclosed an information sheet that should hopefully answer any questions you may have about this research project. I would be grateful if you could take the time to read this.

The study involves completing a short questionnaire, and then attending a focus group. Should you wish to take part, please complete the enclosed reply slip and we will contact you within ten days of receiving your reply slip. We will then send you further details of the questionnaire we would like you to complete, before attending the focus group. A focus group is when a few (up to ten) patients come together to discuss a topic. In this case, we would like to talk to you about medicines. The questionnaire will ask a few short questions about your medicines, and the information we receive from the questionnaire will form the basis of discussion for the focus group.

With your permission, the focus group will be tape-recorded. We will make sure that you are not identified in any report or paper that comes from the project.

If you wish to discuss any aspect of the project, please do not hesitate to contact me using the details given below.

Yours Sincerely,

Dr. Cathal Cadogan
Research Fellow
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast BT9 7BL

Telephone: (028) 9097 2348
Email: c.cadogan@qub.ac.uk

Appendix 3.4: Patient information sheet (focus groups)

Queen's University Belfast

Patient Participant Information Sheet

Study Title: Development of an intervention to improve appropriate polypharmacy in older people in primary care.

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important that you understand why this research is being completed and what you will be asked to do. Please take time to read the following information and do not hesitate to ask questions about anything that might not be clear to you. Contact details for the researcher can be found at the end of this information sheet. Please take time to decide whether you would or would not like to take part in the study.

What is the purpose of this study?

Patients with medical conditions are often prescribed several medicines. We know from other research studies, that some patients often find taking all their prescribed medicines which has been prescribed by their General Practitioner (GP) and dispensed by the community pharmacist, difficult to do. Therefore, we want to put together a plan to try and help patients who take several medicines. In order to understand what patients think is important about taking many medicines, we want to get your views.

Why have you been chosen?

You have been identified as a patient registered in a general practice, who is currently taking four or more prescribed medicines every day. Some of the GPs in your practice are also taking part in the study.

Do you have to take part?

It is your decision whether or not you would like to take part in the study. You should read this information sheet and ask the researcher (Dr. Cathal Cadogan) to answer any questions that you have. If you do decide to take part, you will be asked to sign a consent form. You will be given a copy of this consent form. Your decision whether or not to take part will not affect your medical care. If you decide to take part, you can withdraw from the study at any stage. You are not required to give a reason for your withdrawal and it will not affect your normal care.

What will happen if you take part?

If you would like to take part, please complete the enclosed reply slip, and the researcher (Dr. Cathal Cadogan) will telephone you within ten days of receiving your reply slip. We will then send you a short questionnaire that we would like you to complete, along with a consent form. The purpose of this questionnaire is to understand what you think about your medicines. You will also be asked to give us some information about you, including your age, the number and type of medicines you take, why you take them, how long you have been taking them for and how often you visit your GP and community pharmacist. You will be asked to return this questionnaire to the research centre, along with the consent form which you should sign. We will look at your answers to the questionnaire, along with questionnaires from other patients. We will then ask you to attend a focus group (group discussion) with up to nine other patients from your practice, all of whom are taking four or more medicines daily. We will ask you to discuss your views of your medicines. The questions we will ask will be based on the information we received from the questionnaire. You can also talk about other things that you think are important about your medicines.

Two researchers will lead the focus group and it will take place in a convenient location for you, either in a room in your general practice or in local community centre, or at Queen's University Belfast. It should last no longer than two hours and refreshments will be provided. The researchers will record the focus group discussion (with your permission). Once the focus group has finished, the recording will be typed up, word for word. You will not be identified in any of typed records of the focus group. We will use this information to develop a plan to help patients who take several medicines. Your GP and community pharmacist will be notified by letter to tell them that you have taken part in the study and a copy of your consent form will be sent to them. **You will receive £50 for taking part in the study and we will also cover any travel costs that you might have to pay in order to attend the focus group.**

Are there any risks or disadvantages of taking part in the study?

There is little risk in taking part in the study and you can withdraw at any time. It is possible that the discussion may make you to think about upsetting aspects of your medicines and conditions for which you take your medicines. If you find this distressing, you may withdraw any time. If you become upset or distressed and decide to withdraw from the study, your medical team will be informed that you are no longer taking part in the study. Your GP and community pharmacist will be sent a letter to tell them that you became upset during the meeting and they may follow this up with you. If you would like to discuss this with someone, you may contact a member of your medical team to do so. To make it easier for you to participate, the meeting will be held at a time and location convenient to you and other patients.

What are the benefits of taking part in the study?

By taking part in this study you would be providing information which will help us to develop our plan to help patients who take several medicines daily.

What will happen if you decide you no longer wish to take part?

You are free to withdraw from the study at any stage. If you decide to do so, the information recorded up until the time you left the study may still be included in the study. Your normal medical care will not be affected if you decide you no longer wish to take part.

Will your details be kept confidential?

All information collected as part of the study will be treated in a confidential manner. Audio-recordings will be anonymous and your name will not appear in any publications. Information collected during the study including your signed consent form will be stored securely at the School of Pharmacy, Queen's University Belfast. It will be kept for five years and then destroyed. This is in line with the Data Protection Act (1998).

However, if you mention something that suggests that you have been given the wrong treatment or that a health care professional has not acted in a proper way, we may need to report this to the healthcare professional who cares for you, or to another authority.

In order to ensure that studies involving human participants are carried out to a high standard, the University is required to monitor ongoing research studies and as a result, staff from Queen's University may need to review information collected as part of the research.

Appendix 3.4 (cont'd): Patient information sheet (focus groups)

What will happen to the results of the research?

The results from the research will be used as part of a research project at Queen's University Belfast. They may be published in academic journals and presented at conferences. All results will be anonymous and you cannot be identified. You will be provided with a report of the results at the end of the study.

Who is organising and funding the research?

This research is being organised by the Schools of Pharmacy and Medicine, Queen's University Belfast. It is funded by the Dunhill Medical Trust.

Who has reviewed the study?

The study has received approval from the Office for Research Ethics Committees in Northern Ireland. The project has been peer reviewed by independent reviewers on behalf of the Dunhill Medical Trust.

Who can you contact for further information?

Please do not hesitate to contact the researchers as detailed below.

Dr. Cathal Cadogan
Research Fellow
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast BT9 7BL
Telephone: (028) 9097 2348
Email: c.cadogan@qub.ac.uk

Prof. Carmel Hughes
Professor of Primary Care Pharmacy
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast BT9 7BL
Telephone: (028) 9097 2147
Email: c.hughes@qub.ac.uk

Appendix 3.5: Patient consent form (focus groups)

Queen's University Belfast

Patient Participant Consent Form

Study Title: Development of an intervention to improve appropriate polypharmacy in older people in primary care.

Please initial the following statements.

I have read (or had read to me) the information that I have received in relation to the above study and have asked any necessary questions. I understand what the study involves.	
I agree to complete and return the questionnaire to the researchers before the focus group.	
I agree for the focus group to be audio-recorded.	
I agree for my GP and community pharmacist to be notified that I am taking part in the study. I agree for my GP and community pharmacist to be notified if I become upset or distressed during the study.	
I understand that I may withdraw from the study at any time without giving a reason and that this will not affect my medical care.	
I understand that my personal information (including consent forms) will be confidential and stored in a safe manner in the School of Pharmacy, QUB. I am aware that results from the study will be anonymous.	
I understand that relevant sections of information collected during the study may be looked at by individuals involved in the study, or from Queen's University, for audit purposes.	
I agree to take part in this study.	

Please write your name, sign and date the form below.

Participant Name (Print): _____

Participant Signature: _____ Date: _____

Researcher Name (Print): _____

Researcher Signature: _____ Date _____

Appendix 3.6: ORECNI favourable opinion letter

Business Services Organisation

Office for Research Ethics Committees Northern Ireland (ORECNI)

Customer Care & Performance Directorate
Office Suite 3
Lisburn Square House
Haslem's Lane
Lisburn
Co. Antrim BT28 1TW
Tel: + 44 (0) 28 9260 3107
Fax: + 44 (0) 28 9260 3619
www.orecni.hscni.net

HSC REC 2

16 August 2013

Professor C.M. Hughes
Professor of Primary Care Pharmacy
School of Pharmacy
Queen's University, Belfast
97 Lisburn Road
Belfast
BT9 7BL

Dear Professor Hughes

Study title:	**Development of an intervention to improve appropriate polypharmacy in older people in primary care**
REC reference:	**13/NI/0114**
Protocol number:	**1**
IRAS project ID:	**135743**

The Research Ethics Committee reviewed the above application at the meeting held on 08 August 2013.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Mrs Katrina Greer, katrina.greer@hscni.net.

Ethical opinion

The members of the Committee present gave a **favourable ethical opinion** of the above research on the basis described in the application form, protocol and supporting documentation, **subject to the conditions specified below**.

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

1. The Committee request a copy of the peer review from Dunhill Trust.
2. The Committee request a copy of the questionnaire 'Beliefs About Medicines'.
3. The Committee request that the information sheet for patients clearly states that £50 compensation will be paid upon completion of the study.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering Letter	Signed Prof Carmel Hughes	25 July 2013
Investigator CV	Prof Carmel Hughes	25 July 2013
Letter from Sponsor	QUB	25 July 2013
Other: Appendix 1	1.0 (NI Clinical Research Network (Primary Care) Support Letter	25 February 2013
Other: Appendix 2	1.0 (GP"s Invitation Letter)	25 July 2013
Other: Appendix 3	1.0 (GP"s Information Sheet)	25 July 2013
Other: Appendix 5	1.0 (Healthcare Professional Certificate of Participation)	25 July 2013
Other: Appendix 6	1.0 (Community Pharmacist's Invitation Letter)	25 July 2013
Other: Appendix 8	1.0 (Patient Participant Invitation Letter)	25 July 2013

Appendix 3.6 (cont'd): ORECNI favourable opinion letter

Other: Appendix 10	1.0 (Patient Participant Reply Slip)	25 July 2013
Other: Appendix 11	1.0 (Cover Letter on how to complete the questionnaire for patients)	25 July 2013
Other: Appendix 13	1.0 (Protocol for handling participants becoming upset or distressed during data collection)	25 July 2013
Other: Letter from Funder	The Dunhill Medical Trust	11 June 2013
Participant Consent Form: Appendix 4	1.0 (Healthcare Professional)	25 July 2013
Participant Consent Form: Appendix 12	1.0 (Patient Participant)	25 July 2013
Participant Information Sheet: Appendix 7	1.0 (Community Pharmacist's)	25 July 2013
Participant Information Sheet: Appendix 9	1.0 (Patient Participant)	25 July 2013
Protocol	1.0	25 July 2013
REC application	3.5	26 July 2013

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

No member declared a conflict of interest with this study

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

13/NI/0114 **Please quote this number on all correspondence**

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

Katrina Greer

Dr Ronald Atkinson
Chair

Email: katrina.greer@hscni.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: *Dr Stephen Liggett, Research Policy Officer: QUB*

Dr Cristin Ryan
Lecturer in Clinical Pharmacy
School of Pharmacy
Queen's University, Belfast
97 Lisburn Road
Belfast
BT9 7BL

Appendix 3.7: Patient focus groups topic guide

Introduction

Thank you all for coming along today. My name is Cathal Cadogan and this is Deborah Patton who is here to help me. We both work as part of a research team in Queen's University Belfast.

You were all invited here today because each of you is being prescribed at least four medicines regularly by your GP. We are interested in hearing about your experiences of taking several medicines each day, as well as the appointments or visits that you have with your GPs and community pharmacists about these medicines. This is one of a number of group discussions that we are running with people like yourselves throughout Northern Ireland.

I have a number of topics that I would like you to discuss as a group. My role is to guide you in your discussions. I should point out that there are no right or wrong answers. So please feel free to share your views or experiences, even if they differ from what others have said. You don't need to agree with others and it's ok to say that you've had different experiences.

Before we start, it's generally helpful to note some important points. You can see what's known as the RICE acronym on the sheet of paper in front of you:

Respect: You don't need to agree with others, but I would ask that you listen respectfully to other members of the group. As we are digitally recording what is said in this session, I would ask that only one person speaks at a time. I would also ask that you turn off your mobile phones or switch them to silent at least.

Involvement: I am interested in hearing from everyone, so if you are talking a lot, I may interrupt you from time to time and if you're not talking at all, I may ask you what your thoughts are on the subject under discussion.

Confidentiality: We can assure you all that we will keep anything that is shared strictly confidential. Deborah will be taking notes but this is only to make sure that we don't miss any important points. Your GPs and community pharmacists will NOT have access to the recording from this session and we will not tell them anything that you have said. Your name will not appear in any report that comes from this research and your name will not be linked to anything you say. I would, however, ask you all to agree that you won't discuss anyone's personal details with anyone outside the group. I would also ask that you don't name any GPs or pharmacists that you go to.

Equality: Everyone's experiences and views are equally valid and, as I've said, we'd like everyone to be involved in the discussion.

Does all of that sound ok to everyone? Would anyone like to add anything else?

Opening question

We'll start then by getting everyone to introduce themselves to the group [NOTE: will have name cards/tags for participants as well]. So as we go around the table, could you tell us your first name and roughly how long you have been attending this practice as a patient?

Introductory questions

Before you came here today, we asked you to complete a short questionnaire about the prescription medicines that you take. As you will see, some of what is discussed today will touch on parts of the questionnaire.

Encounters with GPs

But just to get the discussion started, could you tell me how you would normally go about ordering a prescription for your regular/repeat medicines from your GP's surgery? **Prompt:** Does anyone go through a different process/procedure?

I wanted to ask you about medication reviews with your GP. This is where the GP would sit down and talk to you about all the different medicines that you take and check how you are getting on with them. Has the GP ever tried to do this with you? **Prompt**: For example, the GP might have tried to find out if you still needed the medicine or if a change in the strength or type of medicine would help you.

1. Do you know why this review happened? Tell me about the reasons for such a review?
2. What did it involve?

Encounters with pharmacists

How would you normally go about getting the prescription with your regular/repeat medicines dispensed in the community pharmacy? **Prompt:** Does anyone go through anything different? What about talking to the pharmacist about your medicines? Would the pharmacist usually talk to you about your medicines? What kinds of things would they talk to you about?

Patients' perceptions of HCPs' roles

What do you think the GP's role is in making sure that you receive the best combination of medicines to manage your health? Tell me about the conversations that the GP has with you about your medications?

What do you think the community pharmacist's role is in making sure that you receive the best combination of medicines to manage your health? Tell me about the conversations that the GP has with you about your medications?

Appendix 3.7 (cont'd): Patient focus groups topic guide

Transition question

Ok. And just following on from that, I'd now like to ask the group some questions about the medicines that you take and particularly how (or if?) you take them. I'd like you all to think for a moment about all the different medicines that you take every day. Now, if you look at the coloured sheet in front of you, you will see three different statement. I would like you to think about which of these three answers best applies to you. ***[Knowledge]***

•'I know what every medicine that I take is for'

•'There is one medicine that I take and I don't know what it is for'

•'There are several medicines that I take and I don't know what that they are for'

Please remember that whatever answer applies to you is ok. So, raise your hand if you don't know what... several of the medicines that you take are for? ...one of the medicines that you take is for? ...every medicine that you take is for?

And, then if you look at the other coloured sheet in front of you, I would like you to think about which of these three statements best applies to you ***[Skills]***

• 'I know how to take all of my medicines'

•'I don't know how to take one of my medicines'

•'I don't know how to take several of my medicines'

As I said before, whatever answer applies to you is ok. So, raise your hand if you... don't how to take several of your medicines? ... don't how to take one of your medicines?... know how to take all of your medicines? And what about making sure that you take your medicines as advised? Whose role do you think it is it to make sure that this happens?

Key questions

As I mentioned at the start, we asked you to come here today because you all take several medicines every day. How important is it to you to take all of your different medicines as the GP has instructed/directed/prescribed? ***[Motivation and goals]***

When would it be less important to you to take all of your different medicines as the GP has instructed/directed/prescribed? ***[Motivation and goals]***

What do you think the benefits are of taking all of your medicines as prescribed? ***[Beliefs about consequences]***

What do you think the disadvantages are to taking all your medicines as prescribed? ***[Beliefs about consequences]***

Are the benefits of taking all of your medicines worth the possible disadvantages? ***[Beliefs about consequences]***

If you were think about how you fit having to take several medicines into your daily routine when you're at home:

- What makes this difficult to do when you are at home? ***[Environmental context and resources]***
- What helps you to do this when you are at home? ***[Environmental context and resources]***

Do you feel confident that you can take all your medicines as advised by your GP or community pharmacist? ***[Beliefs about capabilities]***

What are the biggest problems/challenges in having to take at least four medicines every day? ***[Beliefs about capabilities]***

What would help you to overcome these problems/challenges? [Behavioural regulation]

Prompt: Practical strategies/procedures

How would you feel if you didn't take your medicines as advised? ***[Emotion]***

Does anyone have any routines or habits that help them to make sure they take their medicines as instructed/directed/prescribed? ***[Nature of the behaviours]***

And apart from forgetting to take your medicines, would you ever decide not to take your medicines as instructed/directed? What would be the reasons that you would deliberately decide not to take the medicines as instructed/directed? ***[Memory, attention and decision processes]*** **Prompt:** Any other reasons?

Who else influences your decisions about whether you to take your medicines as instructed/directed? ***[Social influences]*** **Prompt:** What about the influence of family? carers?

Contribution to decision-making about medicines

Are any of you involved with your GP or pharmacist in making decisions about your medicines? **Prompt:** If yes.... can you tell me more? Is it important to you? If no....can you tell me why?

If your GP or pharmacist recommended a change to your current medicines, would this affect you in any way?

How would you feel/react if your GP said that you no longer needed one of your regular medicines and stopped prescribing it to you? Why would you feel like that? Would it make a difference if it was the GP or the pharmacist that advised you to stop?

Appendix 3.7 (cont'd): Patient focus groups topic guide

Future planning

As I mentioned at the start, we are interested in the care of people, like yourselves, who are prescribed multiple medicines on an ongoing basis. You've already talked me through how you go about getting your prescriptions from the GP and then having the medicines dispense by the pharmacist.

If you were to think about the way in which your regular medicines are currently prescribed by the GP, can you tell me:

1. What works well with that process/system?
2. What could be done differently that may make things better?

And then if you were to think about the way in which your regular medicines are currently dispensed by the community pharmacist, can you tell me:

1. What works well with that process/system?
2. What could be done differently that may make things better?

If your GP or pharmacist arranged to sit down with you and go through all the medicines that you take, what would you like to see happen as a result?

Concluding questions/Summary

So just to recap on what's been discussed today… [Cathal/Deborah to give short oral summary of key questions and responses] Is this an adequate summary?

Additional comments

Have we missed anything? Is there anything that we should have talked about but didn't?

Briefly, before we finish up, is there anything else that anyone would like put to the group that is relevant to making sure that patients aged 65 years and above receive/take the best combination of medicines?

Thank you all very much for your time.

Appendix 3.8: Completed COREQ checklist (focus groups) (Tong et al. 2007)

Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Interviewer/ facilitator	Which author/s conducted the interview or focus group?	Two researchers carried out the focus groups. CC acted as the moderator and DP took notes and provided a brief summary at the end of each session.
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	CC had a PhD and BSc in pharmacy. DP had an MPharm degree and was a PhD candidate. CC and DP were both qualified pharmacists.
3. Occupation	What was their occupation at the time of the study?	CC was working as a Post-doctoral Research Fellow and DP was a PhD student at the time of the research study. DP continued to practise in the community pharmacy setting on a part time basis.
4. Gender	Was the researcher male or female?	CC-male, DP-female.
5. Experience and training	What experience or training did the researcher have?	CC and DP had both undertaken training in qualitative research methodologies and CC had previous experience.
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	No prior relationship was established between the interviewers and focus group participants, other than contact with CC to arrange the sessions.
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Participants were aware that both researchers worked at the School of Pharmacy (QUB) and that the research was funded by the Dunhill Medical Trust.
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Both facilitators had an interest in the research topic of polypharmacy. DP had a special interest in medication adherence .

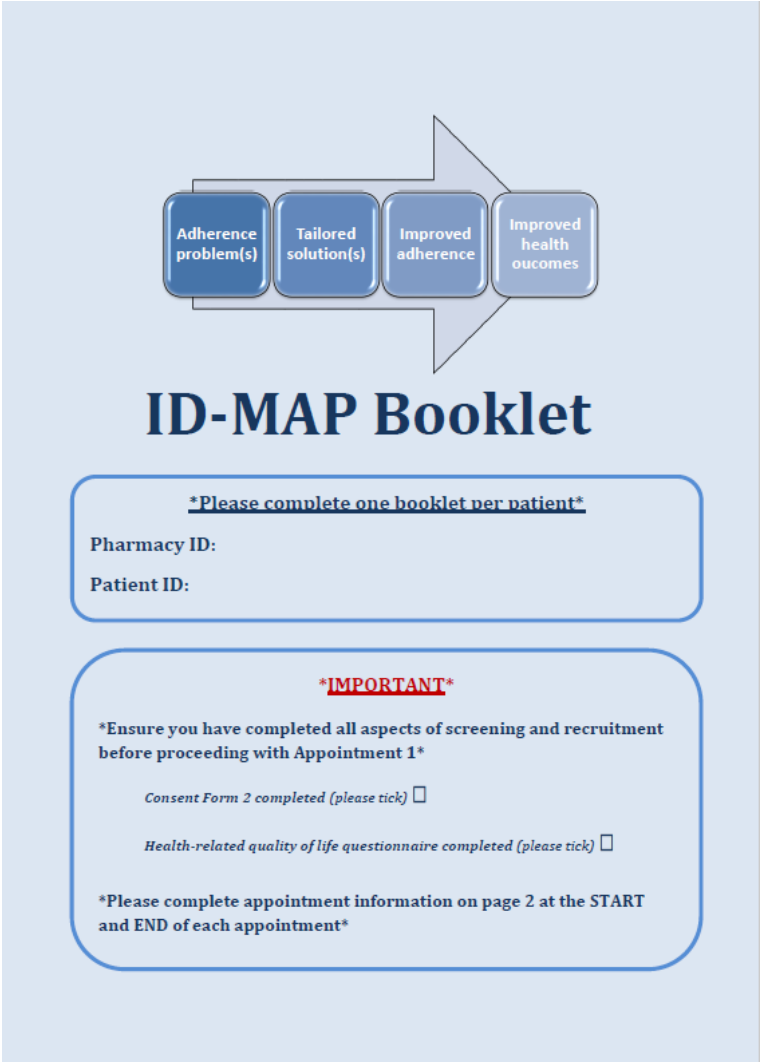
Appendix 3.8 (cont'd): Completed COREQ checklist (focus groups) (Tong et al. 2007)

Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	The focus group topic guide was underpinned by the TDF. Framework analysis was conducted, followed by inductive qualitative content analysis.
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	General practices that had participated in a previous linked study were approached and asked if they would facilitate patient recruitment for the focus groups. This included general practices from across the five HSC Trusts in NI (two per Trust area). A purposive sampling strategy was adopted for this study to identify 'information-rich' participants.
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Participants were mailed letters of invitation (from their general practice).
12. Sample size	How many participants were in the study?	Fifty participants took part in the study over seven focus groups (5-10 participants per group).
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Numbers of refusals were not recorded by nurses from the Northern Ireland Clinical Research Network who were responsible for issuing invitations.
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Data was collected either at the patients' general practice or other convenient location (e.g. local leisure centre)
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	Only CC, DP and focus group participants were present.
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	All participants were aged over 65 years and taking four or more prescribed medications.
Domain 2 (cont'd): study design		
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	A topic guide with prompts was developed and used during the sessions. This was tested and refined prior to use.
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No repeat focus group sessions were required.
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Focus group sessions were audio-recorded.
20. Field notes	Were field notes made during and/or after the interview or focus group?	Field notes were made by DP during the focus group sessions.
21. Duration	What was the duration of the interviews or focus group?	Each focus group ranged from 65-123 minutes (618 minutes in total).
22. Data saturation	Was data saturation discussed?	Data saturation was reached by the seventh focus group as no new themes were emerging.
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Transcripts were not returned to focus group participants.
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	Three researchers (DP, CR, CH) independently coded the data (two researchers per transcript).
25. Description of the coding tree	Did authors provide a description of the coding tree?	Codes represented barriers and facilitators expressed by participants that were assigned to each domain of the TDF.
26. Derivation of themes	Were themes identified in advance or derived from the data?	Themes in each domain were informed by the content of the focus groups.
27. Software	What software, if applicable, was used to manage the data?	NVivo® QSR 10.
28. Participant checking	Did participants provide feedback on the findings?	At the end of each focus group DP provided a summary of the issues discussed and checked this for clarity with participants.

Appendix 3.8 (cont'd): Completed COREQ checklist (focus groups) (Tong et al. 2007)

Domain 3 (cont'd): analysis and findings		
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number	Quotations have been presented in Section 3.4.2 of this thesis with identifiers removed. Each participant was given an anonymous code (e.g. FG01PT01).
30. Data and findings consistent	Was there consistency between the data presented and the findings?	See Section 3.4.2 of this thesis. We endeavoured to report the study findings in a clear, consistent manner in order to accurately reflect the data that has been collected.
31. Clarity of major themes	Were major themes clearly presented in the findings?	
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	

Appendix 4.1: ID-MAP Booklet



Appendix 4.1 (cont'd): ID-MAP Booklet

Contents

Section 1
- Complete medication details as far as possible **BEFORE** Appointment 1
- Confirm medication details **DURING Appointment 1**

Section 2
- Ask all questions in the ID-MAP Tool **DURING Appointment 1** to identify adherence problems (Appointment 1 ends here)
- Map adherence problems to adherence solutions **BEFORE Appointment 2**

Section 3
- Prepare adherence solutions and make planning notes on the Solution Summary **BEFORE Appointment 2**
- Deliver adherence solutions DURING Appointment 2 (Appointment 2 ends here)

Section 4
- Complete review of adherence solutions and give feedback **DURING Appointment 3** (end of intervention)

Reminder instructions for pharmacists

- This booklet will help guide your discussions with the patient for each appointment of the ID-MAP Intervention.
- Please refer to the intervention manual for detailed instructions on how to complete this booklet.
- Brief reminder instructions are provided at the top of each section in blue boxes.
- Examples of what to say to the patient are also included.
- ***Remember to complete the checklist at the end of each appointment.***
- All of the materials you will need to deliver the adherence solutions can be found in the Solutions Folder (including laminated copies of the solution guides).
- You will also need access to a computer with printing facilities (black and white ink).

Appointment information

Please complete for each appointment:

Date of Appointment 1:

Time started:

Time finished:

Carer/relative present (please tick) ☐

Date of Appointment 2:

Time started:

Time finished:

Carer/relative present (please tick) ☐

Date of Appointment 3:

Time started:

Time finished:

Carer/relative present (please tick) ☐

Section 1: Medication Details

Reminder instructions for pharmacists

- Please complete blue parts of this form BEFORE APPOINTMENT 1 using the PMR.
- If there are any discrepancies, the list should be confirmed with the GP surgery before the appointment.
- The grey parts of this form should be completed DURING APPOINTMENT 1. Part of this section is linked with Question 1 (Patient's knowledge) in the ID-MAP Tool on the next page (*Section 2*).
- Use Question 1 to confirm, with the patient, that the medication list is accurate and up-to-date.

Complete BEFORE Appointment 1		**Complete DURING Appointment 1**					
Prescribed medication details (i.e. long-term regular and when required medications)		Details confirmed *(Please tick)*		Linked with Question 1 (Patient's KNOWLEDGE) in ID-MAP Tool *Mark box with a question mark (?) if a knowledge issue is identified*			
Medication (Name, Form, Strength)	Directions (Dose, Frequency)	By Patient	By GP *(if there is a query)*	What it is called	Why they take/ use it	When they take/ use it	How they take/ use it

Other medications (e.g. hospital dispensed or OTC medications) **Complete DURING Appointment 1**

Medication (Name, Form, Strength)	Directions (Dose, Frequency)

Date completed:	Signature:
List confirmed with GP if there is a query *(please tick)* ☐ Date:	Signature:
Date list confirmed with patient:	Signature:

Section 2: ID-MAP Tool

Reminder Instructions for pharmacists

- The questions in this tool will help you identify individual adherence problems. Use prompts if necessary.
- **IMPORTANT:** Question 1 should be asked in conjunction with the medication list on the previous page. Ask the WHAT, WHY, WHEN and HOW aspects of this question for EACH medication. Place a question mark (**?**) in the corresponding box in Section 1 if a knowledge issue is identified.
- For all seven questions in this ID-MAP Tool, tick either the YES or NO box for each "Adherence problem" statement in the left hand column and make brief notes of the key issues in the space provided (e.g. which medication/s, specific reason for forgetting, misconceptions about their medicines etc.)
- Ignore the adherence solution(s) column during Appointment 1.

What to say to the patient: *"As I mentioned previously, the aim of this discussion is to find out a bit more about how you take or use all of your medicines and to see if there is anything we can do to help you get the most from them. If it is ok with you, I would like to start by asking you a few questions about the medicines you are currently taking (or using). If you don't mind, I will take some notes as we go along."*

Question 1 (Patient's Knowledge) **Use in conjunction with medication list (Section 1) **

- **What** – *"Can you tell me WHAT medications you are currently taking (or using)?" (Confirm each medication in list)*
- **Why** – *"Do you know WHY you are taking/using this medication?" (Go through each medication in list)*
- **When** – *"WHEN do you take/use this medication?" (Go through each medication in list)*
- **How** – *"Do you know HOW to take this medication/use this device?" (Ask as appropriate for each medication in the list)*

Adherence problem	YES	NO	Notes	Adherence solution(s)
Lacks knowledge of **WHAT** medications they are taking/using Lacks knowledge of **WHY** they are taking/using their medication(s)	☐ ☐	☐ ☐		1. Where knowledge gaps are identified, explain what each medication is and why they need to take/use it 2. Emphasise this by directing the patient to the back page of their medication diary (Solution A)
Lacks knowledge of **WHEN** to take/use medication(s) or incorrect timing Taking/using incorrect dose or other medication error(s)	☐ ☐	☐ ☐		1. Give verbal feedback on what they are doing incorrectly 2. Explain importance of taking/using medications at correct time/following any special instructions/ correct dose 3. Emphasise this by directing the patient to the back page of their medication diary (Solution A)
Lack of or incorrect knowledge on **HOW** to take their medication(s)/ use devices	☐	☐		1. Give verbal feedback on what they are doing incorrectly 2. Emphasise importance of correct use and if possible, write this in the special instructions section on the back page of their medication diary (Solution A)

Question 2- (Routine/organisational barriers): ***"Can you describe your typical daily medicine routine or tell me how you go about taking/ using your medicines when you are at home?"***

Prompt- *"Do you set your medications out in advance?"*

Prompt- *"Do you ever forget to order your medications and have to go without them?"*

Adherence problem	YES	NO	Notes	Adherence solution(s)
Lack of an effective routine	☐	☐		1. Advise to link medication use to routines already in place e.g. meals/ brushing teeth/TV show [Solution B] 2. Emphasise the importance of using the medication diary every day as they develop their routine [Solution A]
Lack of planning (e.g. forgets to order medication)	☐	☐		1. Emphasise the importance of using the medication diary every day as they develop their routine [Solution A] 2. Advise patent to mark re-order dates on the diary provided (e.g. a star beside medications that need re-ordered that week)

Question 3-(Practical barriers): ***"Do you have difficulty taking (or using) any of your medicines?"***

Prompt- *"Do you have difficulty opening the packaging/ using your devices/ swallowing the medication/ reading or understanding the labels?"*

Adherence problem	YES	NO	Notes	Adherence solution(s)
Difficulty opening medication packaging Difficulty with administration/ accessing medication	☐ ☐	☐ ☐		1. Provide/source appropriate containers or administration aids if possible (e.g. inhaler aids) OR refer to GP/arrange appropriate solution (example if MDS is required) 2. Put a note on the PMR to ensure on-going support OR Complete GP communication form [Solution B]
Problem with the formulation (e.g. difficulty swallowing) Problem with regimen (e.g. too complex)	☐ ☐	☐ ☐		1. Use your professional judgement to decide on the best course of action. Refer to GP if it is affecting adherence 2. Complete GP communication form [Solution B]
Difficulty reading or understanding labels	☐	☐		1. Provide patient with LARGE PRINT labels that are clear/easy to understand 2. Put a note on the PMR [Solution B]
Other (Please document) _____	☐	☐		1. Decide on an appropriate course of action OR refer to GP [Solution B] 2. Complete GP communication form

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Question 4- (Social support): ***"Does anyone at home help you with your medicines?"***

Prompt- *"Do you have any friends or relatives that might be able to help?"* (For example, help you to order your medicines, collect prescriptions/medicines or remind you to take/use your medicines)

Prompt- *"Could the pharmacy staff do anything to help you?"* (For example, prescription collection or delivery)

Adherence problem	YES	NO	Notes	Adherence solution(s)
Current lack of social support from family/friends Current lack of social support from healthcare professionals	☐ ☐	☐ ☐		Encourage patient to ask a relative/friend to remind them or help organise medications (order, collect, dispose) AND/ OR Arrange for social support from pharmacy staff/other healthcare professionals e.g. prescription collection or delivery [Solution B] *Note- the patient may not want additional social support*

Question 5 (Forgetting): ***"Think back to the last time you forgot to take (or use) your medications, can you tell me why you think you forgot to take (or use) them?"***

Prompt- *"Were you out of the house, on holidays or just busy doing other things?"*

Prompt- *"Does someone usually remind you or do you have something else in place to help you remember, for example an alarm or mobile phone reminder?"*

Adherence problem	YES	NO	Notes	Adherence solution(s)
General difficulties remembering Forget when busy with other household tasks Lack of routine Lack of reminder strategies	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐		1. Emphasise the importance of the daily medication diary [Solution A] 2. Advise to link medication use to routines already in place e.g. meal times/ brushing teeth/TV programmes AND/OR Advise storage of medications in a visually prominent place AND/OR Encourage the use of reminder stickers in visually prominent places [Solution B]
Forget when not at home/out-of-routine (e.g. day trips, meetings, appointments, holidays)	☐	☐		1. Emphasise the importance of the daily medication diary [Solution A] 2. Advise patient to mark travel dates on the diary (e.g. with the letter H) AND/OR place a reminder sticker [Solution B] in their own travel itinerary when planning their holiday
Forget when no-one is there to remind them (e.g. spouse, family)	☐	☐		1. Emphasise the importance of the daily medication diary [Solution A] 2. Encourage the use of reminder stickers in visually prominent places at home AND/OR Advise storage of medications in a visually prominent place [Solution B] 3. If patient lives alone, encourage them to get other relatives /friends involved in helping them (if possible) e.g. reminder phone calls [Solution B]

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Question 6- (Intentional non-adherence): ***"People sometimes miss taking (or using) their medicines for reasons other than forgetting. Have you ever cut back or stopped taking (or using) any of your medicines without telling your doctor?"***

If YES- In relation to the medicine(s) you don't take (or use) as often as you should, can you tell me why?"

Prompt- *"Are you experiencing, or worried about, side effects or long-term effects of your medicine(s)?"*

Prompt- *"Do you find the medication is not working for you?"*

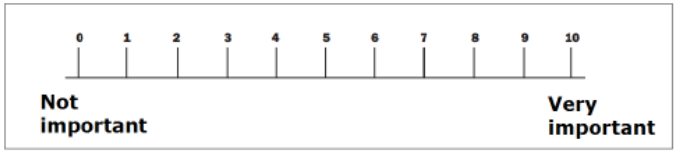
Adherence problem	YES	NO	Notes	Adherence solution(s)
Patient **makes decision** to stop, cut-back or alter dose of medication(s) **without informing GP**	☐	☐		1. Give feedback on what they are doing incorrectly 2. Emphasise/discuss why the medication should not be stopped/altered 3. Provide/discuss 'Voicing concerns about your medication' leaflet **(Solution C)**
Has experienced **side effects** Worried about side effects and/or long-term consequences	☐ ☐	☐ ☐		1. Can the side effect(s) be managed? If not, refer to GP. Complete GP communication form **(Solution B)** **OR** if side effects can be managed, reassure the patient and discuss any misconceptions **(Solution C)** 2. Provide/discuss 'Voicing concerns about your medication' leaflet **(Solution C)**
Thinks the medication **isn't working** Thinks one (or some) medications are **less important** than others	☐ ☐	☐ ☐		1. Inform them of the benefits/necessity of **ALL** their medications and discuss any misconceptions 2. Provide/discuss 'Voicing concerns about your medication' leaflet **(Solution C)**
Unsure of the **consequences** of non-adherence Thinks it is OK to miss a few days/doses of medication	☐ ☐	☐ ☐		1. Give feedback on what they are doing incorrectly 2. Explain consequences of non-adherence **AND/OR** discuss importance of not missing doses if it can be avoided 3. Provide/discuss 'Voicing concerns about your medication' leaflet **(Solution C)**
Believe **generic medicines** are less effective compared with branded medicines Concerns about generic medicines	☐ ☐	☐ ☐		1. Provide/discuss 'Voicing concerns about your medication' leaflet 2. Provide/discuss 'Generic Medicines Fact Sheet' **(Solution C)**

Question 7- (Patient's motivation): ***"On a scale of 0 to 10, how important is it for you to take (or use) all of your medicines as prescribed?" (Show patient the scale below and circle score)***

If patient indicates a score of 7 or less on scale then ask: ***"What would motivate you to take (or use) all of your medicines as the GP has prescribed?"***

Prompt- *"Is there anything that you would like to achieve from taking/using your medicines?"* (E.g. stay healthy/active, stay out of hospital, stay at home, be free from symptoms, reduced symptoms)

Adherence problem	YES	NO	Notes	Adherence solution(s)
Patient's **motivation** to take/use medications **could be increased** by setting a positive general health goal *(Tick NO if patient appears to be already highly motivated i.e. score of 8 or above on the scale below)*	☐	☐		Together with the patient, set an overall general health goal. ***(Note: this goal will be in addition to the patient's specific medication use goal/s).*** This goal should be focused on a positive outcome of taking/using their medicines e.g. stay out of hospital **(Solution D)**



********This is the end of Appointment 1*********

What to say to the patient: *"Those are all the questions I have for you today. Is there anything you would like to ask me? The next stage is to look at what options we have to help you get the most from your medicines. I would like to arrange another appointment to take place in 1-2 weeks if that suits you? This will give me some time to prepare a medication diary for you and arrange other solutions that I think you might find useful. Would any particular day or time suit best?"*

Appointment 1 check list

Fill in this checklist at the end of Appointment 1

ALL blue boxes **MUST** be ticked. White boxes should be ticked if applicable.

Section 1- Medication Details section has been completed and confirmed as accurate ☐

Section 2- ID-MAP Tool has been completed (at least one problem identified) ☐

Urgent adherence problems have been resolved and GP contacted (if necessary) ☐

Appointment 2- Date and time arranged _____ ☐

Appendix 4.1 (cont'd): ID-MAP Booklet

Section 3: Solution Summary (page 1 of 3)

Reminder instructions for pharmacists

- Go back through Section 2 and map adherence problems (red YES column ticks) across to adherence solutions.
- Note: ***All patients will receive Solution A*** *(Medication diary)* ***AND Solution D*** *(Goals and action plan sheet).*
- Please **tick any additional optional solutions** (B and/or C) required (on coloured boxes on page 10 & 11)
- A space for planning notes is provided for each adherence solution: **use a RED pen for planning notes.**
- Additional space is provided for any notes made during Appointment 2: **use a BLACK pen for additional notes**
- Prepare adherence solutions in advance (instructions and materials can be found in the Solutions Folder).
- Make brief summary notes on the adherence problems discussed at Appointment 1 (black box below). This will allow you to quickly recap on these discussions at the start of Appointment 2.

What to say to the patient: *"Thank you for coming along today. The purpose of today's appointment is to discuss things that might help you with taking (or using) your medicines. To start us off, I would like to recap on some of the things we discussed at the last appointment."*

Recap of discussions from Appointment 1 (Summary notes)

Space for additional notes

Solution Summary (page 2 of 3)

☑ **Solution A – Patient medication diary (compulsory)**

- *Prepare medication diary in advance using the confirmed list of medications (prescribed medications only).*
- *Provide* ***ALL PATIENTS*** *with medication diary during Appointment 2 and explain how to use it.*
- *Ask the patient to bring the diary along with them to their next appointment (at least four weeks later).*

☐ *Please tick if additional verbal advice/feedback is required* ***(e.g. knowledge gaps identified).***

Planning notes:

Additional notes:

☐ **Solution B – Practical, reminder and social support options (optional)** *(tick if delivered)*

- *Tick possible options identified using the ID-MAP Tool and if necessary prepare these before Appointment 2.*
- *During Appointment 2, agree which option is most suitable (**Note**: may require more than one option).*
- *Provide resource(s)/make notes in PMR where necessary.*

Possible options	***Option agreed with patient***
[ ] Provide more suitable packaging _____	[ ]
[ ] Provide large print labels /clearer wording _____	[ ]
[ ] Link medication taking to other routines _____	[ ]
[ ] Advise storage in a visually prominent place _____	[ ]
[ ] Provide reminder stickers _____	[ ]
[ ] Social support plan (relatives/friends/healthcare team) _____	[ ]
[ ] Other (please detail) _____	[ ]
[ ] Referral to GP (Fill in GP communication form: reason(s) _____	[ ]

Planning notes:

Additional notes:

Solution Summary (page 3 of 3)

☐ **Solution C –Discussion around medication concerns (optional)** *(Tick box if delivered)*

- *Make planning notes in relation to issues that need to be discussed during Appointment 2.*
- *During Appointment 2, discuss these issues using the 'Voicing concerns about your medicines leaflet' as a visual aid.* ***Emphasise the health consequences of non-adherence.***
- *Complete section on the back of the leaflet ('Who to contact if you have concerns').*
- *If the patient has concerns about generic medicines, also provide/discuss 'Generic medicines fact sheet'.*
  - *Please tick if the 'Generic medicines fact sheet' is also required.*

Planning notes (issues to discuss):

Additional notes:

☑ **Solution D – Goals and action plan sheet (compulsory)**

- *List possible medication use goals, general health goals (optional) and action plans in the planning section below in advance of Appointment 2.*
  - *Please tick if an overall general health goal is also required (to help increase motivation)*
- *Purpose of setting goals and having an action plan should be explained during Appointment 2.*
- *Fill in the goals and action plan sheet for* ***ALL PATIENTS****. You may need to prompt them to set goals.*
- *Give top copy to patient. Keep duplicate copy for your records.*

Planning notes (potential medication use goal/s):

Examples*-take my blood pressure medicines every day/take my inhalers when I am out for the day*

Planning notes (potential general health goal if required):

Examples*- to stay well and in my own home/to be free from night-time asthma symptoms*

Planning notes (potential action plan/s):

Can include: details of new routine, exactly when/where to take, who to contact if concerned, who will provide support etc.
Examples*-* IF I am concerned, THEN I will speak to my pharmacist/ IF I see my medicines sitting on the kitchen bench, THEN I will take them

Additional notes:

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********This is the end of Appointment 2*********

What to say to the patient: *"Hopefully you have found today's appointment useful. Do you have any further questions you would like to ask?*

Please let me know if you have difficulties with the medication diary or anything else we discussed today. If any of your medicines change during the next four weeks, please contact me as soon as you can. We can make any changes needed to the diary if this happens.

I would like to arrange another appointment for four weeks' time if that suits you. We can find out how you got on with everything at this next appointment. Would any particular day or time suit best?

Appointment 2 check list

Fill in this checklist at the end of Appointment 2

ALL blue boxes **MUST** be ticked. White boxes should be ticked if applicable.

Section 3- Solution Summary pages have been fully completed	☐
Solution A- Purpose of the medication diary explained	☐
- **Personalised** medication diary provided to patient	☐
- Additional information provided **if** knowledge gaps were identified	☐
- Patient asked to bring completed medication diary to the next appointment	☐
Additional solution B provided if necessary	☐
- Recommended action taken/resources provided/advice given	☐
Additional solution C provided if necessary	☐
- Leaflet(s) discussed and completed if necessary	☐
- Patient given leaflet(s) to take home	☐
Solution D- Purpose of setting goals and having an action plan explained to the patient	☐
- Goals and action plan sheet completed	☐
- Top copy given to patient, bottom copy retained for records	☐
Appointment 3- Date and time arranged _____	☐

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Section 4: Review of solutions/feedback

Reminder instructions for pharmacists

- At Appointment 3 you will find out how the patient got on with the recommended adherence solutions.
- You will need to review compulsory solutions A and D.
- You will also need to review optional Solutions B and/or C if these were delivered.
- Indicate *"N/A"* or *"Not applicable"* in the notes section if a solution was **not** delivered.
- The table below will help guide this appointment. Make brief notes about your discussions.

What to say to the patient: *"Thank you for coming along again today. The purpose of today's appointment is to review how you got on with everything we discussed at the last appointment. If it is okay with you, I would like to start by taking a look at your medication diary—did you bring this along with you?"*

Solution	Steps to review it	Notes
Solution A: Medication diary	1. **Did they use the daily medication diary?** If not, discuss why. Discuss reasons for missed doses. 2. **If possible, give the patient feedback on their adherence behaviour based on the diary**. Was there any improvement or is there still some room for improvement? 3. Ask if they are happy for you to **keep the diary for the research team to examine!** You can print out a separate list of medications if the patient would like this for their own reference. ***Ensure this is kept up-to-date***	
Additional solution B (practical, reminder, social support)	1. **Did the recommendations help?** *(Refer to page 10 & 11 for what was recommended)* 2. **Are any further actions required?** If so, please make a note of these.	
Additional solution C (discussion around medication concerns)	1. **Did they find the leaflet(s) helpful?** Do they have any more concerns that they wish to discuss? 2. **Are they aware of the health benefits** of taking/using their medications as prescribed and the possible consequences of non-adherence?	
Solution D: Goals and action plan	1. **If an overall general health goal was set, is this still their motivation** for taking/using their medicines? 2. **Did the patient meet their medication use goal(s)?** If the medication diary indicates that they did not fully meet their goal(s), then discuss the possible reasons why. 3. **Complete the 'Review of goal' section on Goals and action plan sheet** for each medicine use goal by ticking the relevant option (goal met or goal not met).	

*******This is the end of the ID-Map intervention********

What to say to the patient: *"Thank-you for coming along to all three appointments; I hope you have found them useful. This is the last official appointment but if you have any more questions about your medicines please feel free to call into (or telephone) the pharmacy at any time. I would be happy to answer any questions you may have. To find out more about what you thought of the appointments, the research team will telephone you over the next few days; does any particular time suit you best?"*

Appointment 3 checklist

Fill in this checklist at the end of Appointment 3

ALL blue boxes **MUST** be ticked. White boxes should be ticked if applicable.

Section 4- Solution review table has been completed/notes made	☐
-Medication diary has been returned by the patient	☐
-Medication list supplied (if requested by patient)	☐
-Further recommendations made (if necessary)	☐
Patient advised that the research team will follow-up with them in the next few days	☐
Most appropriate time for research team to telephone _____	☐

Appendix 4.2: Medication diary

Front page *(Not to scale: A4 size)*

MY MEDICINES DIARY

How to use your medicines diary

- This diary will help you keep track of the medicines prescribed by your Doctor
- Tick the box for each day and time that you take (or use) your medicines
- If you miss a dose, you should leave the box blank
- Keep this diary close to where you store your medicines
- Please complete this every day and bring it to your next appointment with your pharmacist

Name: ____________________

Start date: ____________________

Next appointment: ____________________

Date created: ________ Signature: ________ Date reviewed: ________ Signature: ________

Back page

Medicine name and strength (e.g. simvastatin 40mg)	Form (e.g. Tablets)	When and how much to take (or use)				Special instructions (e.g. with food, WHEN REQUIRED)	Why I need to take (or use) this medicine (e.g. for blood pressure)
		Morning	Lunch	Tea-time	Bed-time		

Pharmacy ID: Patient ID: Date created: Date reviewed:

Inner pages (coloured grid section flips over: one page per week)

	Week beginning:																											
	Monday				Tuesday				Wednesday				Thursday				Friday				Saturday				Sunday			
Medicine name and strength	Morning	Lunch	Tea-time	Bed-time	Morning	Lunch	Tea-time	Bed-time	Morning	Lunch	Tea-time	Bed-time	Morning	Lunch	Tea-time	Bed-time	Morning	Lunch	Tea-time	Bed-time	Morning	Lunch	Tea-time	Bed-time	Morning	Lunch	Tea-time	Bed-time

Pharmacy ID: Patient ID: Date created: Date reviewed:

Appendix 4.3: Voicing concerns about your medicines leaflet

Medicine myths

Myth 1. I can just take my medicines when I feel like it.
False- You should always take your medicines as directed, even if you feel better. If you don't they might not work as well.

Myth 2. Medicines do not work
False- Your GP has given you medicines that have been shown to work for other people. If you think it is no longer working for you, then discuss this with your GP.

Myth 3. Cheaper medicines do not work as well as brand name medicines
False- Research has shown that these cheaper medicines work just as well as the brand name medicines. Speak to your pharmacist if you are unsure about your medicines.

Myth 4. All medicines will give me side effects
False- The side effects listed in the patient information leaflet are not experienced by everyone. If you are concerned or experience any of them then speak to your pharmacist or GP.

Who to contact if you have concerns

Pharmacist _____

GP _____

Nurse _____

Family member/Carer _____

Other _____

For more information on any of your medicines, look at the **Patient Information Leaflets** provided inside each of your medication boxes. If you have access to the internet you can find further information on the **NHS Choices Website** which can be found at:

www.nhs.uk

Voicing concerns about your medicines

Are you worried about any of your medicines?

"Why should I voice my concerns?"

- Your Pharmacist and GP are experts on medicines. They should be able to answer any questions you may have.
- Worrying about your medicines may stop you from taking them. This could have a bad effect on your health.
- There is often a simple solution.
- With the help of your pharmacist or GP, you can work out the best thing to do.

Hints and tips

- Make a list of your concerns to discuss with your pharmacist or GP.
- Bring along a family member or friend to your pharmacy or GP appointment.

"I'm worried about the side effects!"

- Side effects are unwanted symptoms that you might experience when you take a medicine.
- Side effects are listed on the Patient Information Leaflets found inside your medicine boxes.
- This can be quite a long list but there is **no need to worry** as you may never experience any side effects and if you do there is often a simple solution.

- Some side effects can happen soon after you start taking a medicine.
- Some side effects only happen once every so often but you can learn to manage them.
- Other side effects may make you want to stop a medicine. If this happens, contact your Pharmacist or GP as soon as you can.
- Your GP may want you to try a different medication or may offer you a solution to help manage it.

"Do I need to take all of these medicines?"

- Each one of your medicines has been prescribed for a reason.
- If you are unsure why you are taking a medicine, then check your medicine list on the back of the diary your pharmacist has given you.
- You can ask your pharmacist to explain in more detail why you need each of your medicines.

"What happens if I stop taking my medicines?"

- Stopping medicines without telling your GP could have a **bad effect on your health.**
- If you are thinking about stopping a medicine please let your GP or pharmacist know. Together, you can decide the best option for you.

Appendix 4.4: Generic medicines leaflet

Generic Medicines: Fact Sheet

This leaflet gives you information on generic medicines and how these differ from brand-name medicines. It answers some frequently asked questions (FAQ) about generic medicines.

FAQ: What are generic medicines and brand-name medicines?

Generic name: Each medicine is given an approved (or generic) name. Each medicine will only have one generic name.

Brand-name: The name given by the company that originally made the medicine is called the brand-name. Medicines can have more than one brand name. This brand-name is often more memorable and easier to pronounce. This name is used for advertising.

For example, paracetamol is the **Generic name** given to this painkilling medicine. Lots of companies make paracetamol but some give it their own **Brand name** such as Calpol® or Panadol®. Both of these brand-name versions will contain the medicine paracetamol.

FAQ: Why does the Doctor prescribe generic medicines?

Doctors are encouraged to prescribe medicines using the generic name. This is the name that doctors are trained to use. There can also be more than one brand-name for a medicine but **each medicine will only have one generic name.** Using this generic name helps to avoid any confusion.

Generic medicines are also usually cheaper. This can save the NHS millions of pounds.

FAQ: Generic medicines are often cheaper than brand-name medicines. Does this mean they are poorer in quality?

NO— Generic medicines have to be made to the same standard as brand-name medicines. The Government ensures that they are all safe, effective and of the highest quality.

Generic medicines must contain the exact same medicine as the brand-name version. This means they will work in exactly the same way and will be identical in strength.

Same Medicine ► **Same quality** ► **Same effect**

Appendix 4.4: Generic medicines leaflet

FAQ: Why do I sometimes get different sizes or colours of tablets or a different box?

Companies who make generic medicines may use different colours, flavours, shapes or sizes. This is only the outer appearance of the medicine. This doesn't change how the medicine will work in your body. The medicine inside is always the same!

The packaging of your medicine can also look different, for example different coloured boxes. ***Do not be alarmed if this is the case.***

Always look for the generic name on the box (this name might be in smaller print). You can also check the label your pharmacist has put on the box, to make sure you have got the right medicine. Your pharmacist will be happy to show you where to look on the box if you get confused.

FAQ: What do I do if I experience problems with my generic medicines?

It is unlikely that you will experience any problems as all medicines have to be made to the same standards as brand-name versions.

Very occasionally, extra ingredients in a medicine may not agree with you. These extra ingredients (called excipients) are not the active medicine. If you do experience this, please speak to your pharmacist who can try to supply you with a different generic medicine that is made by another manufacturer. You can try this one to see if it suits you better.

FAQ: Can all of my medicines be prescribed by their generic name?

In rare cases, it might be best for you to take the brand-name medicine. An example would be a medicine with a special coating that makes the medicine work more slowly in your body.

Your pharmacist and doctor will be aware of medicines that need to be prescribed using brand-names. They will always try to ensure you get the brand-name medicine if this is important. If you are concerned or worried, speak to your pharmacist or doctor.

Always speak to your pharmacist or GP if you have any questions about your medicines!

References
http://patient.info/health/generic-vs-brand-name-medicines
http://www.hpra.ie/docs/default-source/publications-forms/information-leaflets/generic-medicines_web.pdf?sfvrsn=2
http://www.hpft.nhs.uk/_uploads/documents/medicines-formulary/3-generic-pil-for-service-users-and-carers.pdf

Appendix 4.5: Goal setting exercise sheets
(duplicate sheets: copy for patient and copy for pharmacist)

My goals and action plan

Together with your pharmacist, you will agree on things that might help you to take (or use) your medicines.

A **GOAL** is something you would like to achieve

Follow your **ACTION PLAN** to help you reach your goal

If you are not very confident that you could achieve your goal, then your pharmacist will help you set a new goal.
You can discuss with your pharmacist how you got on with your goal at your next appointment.

My general health goal is:

Patient ID:

Appendix 4.5 (cont'd): Goal setting exercise sheets

My medicine goal (What I am going to do)	My action plan (How I will reach my goal)
How confident am I that I can achieve my medicine goal? Not at all confident 0 1 2 3 4 5 6 7 8 9 10 Extremely confident	
What prevents me from achieving my goal?	What would help me achieve my goal?
My NEW medicine goal (What I am going to do)	My NEW action plan (How I will reach my goal)
How confident am I that I can achieve my NEW medicine goal? Not at all confident 0 1 2 3 4 5 6 7 8 9 10 Extremely confident	
Review of goal (your pharmacist will fill this in at your next appointment)	☐ Goal met ☐ Goal not met

Patient ID:

Appendix 4.6: Reminder stickers

Appendix 4.7: GP communication form

Queen's University Belfast

Date:

Dear _____

Re: Feasibility testing of the ID-MAP (IDentification of Medication Adherence Problems) intervention in older adults prescribed polypharmacy in primary care

The following patient, from your practice, has been involved in the above research study being conducted by Queen's University Belfast. Please find below a summary of adherence problems identified and steps taken by the pharmacist to resolve these issues. If necessary, further actions for you to consider are also documented below.

- ☐ Adherence issues identified- **Action is required** *(see below)*
- ☐ Adherence issues identified- No action required/information purposes only *(see below)*
- ☐ No adherence issues identified

Patient name:	Date of Birth:
Patient Address:	Telephone number:
H&C number:	Carer name and telephone number (if applicable):

Summary of adherence problems identified (indicate "N/A" if this section does not apply):

Summary of problems resolved by pharmacy (indicate "N/A" if this section does not apply):

Please consider the following action(s) (indicate "N/A" if this section does not apply):

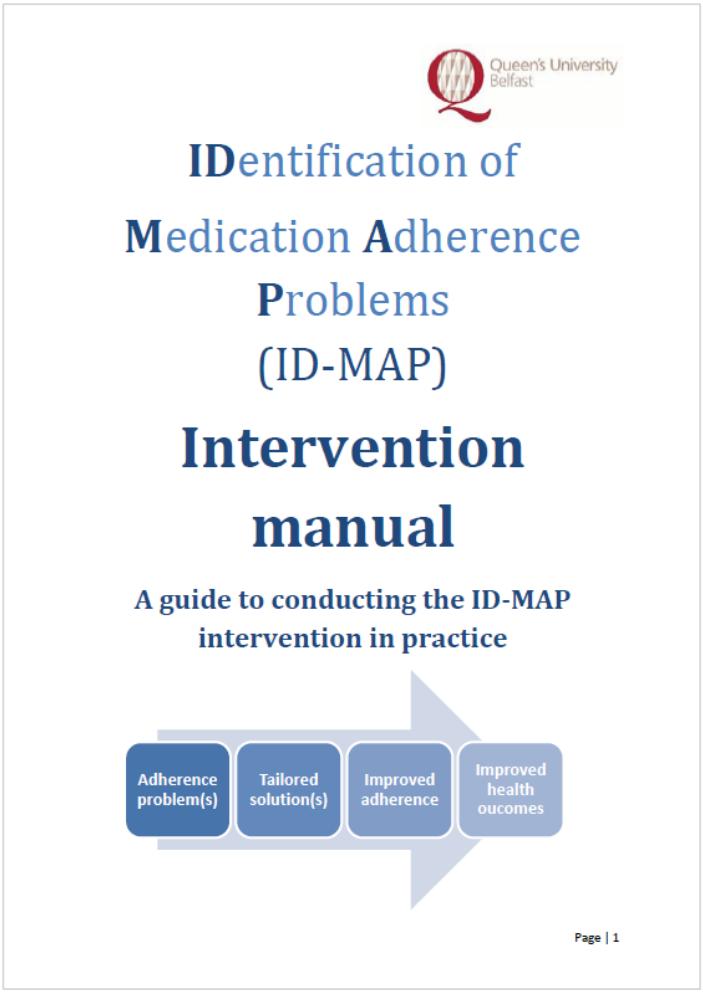
Please do not hesitate to contact me if you have any queries in relation to the information provided above.

Pharmacist Name:

Signature: Date:

Pharmacy stamp

Appendix 4.8: Intervention training manual for community pharmacists



Contents

1. Introduction to the ID-MAP intervention

The population of older adults is continually rising and patients with a diagnosis of two or more chronic conditions are now the norm rather than an exception. It is not uncommon for these older patients to be prescribed four or more regular medications, a concept often referred to as polypharmacy. These medications, which may include a range of formulations (e.g. tablets, patches, inhalers etc.), can sometimes require multiple daily doses. These factors, in combination with the decline in cognitive and physical functioning that occurs with ageing, can make it very difficult for older patients to manage their medications. The term 'adherence' (previously referred to as 'compliance'), is used to describe the medication-taking behavior of individuals as agreed and prescribed by their GP. However, it is estimated that between 25-75% of older adults are non-adherent with their prescribed regimens. Improving adherence in this population group could have a positive impact on patients' overall health, as well as helping to reduce GP visits and hospital admissions. This, in turn, could lead to significant cost savings for the National Health Service (NHS).

There is a range of possible reasons to explain why older patients do not take (or use) their medications as prescribed. For example, they might simply forget, or they may not know exactly how or when they should take/use their medications. Alternatively, they may have difficulty managing or obtaining their medicines. In some cases, patients may intentionally decide not to take (or use) their medications as prescribed by their GP (e.g. by altering the dose, timing or stopping the medication completely). It is also possible that a combination of these factors may contribute to patient non-adherence. A range of possible solutions for improving adherence need to be explored to ensure patients get the most from their medications. These solutions should be tailored to the patient's individual reason(s) for not taking (or using) their medicines as prescribed.

Like other health behaviours, such as exercise or healthy eating, adherence is a complex behaviour and can be difficult change. We have developed this ID-MAP intervention based on research findings. This included discussions with older adults from across Northern Ireland in relation to their medication-taking behaviour. The overall aim of the intervention is to improve the adherence of older adults who are taking (or using) multiple medications and demonstrate the effect that this might have on their overall health and use of healthcare services.

This intervention will be targeted at patients who are failing to take/use their medications as prescribed (i.e. non-adherers). We have developed a tool that will help you explore the key adherence problems faced by each individual patient (ID-MAP Tool). This tool will also assist you in the selection of the most appropriate adherence solutions and guide you in tailoring these to the individual patient.

This manual is for training purposes. It will supplement the face-to-face training session that you should have received. The manual gives you a step-by-step guide on how to deliver the intervention in practice. It provides information on how to identify suitable patients, explore adherence problems, deliver adherence solutions and review the patient's progress. Please contact the research team if you have any further questions.

2. Study stages

- Patient screening for eligibility (page 5-7)
- Patient recruitment into the study (page 8-9)
- Preparation for Appointment 1 (page 10)
- **Appointment 1**: Identify adherence problems (page 10-13)
- Preparation for Appointment 2 (page 14)
- **Appointment 2**: Deliver adherence solutions (page 14-23)
- **Appointment 3**: Review of adherence solutions (page 24-25)

3. Documentation required for eligibility screening and recruitment (Patient Pack contents)

To be eligible to take part in this study, patients must undergo an eligibility screening process prior to being recruited. All of the documentation to be completed as part of screening and recruitment has been pre-printed and is available in individual patient packs for your convenience.

Each Patient Pack will contain:

- ✓ **An Eligibility Screening Form** (Appendix 1)
- ✓ **Consent Form 1** (for questionnaire completion) (Appendix 2)
- ✓ **An Eligibility Screening Questionnaire and scoring instructions**(Appendix 3)
- ✓ **A patient study information sheet** (Appendix 4)
- ✓ **Consent Form 2** (for research study participation) (Appendix 5)
- ✓ **A Recruitment/retention Form** (Appendix 6)
- ✓ **Pre-printed patient ID stickers** (to place on documentation as needed)

The next two sections of this manual provide instructions on how to screen patients for their eligibility (Section 4) and recruit them into the study (Section 5).

4. Screening patients for eligibility

To be eligible to participate in this research study, patients must meet specific criteria. These criteria are detailed below in Table 1.

Table 1: Eligibility criteria

Patients should meet the following criteria:	Source of information	Time of screening
65 years or older	Patient Medication Record (PMR) and/or prescription	Before patient presents to the pharmacy (for prescription collection) or when they hand in a prescription to be dispensed
Prescribed four or more regular medications (excluding OTC and when required medications) *(NOTE: Patients prescribed medications for dementia are not eligible)**	PMR and/or prescription	Before patient presents to the pharmacy (for prescription collection) or when they hand in a prescription to be dispensed
At least 6 months' PMR data available from the date of screening	PMR	Before patient presents to the pharmacy (for prescription collection) or when they hand in a prescription to be dispensed
Attends study site pharmacy only for regular medications	Ask patient	Prior to dispensing or when the patient presents to collect their prescription
Lives in their own home	Ask patient	Prior to dispensing or when the patient presents to collect their prescription
Identified adherence problem(s)	Eligibility Screening Questionnaire**	Prior to dispensing or when the patient presents to collect their prescription *(can be self-completed whilst they wait or in the consultation room)*

Patients who are prescribed **acetylcholinesterase inhibitors (donepezil, galantamine or rivastigmine) or an **NMDA receptor antagonist** (memantine) for the treatment of dementia are **NOT eligible** to participate in this research study. This intervention has not been designed to account for the additional challenges faced by this patient group.*

*** Instructions on how to complete/score the Eligibility Screening Questionnaire can be found on page 7 of this manual.*

Use the **Eligibility Screening Form** (Appendix 1) to record details of this screening process. A copy of this form will be available in each Patient Pack. The process of screening patients is illustrated in a flow chart on Page 6 of this manual.

Appendix 4.8 (cont'd): Intervention training manual for community pharmacists

Flow chart of the eligibility screening process

Screen prescriptions and Patient Medication Records (PMRs) for potential participants.
Is the patient 65 years or older and prescribed four or more regular medicines*? Do you have access to at least 6 months' dispensing data on the PMR?
**Excluding when required and over-the-counter medicines*

YES → **Is the patient taking memantine, donepezil, galantamine or rivastigmine** (for the treatment of dementia)?
NO → Not eligible

YES → Approach patient if they are waiting in the pharmacy or when they call to collect their prescription. Inform patient about the research study (testing of a new service to help patients who are prescribed several medicines). If interested: **Is the patient currently living in their own home and do they only attend the study pharmacy to collect regular medications?**
YES → Not eligible

NO → Invite patient to complete an Eligibility Screening Questionnaire (in the pharmacy). Explain purpose of the questionnaire (to check whether they might benefit from the new service. If so, they will be invited to take part in the study but will be given time to think about this.) If interested: **Is the patient able and happy to provide written informed consent for the questionnaire completion?**
NO → Not eligible

YES → Ask patient to read and complete Consent Form 1 before completing the Eligibility Screening Questionnaire. Score this questionnaire while the patient waits (see page 7). This score will relate to low, medium or high adherence.
Does the patient have medium or low adherence?
NO → Not eligible (High adherence)

YES → **Eligible to take part: proceed with recruitment.**

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How to complete the Eligibility Screening Questionnaire

- **You should explain the purpose of the questionnaire to the patient** i.e. to help to identify any problems they may be experiencing with their medications and whether they might benefit from a new service. If they would benefit, then they will be invited to take part in a research study being conducted by QUB.
- The patient must provide **written consent** indicating they are happy to complete the questionnaire and allow feedback on the questionnaire to be provided to their GP and the research team. The patient will also be providing consent to allow you to obtain information from their GP on the medicines they are prescribed. However, this will only be done in the event that they verbally agree to part in the study when you telephone them (see page 8 & 9 of this manual).
- A copy of **Consent Form 1** (Appendix 2) can be found in each Patient Pack.
- The Eligibility Screening Questionnaire (Appendix 3) will help you identify if the patient is eligible for the intervention (i.e. meets 'identified adherence problem(s)' eligibility criterion). See Table 2 below.

Table 2: Eligibility Screening Questionnaire

Question types	Completed by	Location	Completion time	How to score
8 questions about the patient's adherence to **all** of their prescribed medicines e.g. "Do you sometimes forget to take your medicines?"	Patient	In pharmacy	5 minutes	**Scored out of 8** (Appendix 3). - **Low** adherence (score <6) - **Medium** adherence (score between 6 and <8) - **High** adherence (score of 8) adherence. *(A scoring sheet with instructions will be included in each Patient Pack)*

IMPORTANT: Ensure all blue boxes on the screening checklist* are ticked before proceeding to recruitment.

**This checklist can be found on the Eligibility Screening Form in the Patient Pack.*

Screening checklist
IMPORTANT: All blue boxes must be ticked before proceeding to the next stage (recruitment)

Patient meets the following criteria:	Yes	No
- 65 years or older		
- Prescribed four or more regular medications (excluding OTC and when required)		
- At least six months' PMR data available from date of screening		
- Attends study site pharmacy only for regular medications		
- Lives in their own home		
- Patient is NOT prescribed donepezil, rivastigmine, galantamine or memantine		
- Patient is able to provide written informed consent		
Eligibility Screening Questionnaire has been completed		
- Adherence problem(s) identified		

If the patient is not eligible, please detail the reasons on the Eligibility Screening Form.

If a patient, who has been deemed ineligible for the research study, expresses concerns about their medications, use your professional judgement to decide on the best course of action. You will need to inform the patient that they are not formally part of the research study but you are happy to answer any questions or concerns they have in relation to their medications. Make notes on any recommended actions in the notes section provided at the bottom of the Eligibility Screening Form.

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Appendix 4.8 (cont'd): Intervention training manual for community pharmacists

5. Patient recruitment

If a patient meets all of the screening criteria in Table 1 (page 5 of this manual), they can be invited to take part in the research study. The flow chart below illustrates the recruitment process.

Flow chart of the recruitment process

Invite eligible patients to take part in the research study.
Is the patient interested in finding out more about the study?

YES

Give the patient a brief overview of what will be required of them (see blue box below). Provide a study information sheet and Consent Form 2 for the patient to read at home. Copies of these forms can be found in each Patient Pack. **Ensure you have documented the patient's telephone number** on the Eligibility Screening Form.

Telephone the patient after one week.
Does the patient wish to take part?

YES

Document that **verbal consent** has been obtained on the Recruitment/retention Form. Arrange an initial appointment and ask the patient to bring the consent form along with them to this appointment. **You will complete Consent Form 2 together at Appointment 1.**

They should also bring along all the medicines they take (or use) (including those dispensed by the hospital). If they have a medication list they should bring this too.

NO

Thank the patient for their time and inform them that their medical care will not be affected by their decision.

NO

The patient will be required to:

- Attend three appointments at the pharmacy (30-40 minutes each). The aim is to look at how they are currently taking (or using) their medicines, any problems they face and what might help them.
- Take part in a telephone interview with the researcher after they attend all three appointments. The aim is to find out what they thought about the appointments.
- Complete a postal questionnaire three months after the appointments. This will include questions about their medicines and general health and should only take 10-15 minutes to complete.

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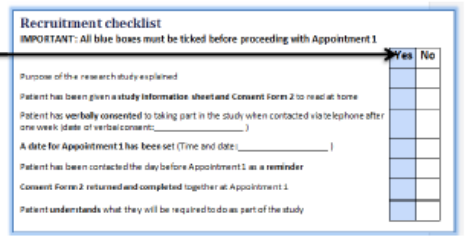
The recruitment process can be documented on the Recruitment/retention Form (Appendix 6). This form can be found in each Patient Pack.

IMPORTANT: Ensure all blue boxes on the recruitment checklist* are ticked before proceeding with Appointment 1.

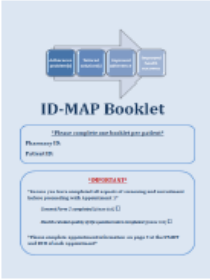
**This checklist can be found on the Recruitment/retention Form in the Patient Pack.*


Recruitment checklist
IMPORTANT: All blue boxes must be ticked before proceeding with Appointment 1

	Yes	No
Purpose of the research study explained		
Patient has been given a study information sheet and Consent Form 2 to read at home		
Patient has verbally consented to taking part in the study when contacted via telephone after one week (date of verbal consent:_____)		
A date for Appointment 1 has been set (Time and date:_____)		
Patient has been contacted the day before Appointment 1 as a reminder		
Consent Form 2 returned and completed together at Appointment 1		
Patient understands what they will be required to do as part of the study		

If the patient decides not to take part or drops out at any stage, please detail the reasons why (if known) on the Recruitment/retention Form.

6. Delivery of the ID-MAP intervention



- A separate ID-MAP Booklet will be used for each patient.
- This booklet will guide the ***three appointments*** in this intervention (each appointment should last approximately 30-40 minutes).
- The booklet also acts as a written record of the adherence problems identified and solutions recommended during the appointments.
- There are four main sections to the ID-MAP booklet. See outline below. **Please refer to the relevant pages in this manual for more details on how to complete each section.**

Section 1	• **Medication Details:** Page 11 of this manual	Before and during Appointment 1
Section 2	• **ID-MAP tool:** Pages 12-13 of this manual	During Appointment 1 and before Appointment 2
Section 3	• **Solution Summary:** Page 14 of this manual	Before and during Appointment 2
Section 4	• **Review of solutions/feedback:** Page 24 of this manual	During Appointment 3

IMPORTANT: At the end of each appointment there is a checklist—please ensure you complete this before concluding the appointment (see pages 8, 12 & 14 of the ID-MAP Booklet). All blue boxes should be ticked.

Fill in this checklist at the end of Appointment 1

ALL blue boxes MUST be ticked. White boxes should be ticked if applicable.

- **Section 1**- Medication Details section has been completed and confirmed as accurate
- **Section 2**- ID-MAP Tool has been completed (at least one problem identified)
- Urgent adherence problems have been resolved and GP contacted (if necessary)
- **Appointment 2**- Date and time arranged _____

- The timeline below illustrates when each of the three appointments should take place.

6.1. Appointment 1

IMPORTANT: To make the best use of time in Appointment 1, you should **prepare the medication list** (Section 1 of ID-MAP Booklet) **in advance** using the PMR. If you notice any discrepancies at this stage, contact the patient's GP surgery to confirm the list.

- At the start of Appointment 1, you should go through the study information sheet with the patient and confirm that they understand what they will be asked to do as part of the study.
- The patient should then read (or you can read to them) the statements on Consent Form 2. They should INITIAL each of the boxes to indicate that they agree with each statement. You should both then sign and date the consent form.
- **At this stage, ensure you have fully completed the Recruitment/retention Form.**
- Once the recruitment process is finalised, ask the patient to complete the health-related quality of life questionnaire (Appendix 7) before proceeding with the intervention. Explain that this questionnaire is about their general health and how they are feeling today (see Table 3 below).

Table 3: Health-related quality of life questionnaire

Question types	Completed by	Location	Completion time	How to score
5 sections about their quality of life (three statements to choose from) and a scale of 0 to 100 for the patient to indicate how good their health is today	Patient	In pharmacy (when patient presents for Appointment 1)	5-10 minutes	No scoring required *(Research team use only)*

Appointment 1: How to complete Section 1 of the ID-MAP Booklet: Medication Details

WHEN — **Complete BEFORE AND DURING Appointment 1**

Blue parts in Section 1 should be completed (as much as possible using the PMR) before Appointment 1.

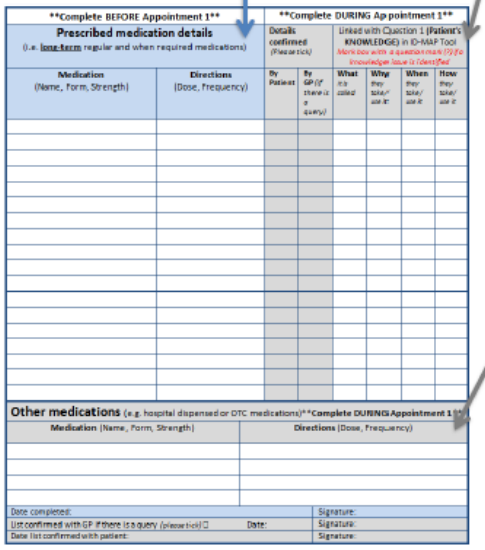
This includes details of prescribed medications. If you have any queries in relation to the medication list, please contact the GP surgery in advance of Appointment 1. Otherwise, this list can be confirmed with the patient during Appointment 1.

Grey parts of this section should be completed during Appointment 1.

Part of this section will be used in conjunction with Question 1* of the ID-MAP Tool in Section 2 (*see page 12 of this manual*).

**This question is about the patient's knowledge of each of the listed medications.*

Make sure you are familiar with the layout of both of these sections.



During Appointment 1, you should ask the patient about any medications that they purchase from the pharmacy, local garage, supermarket etc. (i.e. OTC medications)

OR

medications that they receive from the hospital pharmacy (as you may not have a record of these on the PMR).

Appointment 1: How to complete Section 2 of the ID-MAP Booklet: ID-MAP Tool

WHEN — **Fill in relevant parts during DURING Appointment 1**

Section 2 is made up of seven open-style questions that will be asked during Appointment 1. This will help you **identify the nature of the adherence problems** faced by the patient. Prompts can be used to gather further information.

Question 1, which is about the patient's knowledge of all their regular medications, is linked with the pre-prepared medication list in Section 1 (*see page 11 of this manual*).
For each prescribed medication in the list ask the WHAT, WHY, WHEN and HOW components of this first question (see below). If any knowledge issues are identified, a question mark should be placed in the relevant box in Section 1 (this will indicate that there is an issue in relation to WHAT, WHEN, WHY or HOW).
IMPORTANT: PLEASE CONFIRM THE MEDICATION LIST IN SECTION 1 IS ACCURATE USING QUESTION 1!

Tick the YES box in the red column for any statements (i.e. adherence problems) that are relevant to the patient.

Tick the NO box if it is not a problem for the patient.

Make notes of any adherence problems (e.g. what medication, specific details about the problem).*

**This will help you when it comes to tailoring adherence solutions at Appointment 2.*

Question 1 (Patient's Knowledge) **Use in conjunction with medication list (Section 1) **

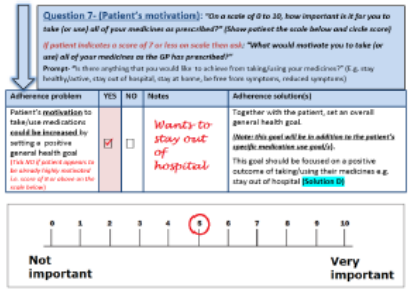
- What: "Can you tell me WHAT medications you are currently taking (or using)?" (Confirm each medication in list)
- Why: "Do you know WHY you are taking/using this medication?" (Go through each medication in list)
- When: "WHEN do you take/use this medication?" (Go through each medication in list)
- How: "Do you know HOW to take this medication/use this device?" (Ask as appropriate for each medication in the list)

Adherence problem	YES	NO	Notes	Adherence solution(s)
Lacks knowledge of **WHAT** medications they are taking/using	☐	☐		1. Where knowledge gaps are identified, explain what each medication is and why they need to take/use it 2. Emphasise this by directing the patient to the back page of their medication diary (Solution A)
Lacks knowledge of **WHY** they are taking/using their medication(s)	☐	☐		
Lacks knowledge of **WHEN** to take/use medication(s) or incorrect timing	☐	☐		1. Give verbal feedback on what they are doing incorrectly 2. Explain importance of taking/using medications at correct time/following any special instructions/ correct dose 3. Emphasise this by directing the patient to the back page of their medication diary (Solution A)
Taking/using incorrect dose or other medication error(s)	☐	☐		
Lack of or incorrect knowledge on **HOW** to take their medication(s)/ use devices	☐	☐		1. Give verbal feedback on what they are doing incorrectly 2. Emphasise importance of correct use and if possible, write this in the special instructions section on the back page of their medication diary (Solution A)

Recommended adherence solutions are in the right hand column. ***Ignore this column during Appointment 1.****

**Following Appointment 1, you will go back through the ID-MAP Tool in preparation for Appointment 2. The information in this column and the notes column will be used to prepare adherence solutions and make planning notes (see Section 3 on page 14 & 15 of this manual)*

Questions 2-7 in the ID-MAP Tool aim to identify any adherence problems related to routine or organisational barriers (Q2), practical barriers (Q3), a lack of social support (Q4), forgetfulness (Q5), intentional non-adherence (Q6) or a lack of motivation (Q7). Question 7 is illustrated below as an example of how a question should be completed.



Please familiarise yourself with the other questions in the ID-MAP Tool (pages 4-8 of ID-MAP Booklet).

IMPORTANT: If any ***urgent medication problems*** are identified during Appointment 1, you should attempt to resolve these immediately (instead of waiting until Appointment 2) and contact the GP if necessary.

Appointment 1: Summary of activities

Preparation for Appointment 1
Prepare medication list in advance of Appointment 1 using the PMR.

Arrival, welcome and introduction
- Welcome patient on arrival and invite them into the consultation room.
- Go through Consent Form 2 with the patient and check they understand what will be expected of them. You should now both sign and date the consent form.
- Explain purpose of Appointment 1.
- Check if the patient has brought their medications with them (or a medication list).

Adherence assessment: Identify adherence problems
- Ask all seven questions in the ID-MAP Tool to identify specific adherence problems.
- Use Question 1 to confirm that the pre-prepared medication list is accurate.

End of Appointment 1
- Complete end of Appointment 1 checklist (page 8 of ID-MAP Booklet).
- Schedule Appointment 2. This should take place in 1-2 weeks.*

* If necessary, resolve urgent issues immediately.

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6.2. Appointment 2

Appointment 2: How to complete Section 3 of the ID-MAP Booklet: Solution Summary

WHEN | **BEFORE and DURING Appointment 2**

In preparation for Appointment 2, you will need to go back through the ID-MAP Tool (**Section 2 of ID-MAP Booklet**) and map any adherence problems identified (ticks in red YES column) across to the corresponding solutions in the right hand column. See examples on page 12 & 13 of this manual.

There are four types of adherence solutions in this intervention; each is colour coded as follows:

Solution A- Patient medication diary*
Solution B- Practical, reminder and social support actions
Solution C- Discussion around medication concerns
Solution D- Goals and action plan sheet*

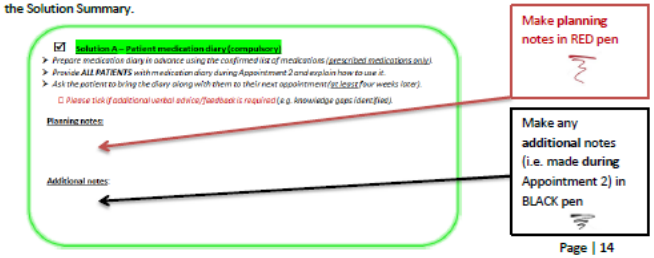
***IMPORTANT: ALL PATIENTS will receive Solution A and Solution D** regardless of their answers to questions in the ID-MAP Tool (**Section 2**). However, the questions in this tool will help you decide exactly how to tailor these compulsory solutions to the individual patient's needs.
Prepare solutions (e.g. medication diary) as far as possible **before** Appointment 2

You will need to complete the following on the Solution Summary on pages 9-11 of the ID-MAP Booklet:

- You should make some brief summary notes on the key adherence problems discussed during Appointment 1. This will allow you to quickly **recap** on these at the start of Appointment 2.
- Solutions A and D will be pre-ticked on the Solution Summary as these will be delivered to ALL patients.
- If additional Solutions B and/or C are recommended, tick the relevant box(es).
- Each solution has a colour coded box (see example of Solution A below).
- You should make planning notes in the space provided for each adherence solution in advance of Appointment 2 (in RED pen).
- You can then add additional notes during Appointment 2 (in BLACK pen).

Examples of planning notes: *knowledge gaps to address as part of Solution A or ideas for the types of goals that the patient could set as part of Solution D.*

The image below shows Solution A as an example. Please familiarise yourself with the other solutions on the Solution Summary.



Appointment 2: How to deliver tailored adherence solutions

Once you have made planning notes on the Solution Summary pages (**Section 3 of ID-MAP Booklet**) and prepared the solutions, you are ready to deliver these at Appointment 2.

Detailed guides on how to deliver each solution can be found on pages 16-22 of this manual—please familiarise yourself with these solutions as much as possible.

Solution A	**Patient Medication diary:** this daily diary will help the patient keep track of their long-term medications. Daily monitoring will exclude over-the-counter (OTC) medications and short-term medications e.g. antibiotics. ***See guide to Solution A for instructions on how to do this (pages 16-17 of manual).***
Additional Solution B and/or Solution C	The questions in the ID-MAP Tool **(Section 2 of ID-MAP Booklet)** will help you identify if any additional solutions (B and/or C) are required. For example, someone who routinely forgets to take/use their medication could benefit from a reminder sticker (Solution B). Alternatively, a patient who thinks they don't need to take their blood pressure medication would benefit more from a discussion around the possible consequences of non-adherence using the 'Voicing concerns about your medicines' leaflet (Solution C). ***See guides to Solution B and Solution C for more information (pages 18-20 of manual).***
Solution D	A Goals and action plan sheet will include what the patient wants to achieve in terms of taking (or using) their medicines (i.e. their goal/s) and what they will do to help them to achieve their goal/s (i.e. their action plan). ***See guide to Solution D for more information on how to set goals and action plans (pages 21-22 of manual).***

Appointment 2: Solutions Folder contents

This is a large expandable folder that includes everything you will need to deliver adherence solutions. Laminated copies of Solution guides (pages 16-22 of this manual) will be included in the folder for quick reference. Plastic folders to give to patients will also be provided for them to store materials in.

Solution A - Patient medication diary Word templates (electronic and hard copies) (Appendix 8)
- Blank A4 spiral bound medication diaries
- Blank A4 sticker sheets for printing/writing on

Solution B - Reminder stickers (Appendix 9)

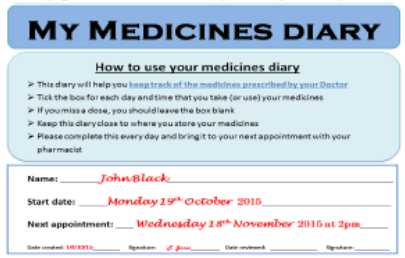
Solution C - Pre-printed 'Voicing concerns about your medicines' leaflets (Appendix 10)
- Pre-printed Generic Medicines Fact Sheets (Appendix 11)

Solution D - Goals and action plan (duplicate) sheets (Appendix 12)

Guide to Solution A - Patient medication diary

STEP ONE: Preparation

- Fill in the front page of the medication diary (see example below).



MY MEDICINES DIARY

How to use your medicines diary

- This diary will help you keep track of the medicines prescribed by your Doctor
- Tick the box for each day and time that you take (or use) your medicines
- If you miss a dose, you should leave the box blank
- Keep this diary close to where you store your medicines
- Please complete this every day and bring it to your next appointment with your pharmacist

Name: John Black

Start date: Monday 19th October 2015

Next appointment: Wednesday 18th November 2015 at 2pm

- All long-term medications will be monitored daily by the patient using this diary.
- Some patients may be prescribed 10 or more medications. To save time, a Word template (provided on a USB stick in the Solutions Folder) can be used to generate a list of the patient's long-term medications.
- Alternatively, the list can be handwritten if you prefer (hard copies will also be available in the Solutions Folder).
- The list should include regular and when required medications prescribed for long-term use.
- It **should not** include OTC or medications prescribed for short-term use e.g. antibiotics.
- Fill in the Word template including the medicine name, strength, form, details of when and how to take (or use) the medicine, any special instructions and reason why the patient needs to take/use it. **See example below.**

Medicine name and strength	Form	When and how much to take (or use)				Special instructions	Why I need to take (or use) this medicine
		Morning	Lunch	Tea-time	Bed-time		
Simvastatin 20mg	Tablets				One tablet		Cholesterol
Amlodipine 5mg	Tablets	One tablet					Blood pressure
Digoxin 125mcg	Tablets	One tablet					For heart
Indapamide 2.5mg	Tablets	One tablet					Blood pressure
Metformin 500mg	Tablets	One tablet	One tablet	One tablet		With food	For diabetes
Gliclazide 80mg	Tablets	One tablet					For diabetes
Aspirin E/C 75mg	Tablets	One tablet				With food	Prevent heart attack

- The list should be printed (or written) on **A4 STICKER paper** (provided in the Solutions Folder).
- The list should then be cut to size and then placed on the inner back page of the medication diary in the space provided (see next page).
- ***You should prepare this list in advance of Appointment 2 using the confirmed list of prescribed medications documented in Section 1 of the ID-MAP Booklet.***

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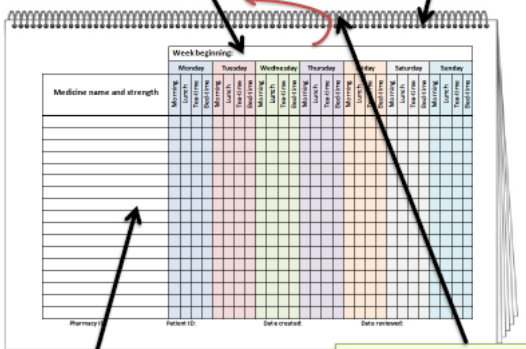
STEP TWO: How to use the medication diary

- The patient should monitor their daily medication use for a **minimum of FOUR weeks** i.e. until Appointment 3.
- Note the date in the 'Week beginning' section on each page of the diary that the patient will fill in.
- Advise the patient to tick the box for each medicine they take (or use) and to indicate the time of day (morning, lunch, tea-time or bed-time).
- If they miss a dose, advise them to leave the relevant box blank.
- *It is important to emphasise that they are not being tested and that it is OK to leave boxes blank if they decide not to take (or use) the medicine that day or forget to take it.*

Note the week beginning date here for each week. Advise the patient to start the diary the day after their appointment. You can circle this day for them.
Note: the start date may not be a Monday and so you may need to fill in five weekly sheets, as the patient **must use the diary for a minimum of four weeks**.

This is an A4 spiral bound medication diary (it can be placed on a bench or hung up on the wall like a calendar).



The back page is made of cardboard. This is where you will place the list of medications (name, strength etc.) that you have printed/written on A4 sticker paper in STEP ONE.

Note: This section of the diary doesn't flip over; therefore the medication list only needs to be printed out once.

Weekly diary sheets can be flipped over at the end of each week.

If the patient flips to the very back page, they will be able to see directions for use, why they are taking/using the medication etc. *You should use this as a basis for discussion if any knowledge gaps were identified.*

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Guide to Solution B – Practical, reminder and social support actions

More suitable packaging/ administration aids 	**Difficulties opening Child Resistant Caps** (CRCs)	Supply medication in non-CRCs.
	Specialised administration aids are required (e.g. eye drop dispensers, inhaler aids)	Try to source these from the manufacturer for free or check if they are available on prescription. If not, the patient can be advised that they are available to purchase or referred to GP for an alternative Fill in the GP communication form.
	Difficulties opening blistered medication packaging	Provide a different generic brand or pop medication into a bottle as an alternative.
	Problem cannot be simply resolved	Refer to GP **OR** make arrangements for the provision of a Monitored Dosage System (MDS) if this is the only suitable option.
Large print labels/ clearer wording	• Use a minimum font size of 12pt (or equivalent) and ensure instruction wording is clear.	
Link medication use to other routines	If the patient lacks a routine or their current routine isn't working, suggest that they link medication use to other daily routines e.g. • Meal times • Specific daily TV programme • Brushing teeth/evening routine 	
Storage in a visually prominent place	Advise the patient to store their medications in a place where they can be easily seen e.g. • Kitchen bench • Mantel piece • Bathroom shelf* ***Note: if children live with them or visit, then this storage place will need to be out of their reach and sight. In this case, a reminder sticker might be more appropriate (see below).***	
Reminder stickers	For suitable patients, a reminder sticker could be placed on: • A cupboard door where the medicines are stored • The fridge door • The bathroom mirror • Beside front door (as a reminder to take/bring medicines when going out) 	
Social support plan	**Support from family or friends**	• Could ask their spouse to place the medication out for them in the mornings or simply ask, "Have you taken your medicines?" • A friend or other family member could give them a daily telephone call or less frequent contact e.g. reminder to order prescriptions.
	Support from healthcare professionals	• The pharmacy could support the patient through collecting prescriptions, delivering etc. • Could offer support through discussions about their concerns. • Inform GP using the GP communication form if deemed necessary.

IMPORTANT: When required, place a note on the PMR as a reminder for pharmacy staff.

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Guide to Solution C- Discussion around medication concerns

This solution is mainly aimed at those older adults who miss taking (or using) their medicines because they think or believe one or more of the following (or have other misconceptions about their medicines which are not listed):

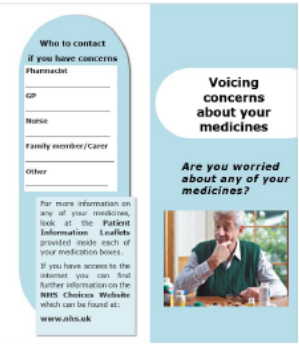
- Think the medicine doesn't work
- Think it could cause them harm or is addictive (where this is not known to be the case)
- They are worried about side effects or long-term effects
- They are unaware of the consequences of non-adherence
- They think missing a few days/doses of medicines is acceptable now and again
- They think some medicines are less important than others
- They believe generic medicines are less effective than branded medicines

There are two leaflets available as part of this solution:

1. ***'Voicing concerns about your medicines' leaflet** (main leaflet)*
   This leaflet contains a number of different sections based around talking to healthcare professionals about any concerns the patient may have about their medications. It recommends that the patient should inform their GP or pharmacist if they plan to stop taking (or using) a medicine. It also aims to emphasise that failing to take/use medicines as prescribed could have negative consequences on their health.
2. ***Generic medicines fact sheet** (additional leaflet)*
   This leaflet contains information on generic and brand-name medicines. It includes frequently asked questions (FAQ) about generic medicines.

STEP ONE: Discuss beliefs/concerns using leaflet(s) as a visual aid

- **Go through the 'Voicing concerns about your medicines' leaflet** with the patient, focusing on any sections that are particularly relevant to them.
- Use this leaflet as a basis for discussing concerns (such as side effects) and tailor your discussion to the patient's own medications.
- **Emphasise the consequences of non-adherence** in relation to their own medications e.g. higher risk of heart attacks/stroke if they do not to take BP medications, potential worsening of asthma symptoms if they do not use steroid inhaler daily.



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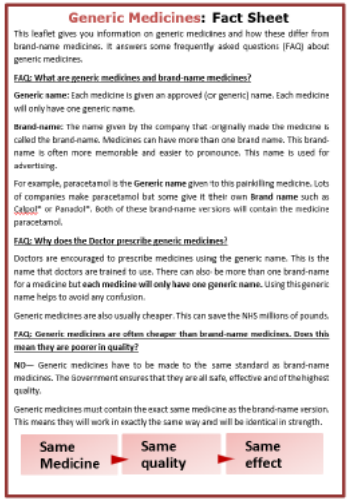
- If the patient is particularly concerned or confused about generic medications, then also **provide 'Generic Medicines Fact Sheet'** and discuss this with the patient (page 1 of 2 is shown below).



Generic Medicines: Fact Sheet

This leaflet gives you information on generic medicines and how these differ from brand-name medicines. It answers some frequently asked questions (FAQ) about generic medicines.

FAQ: What are generic medicines and brand-name medicines?

Generic name: Each medicine is given an approved (or generic) name. Each medicine will only have one generic name.

Brand-name: The name given by the company that originally made the medicine is called the brand-name. Medicines can have more than one brand name. This brand-name is often more memorable and easier to pronounce. This name is used for advertising.

For example, paracetamol is the **Generic name** given to this painkilling medicine. Lots of companies make paracetamol but some give it their own **Brand name** such as Calpol® or Panadol®. Both of these brand-name versions will contain the medicine paracetamol.

FAQ: Why does the Doctor prescribe generic medicines?

Doctors are encouraged to prescribe medicines using the generic name. This is the name that doctors are trained to use. There can also be more than one brand-name for a medicine but **each medicine will only have one generic name.** Using this generic name helps to avoid any confusion.

Generic medicines are also usually cheaper. This can save the NHS millions of pounds.

FAQ: Generic medicines are often cheaper than brand-name medicines. Does this mean they are poorer in quality?

NO— Generic medicines have to be made to the same standard as brand-name medicines. The Government ensures that they are all safe, effective and of the highest quality.

Generic medicines must contain the exact same medicine as the brand-name version. This means they will work in exactly the same way and will be identical in strength.

Same Medicine ► Same quality ► Same effect

STEP TWO: Discuss contact or "go to" options

- **Fill in the 'Who to contact if you have concerns' section on the back of the 'Voicing concerns about your medicines' leaflet.**
- Write your own name in the blank 'Pharmacist' space.
- The patient may prefer to contact their own GP, nurse or another healthcare professional. You can write their names in the relevant spaces also.
- Some patients may prefer to contact a carer or family member initially, for example someone who may be able to answer simple questions or help them get in touch with a healthcare professional.
- *Note: You only need to fill in the relevant spaces—some spaces may be left blank.*
- If the patient has access to the internet, or has a family member who does, then refer them to the NHS choices website. They can use this website as a reliable resource to look up additional information on any of their conditions or medicines. An alternative website is patient.co.uk.
- You can also make use of these websites, to print off patient-friendly advice on their specific conditions/medications if required.

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Guide to Solution D – Goals and action plan sheet

Setting goals and developing an action plan, together with the patient, is a good way of getting them to focus on their behaviour. There are three steps required to deliver this solution— these are individually outlined below.

A Goals and action plan sheet will be used to document the information discussed during Appointment 2. This will be a duplicate sheet; the top copy should be given to the patient and the ***bottom copy retained as a record***.

STEP ONE: Set a positive general health goal if required

Based on the patient's answer to Question 7 in the ID-MAP Tool (what might motivate them to take/use their medications), set a general health goal if this is required. This should be something they would like to happen as a result of taking (or using) their medicines correctly—**this is their motivation**. If the patient appears to be already highly motivated, then this general health goal will not be necessary (indicate this on the goals and action plan sheet with *"N/A* or *"Not applicable"* and explain to the patient that this section isn't relevant to them).

Examples of general health goals:

- To improve my overall health/to stay well and in good health
- To improve my asthma/pain symptoms
- To stay independent/in my own home/out of hospital

Fill in the general health goal box on the goals and action plan sheet if required (see example below). Ensure this is written in simple terms, avoiding any medical jargon.

My general health goal is: *Example: To see an improvement in my asthma symptoms*

STEP TWO: Set medication use goal(s)

Every patient who is part of the study has been deemed to be non-adherent in some aspect of their medication use and so ***every patient should set at least one medication use goal.*** You should guide the patient in setting goal(s) and prompt them where needed. Medication use goal(s)* should meet the SMART goals criteria, outlined in the blue box.

A maximum of two medication use goals can be set.

Examples of medication use goals:

- I will take my blood pressure medication every day
- I will take my insulin every night
- I will take my simvastatin at night instead of the morning
- I will take my water tablet when I go out for the day

Fill in the "My medicine goal" section on the goals and action plan sheet. (See example below)

My medicine goal (What I am going to do)	My action plan (How I will reach my goal)
Remember to take all of my medicines every day	

SMART goals

Specific- It should be simple and very clear

Measurable- the patient should know how to reach it

Achievable- It should not be too difficult

Relevant- It should be important to them

Timely- It should have a completion date i.e. by Appointment 3

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STEP THREE: Develop an action plan

The action plan outlines the exact steps that the patient will take to help them achieve their goal(s). This action pln should be directly linked to the specific medication use goal(s) set in STEP TWO.

Using an **IF-THEN approach** is a good way of outlining this plan to the patient. This will take the form of:
IF X happens, **THEN** I will do Y (X can be a time, place or situation/event and Y is the action that will be taken).

This plan can detail:

(a) **When** it needs to be done (e.g. every night)
(b) **Where** it needs to be done (e.g. at front door before they leave the house)
(c) **Who** is going to help them (if applicable) (e.g. wife to set medication out on breakfast tray)

Examples of IF-THEN action plans:

- **IF** it is a Sunday night, **THEN** I will set out a weekly supply of medication
- **IF** I am concerned about taking my medication, **THEN** I will contact someone listed on the back of my leaflet
- **IF** it is 7pm, **THEN** I will set out tomorrow's medication and place them on the kitchen counter top
- **IF** I see the reminder sticker on my bathroom mirror, **THEN** I will take my cholesterol tablet
- **IF** my wife reminds me, **THEN** I will take my medicines

The action plan can include details from other adherence solutions e.g. reminder stickers (Solution B), medication diary (Solution A)

Fill in the "My action plan" section on the goals and action plan sheet. (See example below)

My medicine goal (What I am going to do)	My action plan (How I will reach my goal)
Remember to take all of my medicines every day	*IF I see my medicines sitting on the kitchen bench, THEN I will take them*

The patient's confidence at following the action plan (put in place to meet their medication use goal) should be assessed (for each goal) using the confidence rating scale, where 0 indicates they have no confidence and 10 indicates they are extremely confident (see example below).

If the patient **scores 7 or less, then the goal is too difficult** (i.e. it doesn't reach the Achievable criteria of a SMART goal) and a new goal should be set.

Find out what prevents the patient meeting the original goal and what might help. The goal might need re-adjusted slightly or changed completely. Re-assess the patient's confidence for meeting their NEW goal.

How confident am I that I can achieve my medicine goal?
Not at all confident 0 1 2 3 4 **5** 6 7 8 9 10 Extremely confident

What prevents me from achieving my goal?	What would help me achieve my goal?
I forget to bring my medicines when I go out for the day	*Something to remind me when I go out for the day*
My NEW medicine goal (What I am going to do)	**My NEW action plan** (How I will reach my goal)
Remember to bring and take my medicines when I am out for the day	*If I see my reminder sticker beside the front door when I am going out, then I will put my medicines in my bag*

How confident am I that I can achieve my NEW medicine goal?
Not at all confident 0 1 2 3 4 5 6 7 8 **9** 10 Extremely confident

Review of goal (your pharmacist will fill this in at your next appointment) ☐ Goal met ☐ Goal not met

Note: This goal will be reviewed at Appointment 3 (see page 24 of this manual)

Appointment 2: Summary of activities

Preparation for Appointment 2
- Map adherence problems (identified in Appointment 1) across to adherence solutions using the ID-MAP Tool.
- Where necessary, prepare solutions in advance and make planning notes.

Arrival, welcome and introduction
- Welcome patient on arrival and invite them into the consultation room.
- Explain the purpose of Appointment 2.
- Briefly recap on adherence problems discussed at Appointment 1.

Delivery of compulsory adherence Solution A
- Provide patient with a personalised medication diary. Explain purpose of the diary and how to use it.
- If required, provide additional information if gaps in knowledge were identified during Appointment 1.

Delivery of optional adherence Solution B if required
- Discuss practical, reminder and social support options.
- Decide on the best option, bearing in mind the patient's preference.

Delivery of optional adherence Solution C if required
- Discuss concerns about medications and consequences of non-adherence, using leaflet(s) as a visual information aid.

Delivery of compulsory adherence Solution D
- Help patient set one (or two) medication use goals.
- If required, also help the patient set an additional overall health goal.
- Develop an action plan to help patient reach their goal(s).

End of Appointment 2
- Check that the patient is happy with all the information and materials provided.
- Offer the patient a plastic folder to store materials in.
- Complete end of Appointment 2 checklist (page 12 of ID-MAP Booklet).
- Schedule Appointment 3. This should take place after **at least** 4 weeks.

IMPORTANT: Remind the patient that if their medications change during the next 4 weeks, then they should contact you as soon as possible. They may need to have their medication diary reviewed.

6.3. Appointment 3

Appointment 3: How to complete Section 4 of the ID-MAP Booklet: Review of solutions/feedback

WHEN **Complete DURING Appointment 3**

- This section includes a table to help guide the last appointment (see image below).
- The middle column details the steps required to review each adherence solution.
- There is also a notes column: **Please make brief notes on what you discussed during Appointment 3.**
- You will need to review compulsory solutions A (Medication diary) and D (Goals and action plan) and any other solutions delivered at Appointment 2 (B and/or C)
- Indicate *"N/A* or *"Not applicable"* in the notes section if the solution was **not** delivered.

Solution	Steps to review it	Notes
Solution A: Medication diary	1. **Did they use the daily medication diary?** If not, discuss why. Discuss reasons for missed doses. 2. **If possible, give the patient feedback on their adherence behaviour based on the diary.** Was there any improvement or is there still some room for improvement? 3. Ask if they are happy for you to **keep the diary for the research team to examine!** You can print out a separate list of medications if the patient would like this for their own reference. ***Ensure this is kept up-to-date***	
Additional solution B (practical, reminder, social support)	1. **Did the recommendations help?** *(Refer to page 10 & 11 for what was recommended)* 2. **Are any further actions required?** If so, please make a note of these.	
Additional solution C (discussion around medication concerns)	1. **Did they find the leaflet(s) helpful?** Do they have any more concerns that they wish to discuss? 2. **Are they aware of the health benefits** of taking/using their medications as prescribed and the possible consequences of non-adherence?	
Solution D: Goals and action plan	1. **If an overall general health goal was set, is this still their motivation** for taking/using their medicines? 2. **Did the patient meet their medication use goal(s)?** If the medication diary indicates that they did not fully meet their goal(s), then discuss the possible reasons why. 3. **Complete the 'Review of goal' section on Goals and action plan sheet** for each medicine use goal by ticking the relevant option (goal met or goal not met).	

IMPORTANT: You should retain the patient medication diary for the research team to review.

Appointment 3: Summary of activities

Arrival, welcome and introduction
- Welcome the patient and invite them into the consultation room.
- Explain the purpose of Appointment 3.

Review of compulsory adherence Solution A
- Review medication diary.
- Provide feedback on their adherence behaviour based on the diary.

Review of optional adherence Solution B and/or C
- Review other optional adherence solutions (B and/or C) if recommended at Appointment 2.
- If necessary, make further suggestions.

Review of compulsory adherence Solution D
- Review medication use goal(s) and action plan(s) set at Appointment 2.
- If an overall health goal was set, review this also.

End of Appointment 3
- Inform patient that this is the final appointment in the pharmacy but they can still ask you questions about their medicines at any time.
- Remind patient that the research team will be telephoning in the next few days to get feedback. Find out the most appropriate time to call.
- Fill in the end of Appointment 3 checklist (page 14 of ID-MAP Booklet).

Appendix 4.8 (cont'd): Intervention training manual for community pharmacists

7. Communication with General Practitioners

- Before recruiting patients, you should contact GPs in your local area to inform them that you are taking part in a research study.
- This is important as some of patients may need to be referred to their GP.
- An "Information for General Practitioners" sheet can be provided to any GPs that want to know more about the study (Appendix 13).
- You should inform them that a "GP communication form" will be used to communicate any important information in relation to their patients (Appendix 14).
- Ask whether they GP would like to receive information on the outcomes of the appointments for all patients under their care.
- Alternatively, GPs can be given the option to receive "GP communication forms" **only** in the event that action is required on their part (in relation to adherence issues).
- The "GP communication form" will clearly indicate whether any action is required on the GP's part or if the form is for information purposes only.
- If a patient becomes distressed at any point during this research study, please follow the Standard Operating Procedure in Appendix 15.
- If at any stage during the study you suspect that a patient may have undiagnosed dementia or where a diagnosis of dementia is made, please follow the relevant Standard Operating Procedure in Appendix 16.

8. Feedback to the research team

At the end of this study, please complete the "Summary of patients" sheet (Appendix 16). This will be an indication of the overall number of patients that you approached and their reasons for ineligibility, refusal etc. You can use the individual eligibility screening and recruitment/retention forms to help complete this (these will be in each Patient Pack).

You will also be asked to provide information from recruited patients' medication records to the research team. This will be subject to patient consent (Consent Form 2). This will include information on:

- Medicines dispensed in the **SIX months prior to Appointment 1**
- Medicines dispensed in the **THREE months after Appointment 3**

Your computer system should allow you to print out this information including:

- Medicine name, strength and form (e.g. amlodipine 5mg tablets)
- Directions for use (e.g. once daily in the morning)
- Quantity dispensed (e.g. 56)
- Date of dispensing (e.g. 17/03/2015)

The researcher will provide assistance in collecting this information.

You will also be asked to complete a telephone interview with the researcher to find out how you got on with the intervention and your recommendations for improvement.

Appendix 4.9: Example patient scenarios for training

Mr John Black (DOB: 10/12/1945)

- Mr Black is a 70 year old man who lives at home with his wife.
- He always attends the study site pharmacy for his regular medications.
- He takes the following seven repeat medications:

Repeat medication (name/strength/form)	Directions	Indication
Simvastatin 20mg tablets	Take ONE tablet at night	Hypercholesterolemia
Ramipril 10mg capsules	Take ONE capsule in the morning	Hypertension
Felodipine M/R 2.5mg tablets	Take ONE tablet in the morning	Hypertension
Metformin 500mg tablets	Take ONE tablet three times daily	Type 2 diabetes
Gliclizide 80mg tablets	Take ONE tablet in the morning	Type 2 diabetes
Indapamide 2.5mg tablets	Take ONE tablet in the morning	Hypertension
Aspirin E/C 75mg tablets	Take ONE tablet in the morning	Anti-platelet (primary prevention)

- When initially approached and informed about the study Mr Black is happy to complete the Eligibility Screening Questionnaire and signs Consent Form 1.
- He indicates on the questionnaire that he sometimes forgets to take his medication.
- Mr Black meets all of the eligibility screening criteria, and is invited to take part in the full research study.
- He is provided with a study information sheet and Consent Form 2 to read at home.
- He reads the information sheet and decides that he would like to take part.
- The pharmacist telephones Mr Black after one week and an initial appointment is arranged. The pharmacist reminds him to bring his medications (or a list of the medications) and the consent form to the appointment.

Appointment 1

- On arrival, Mr Black and the pharmacist go through Consent Form 2 and they both sign it.
- He has no additional questions about the study.
- The pharmacist then asks Mr Black to complete a short questionnaire (5-10 minutes) about how he is currently feeling today (health-related quality of life questionnaire).
- The pharmacist begins the intervention by asking Question 1 from the ID-MAP Tool (ID-MAP Booklet Section 2). This is used to confirm the pre-prepared list of medications (ID-MAP Booklet Section 1). *(Note: Mr Black brought his medications to the appointment)*
- He provides the following information for each question in the ID-MAP Tool:

QUESTION 1. PATIENT'S KNOWLEDGE	Mr Black is unsure why he still has to take indapamide as the GP has started him on felodipine for his blood pressure. He knows what all his other tablets are for and how and when he should take them.
QUESTION 2. ROUTINE/ORGANISATIONAL BARRIERS	He appears to have a routine at home, where he takes his medications with his breakfast, lunch, dinner and these are left sitting on the kitchen counter top. However, he finds it difficult to remember to take his cholesterol tablet at night.
QUESTION 3. PRACTICAL BARRIERS	He reports no difficulty taking the medication. He has no difficulty opening the packaging, reading labels, swallowing etc.
QUESTION 4. SOCIAL SUPPORT	He lives with his wife but she has enough to worry about with her own tablets so he doesn't want to burden her. He finds the pharmacy staff already very helpful as they collect his prescriptions from his GP surgery.
QUESTION 5. FORGETTING	He indicates that he often forgets to bring his medication when he is out for the day (e.g. out playing bowls once a week or on day trips). He also forgets to take his evening simvastatin a few nights each week.
QUESTION 6. INTENTIONAL NON-ADHERENCE	He doesn't report intentionally missing any of his medications and would never stop taking them without speaking to his doctor.
QUESTION 7. PATIENT'S MOTIVATION	He thinks that his medications are very important as they keep him alive.

Appointment 2

- **Solution A:** Mr Black understands what he has to do with the medication diary. The pharmacist explains the importance of taking indapamide and felodipine together (along with ramipril) as these all work together to keep his blood pressure under control.
- **Solution B:** He thinks that setting his simvastatin medication box on his bed side table (beside his denture holder) might help him to remember to take it at night. He has no young grandchildren visiting, so he can leave them sitting there safely.

  He is happy to try a medication sticker beside where he stores his car keys to remind him to bring his medications when he is going out to bowls or on a day trip.
- **Solution C:** Not required.
- **Solution D:** He thinks that he could try to remember to bring his medications when he goes out for the day. The reminder sticker beside his car keys will hopefully help him to do this. He is confident that he can achieve this goal.

  He thinks that setting a goal to remember to take his simvastatin every night might be too difficult (i.e. he is not very confident that he will be able to remember every night). He indicates that he is sometimes just too tired and unwell and forgets. He will see how he gets on with setting the medication box beside his bed might help. But for now, he is more confident that he could try to remember to take his simvastatin on 6 out of 7 nights.

Appointment 3

- **Solution A:** He found the diary useful and only missed taking his statin on one occasion over the four week period. He previously said that he forgets to take it a couple of nights each week.

  He would like a list of his medications printed as he found this useful.
- **Solution B:** He found that having his simvastatin medication box sitting out on his bedside table helped him, as he spotted them when he went to take his dentures out at night. The one night he forgot, he was extremely tired.

  He found the reminder sticker beside his car key holder helpful.
- **Solution C:** Not applicable.
- **Solution D:** He remembered to bring his medications when he went out to bowls each week and therefore met this medicine goal.

  He also met his simvastatin goal (see above).

Appendix 4.9 (cont'd): Example patient scenarios for training

Mrs Elizabeth Jones (DOB: 23/05/1948)

- Mrs Jones is a 67 year old woman who lives at home alone.
- She always attends the study site pharmacy for her regular medications.
- She takes the following eight medications:

Repeat medication (name/strength/form)	Directions	Indication
Adcal® D3 caplets (calcium carbonate 750mg/colecalciferol 200 units)	Take TWO caplets TWICE daily	Osteoporosis
Risedronate sodium 35mg tablets	Take ONE table each WEEK on Wednesdays	Osteoporosis
Citalopram 10mg tablets	Take ONE tablet in the morning	Depression
Salbutamol 200mcg/dose inhaler (MDI)	Inhale two puffs when required	COPD
Seretide 500 Accuhaler® 500 mcg	Inhale ONE puff TWICE daily	COPD
Paracetamol 500mg tablets	Take TWO tablets FOUR times daily (every four to six hours)	Osteoarthritis (knee)
Iburofen 5% gel	Apply THREE times daily (to knee)	Osteoarthritis (knee)
Atorvastatin 20mg tablets	Take ONE tablet in the morning	Hypercholesterolaemia - familial

- When initially approached and informed about the study Mrs Jones is happy to fill in the Eligibility Screening Questionnaire and signs Consent Form 1 for this.
- She indicates on the questionnaire that when her symptoms are under control, she sometimes stops taking her medications and that she feels hassled about adhering to her treatment plan.
- Mrs Jones meets all of the eligibility screening criteria and is invited to take part in the full research study.
- She is provided with a study information sheet and Consent Form 2 to read at home.
- She reads the information sheet and decides that she would like to take part.
- The pharmacist telephones Mrs Jones after one week and an initial appointment is arranged. The pharmacist reminds her to bring her medications (or a list of the medications) and the consent form to the appointment.

Appointment 1

- On arrival Mrs Jones and the pharmacist go through Consent Form 2 and they both sign it.
- She has no additional questions about the study.
- The pharmacist then asks Mrs Jones to complete a short questionnaire (5-10 minutes) about how she is currently feeling today (health-related quality of life questionnaire).
- The pharmacist begins the intervention by asking Mrs Jones Question 1 from the ID-MAP Tool (ID-MAP Booklet: Section 2). This is used to confirm the pre-prepared list of medications (ID-MAP Booklet: Section 1). (*Note: Mrs Jones has brought in her medications to the appointment)*
- Mrs Jones provides the following information for each question in the ID-MAP Tool:

QUESTION 1. PATIENT'S KNOWLEDGE	Mrs Jones doesn't know why she needs to take Adcal® D_3 caplets and says she only takes them once a day in the morning.
QUESTION 2. ROUTINE/ORGANISATIONAL BARRIERS	She doesn't have a set routine for taking her medications, in particular, for her evening doses.
QUESTION 3. PRACTICAL BARRIERS	She reports difficulty with taking the Adcal® D_3 caplets as she finds them difficult to swallow. This means she doesn't take them every day.
QUESTION 4. SOCIAL SUPPORT	She currently lives alone as her husband recently passed away. She has a daughter who lives too far away to help on a daily basis but she does telephones regularly.
QUESTION 5. FORGETTING	She regularly forgets to use her Seretide Accuhaler® in the evening (most evenings) and occasionally forgets her risedronate tablet. Her husband used to help remind her to take her medications but she has struggled since he passed away.
QUESTION 6. INTENTIONAL NON-ADHERENCE	She reports she sometimes skips her risedronate weekly tablet because she is worried about oesophageal side effects.
QUESTION 7. PATIENT'S MOTIVATION	Mrs Jones indicates that she wants to keep her bones strong and avoid another fracture as she doesn't want to have to go into hospital again.

Appendix 4.9 (cont'd): Example patient scenarios for training

Appointment 2

- Solution A: Mrs Jones understands what she has to do with the medication diary. The pharmacist explains the importance of taking her Adcal® D3 caplets twice daily (instead of once daily) to keep her bones strong.
- Solution B: She thinks that setting her Seretide Accuhaler® on the kitchen bench after taking her morning dose might help remind her to take this again at tea-time. She doesn't want to try a reminder sticker.

  Mrs Jones's daughter is present at this appointment and agrees to call her mum every Wednesday to check that she has taken (or will take) her risedronate tablet.

  Mrs Jones agrees that changing her Adcal® D3 caplets to a chewable version might help her take this every day as some days she has difficulty swallowing this and just gives up.
- Solution C: Mrs Jones and the pharmacist discuss the importance of taking risedronate every week and the benefit this provides. The pharmacist advises her on the need to follow the strict administration instructions to help avoid side effects.
- Solution D: Mrs Jones agrees that her general health goal is to avoid bone fractures and stay out of hospital.

  Together, two medication use goals are set: one that focuses on taking risedronate every week on Wednesdays and one that focuses on remembering to take her Seretide Accuhaler® every evening.

Appointment 3

- Solution A: She found the diary helpful and only missed using her Seretide Accuhaler® on two occasions. Previously she forgot to use this most nights.
- Solution B: Having her Seretide Accuhaler® sitting on the bench helped remind her but she is still working on this routine.

  She found the telephone call from her daughter each week helpful and she took her risedronate every Wednesday during the four week period.
- Solution C: She is less concerned about the side effects of risedronate and she agrees to contact someone if she is worried (pharmacist or GP).
- Solution D: She met her goal to take risedronate every week but did not meet her goal to use the Seretide Accuhaler® every evening. Although the goal was unmet, an improvement was seen so this is positive and she will continue to work on this routine.

Appendix 4.10: ORECNI favourable opinion letter

HSC Business Services Organisation

Office for Research Ethics Committees Northern Ireland (ORECNI)

Customer Care & Performance Directorate
Unit 4, Lissue Industrial Estate West
Rathdown Walk
Moira Road
Lisburn
BT28 2RF
Tel: 028 95361400
www.orecni.hscni.net
HSC REC A

04 March 2016

Prof. Carmel Hughes
Professor of Primary Care Pharmacy
Queen's University Belfast
School of Pharmacy
97 Lisburn Road
Belfast, BT9 7BL

Dear Prof. Hughes

Study title:	**Feasibility testing of the ID-MAP (IDentification of Medication Adherence Problems) intervention in older adults prescribed polypharmacy in primary care**
REC reference:	**16/NI/0028**
Protocol number:	**1.0**
IRAS project ID:	**198328**

Thank you for your letter of 29 February 2016, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Kathryn Taylor, RECA@hscni.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study

Providing Support to Health and Social Care

at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Cover letter-ID-MAP study]		25 January 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Queen's University professional indemnity certificate]		20 July 2015
GP/consultant information sheets or letters [GP letter/information]	1.0	25 January 2016
IRAS Checklist XML [Checklist_25012016]		25 January 2016
IRAS Checklist XML [Checklist_29022016]		29 February 2016
Letter from funder [Letter from Harold and Marjorie Moss Charitable Trust Fund_PhD research award]		30 July 2015
Letter from sponsor [Sponsor letter from Queen's University Belfast]		22 January 2016
Letters of invitation to participant [Pharmacist invitation letter]	1.0	25 January 2016
Other [Response letter to REC]		29 February 2016
Participant consent form [Pharmacist consent form]	2.0	29 February 2016
Participant consent form [Patient Consent Form 1 (for eligibility screening questionnaire)]	2.0	29 February 2016
Participant consent form [Patient Consent Form 2 (for study participation)]	2.0	29 February 2016
Participant information sheet (PIS) [Information for pharmacists]	2.0	29 February 2016
Participant information sheet (PIS) [Information for patients]	2.0	29 February 2016
REC Application Form [REC_Form_25012016]		25 January 2016
Referee's report or other scientific critique report [External peer review report (Dr. Margaret Watson)]		18 January 2016
Referee's report or other scientific critique report [Internal peer review report (Dr. Janine Cooper)]		20 January 2016
Research protocol or project proposal [ID-MAP study protocol]	2.0	29 February 2016
Summary CV for Chief Investigator (CI) [Chief investigator CV- Prof. Carmel Hughes]		25 January 2016
Summary CV for student [Student CV-Deborah Patton]		15 January 2016
Summary CV for supervisor (student research) [CV- academic supervisor_Dr Cristin Ryan]		19 January 2016
Validated questionnaire [Morisky Medication Adherence Scale (MMAS-8 item)]	1.0	25 January 2016
Validated questionnaire [Euroqol (EQ)-5D-5L]	1.0	25 January 2016

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Appendix 4.10 (cont'd): ORECNI favourable opinion letter

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

16/NI/0028	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

pp Dr Catherine Hack
Chair
Email: RECA@hscni.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Dr Stephen Liggett, Queen's University Belfast*

Appendix 4.11: Community pharmacist invitation letter

School of Pharmacy
Medical Biology Centre
97 Lisburn Rd
Belfast BT9 7BL
Tel: 028 90972007
Fax: 028 90247794

7th March 2016

Dear Pharmacist(s)

An invitation to take part in the feasibility testing of the ID-MAP ('IDentification of Medication Adherence Problems') intervention to address adherence issues for older adults who are prescribed polypharmacy in primary care.

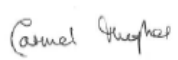
I am writing to invite you to take part in a study which will involve the testing of the above intervention in community pharmacies. The ID-MAP intervention has been specifically developed for older adults who are prescribed four or more medications (i.e. prescribed polypharmacy). This intervention has been developed based on findings from previous research that involved discussions with older adults from across Northern Ireland about their use of several medications. As part of this research, we identified a range of reasons which may help to explain why older patients do not take (or use) their medications as prescribed (i.e. why they are non-adherent). Using the information obtained, we have developed an intervention that targets the key problems that prevent patients taking (or using) their medicines as prescribed.

As part of this intervention, we have developed an adherence assessment tool to help pharmacists identify the key problems faced by individual patients and the best solutions to overcome these. This will allow pharmacists to tailor their recommendations to the patient's needs. As part of this study, you will be asked to identify five patients who are eligible and willing to take part. The intervention will be delivered to recruited patients over three (30-40 minute) appointments which will take place in the pharmacy where you work.

Please find enclosed a study information sheet, which provides further information about the study. If you have any queries, please do not hesitate to contact the researcher (Deborah Patton), or any other member of the research team, using the contact details provided below. We appreciate the time you have taken to read this letter and the enclosed study information sheet. We will be in contact with you over the next week to discuss whether you would like to participate.

Appendix 4.11 (cont'd): Community pharmacist invitation letter

Yours sincerely,



Prof. Carmel Hughes

Professor of Primary Care Pharmacy, Queen's University Belfast.

On behalf of the research team:
Deborah Patton, Prof. Carmel Hughes, Dr. Cristín Ryan

Contact details for more information:

Deborah Patton
Postgraduate Researcher
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast BT9 7BL
Telephone: (028) 902097 2033
Email: dpatton08@qub.ac.uk

Prof. Carmel Hughes
Professor of Primary Care Pharmacy
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast BT9 7BL
Telephone: (028) 9097 2147
Email: c.hughes@qub.ac.uk

Dr. Cristín Ryan
Senior Lecturer in Pharmacy Practice
RCSI School of Pharmacy
Royal College of Surgeons in Ireland
123 St. Stephens Green, D2, Ireland
Telephone: (0035) 31 402 8689
Email: cristinryan@rcsi.ie

Appendix 4.12: Community pharmacist information sheet

Study information sheet

Study Title: Feasibility testing of the ID-MAP (IDentification of Medication Adherence Problems) intervention in older adults prescribed polypharmacy in primary care

You are being invited to take part in a research study. Before you decide whether or not you would like to take part, it is important that you take time to understand why this research is being completed and what will be asked of you should you agree to participate.

Please read the following information and contact the researcher (Deborah Patton) or any other member of the research team if you have any queries. Contact details can be found at the end of this information sheet.

What is the purpose of this study?

Older adults commonly suffer from multiple long-term conditions and are routinely prescribed multiple medications to treat these conditions. Between 25% and 75% of older patients do not take (or use) their medications as prescribed by their GP, and are therefore considered to be non-adherent. This non-adherence has been linked to poor clinical outcomes for patients, increases in hospital admissions and associated increases in healthcare costs. There is a need for an intervention, delivered in the community by pharmacists, that addresses the adherence problems patients are facing. As part of an on-going research project, we have developed the ID-MAP Intervention which targets adherence in older adults who are prescribed four or more medications. This study will involve the initial testing of the intervention to see how it might work in practice. This will allow us to gather valuable feedback from both pharmacists and patients involved and improve the intervention accordingly.

Why have you been chosen?

You have been asked to participate in this study because you are a pharmacist working in the community setting and are therefore ideally placed to identify medication problems faced by older patients.

Do you have to take part?

It is your decision whether or not you would like to take part in this study. Please read this information sheet and do not hesitate to contact the researcher or any other member of the research team, should you have any questions. If you do decide to take part, you will be asked to

sign a consent form. You will be given a copy of this consent form. The original form will be stored securely in the School of Pharmacy, Queen's University Belfast (QUB). If you agree to take part, you are free to withdraw from the study at any time and are not required to give a reason.

What will happen if you take part?

The researcher will contact you a minimum of one week after you receive this information sheet to discuss if you are interested in participating in the study. If you wish to participate in the study, the researcher will arrange to meet you at a time and place that is convenient for you. The researcher will be able to answer any questions you may have about the study at this stage.

If you agree to participate, you will be provided with training on how to deliver the ID-MAP Intervention in practice. A separate date for training will be arranged at a time and place that is convenient for you. During the training session, you will be provided with example patient scenarios to help illustrate the processes involved in delivering the intervention. You will be provided with all of the necessary documentation required to deliver this intervention (*i.e.* intervention manual, patient information sheets, booklets to complete etc.). Once the training is completed, you will be asked to recruit five patients who are eligible to take part in the study; this will allow us to test how the intervention works in practice. To be eligible, patients must meet specific criteria and a short patient questionnaire will help you to make this decision.

As part of the initial testing of the ID-MAP intervention, we will gather feedback from both pharmacists and patients after the intervention has been fully delivered; this will involve a telephone interview. You will also be asked to provide information from recruited patients' medication records to the researchers (with patients' consent). This will include details of long-term medications dispensed in the six months before and three months after intervention delivery.

On completion of the study, you will be offered a certificate of participation. The community pharmacy in which you work will also be offered an honorarium of £200 by way of compensation for the time allocated to study participation.

Are there any risks or disadvantages of taking part in the study?

There is a small risk that poor practice may be identified during this study. In the unlikely event that this occurs, any cases will be reported to the Chief Investigator (Professor Carmel Hughes) who will take appropriate action on a case-by-case basis. This may involve informing the appropriate professional regulatory body (e.g. Pharmaceutical Society of Northern Ireland).

What are the benefits of taking part in the study?

Participation in this study may be beneficial (for both you and your patients), as it will help to determine whether the intervention needs to be refined before further evaluations can be undertaken. In the long-term it is hoped that this type of intervention will lead to improvements in medication adherence, reduce GP visits and hospitalisations and lead to improvements in older people's quality of life.

What will happen if you decide you no longer wish to take part?

You are free to withdraw from the study at any time. However, any data collected prior to your withdrawal may still be used in the final results. The £200 honorarium will only be paid on condition that: five patients who meet inclusion criteria are recruited into the study; the ID-MAP intervention is delivered to each recruited patient and the requested data are returned to the research team.

Will your details be kept confidential?

All information collected as part of the study will be treated in a confidential manner. Your name or community pharmacy will not appear in any reports or publications. The only circumstance in which confidentially will not be maintained is in the unlikely instance that a patient discloses information that would require reporting to an appropriate agency.

Any identifiable information collected during the study (e.g. consent forms) will be stored securely in the School of Pharmacy, QUB. In line with the Data Protection Act (1998), these documents will be kept for five years and then destroyed.

In order to ensure that research studies involving human participants are carried out to a high standard, the University is required to monitor on-going studies. As a result, staff from the Queen's University Governance Office may need to review the information collected as part of this research study.

What will happen to the results of the research?

The results from the research will be used as part of a research project being carried out at the School of Pharmacy, QUB. Data may be presented at conferences or published in academic journals. All data obtained as part of this study will be anonymised. You will be provided with a report of the results on completion of the study.

Appendix 4.12 (cont'd): Community pharmacist information sheet

Who is organising and funding the research?

This research is being organised by the School of Pharmacy at Queen's University Belfast. It is funded by the Harold and Marjorie Moss Charitable Trust Fund.

Who has reviewed the study?

The study has received ethical approval from the Office for Research Ethics Committees in Northern Ireland. The study has also been reviewed by two independent scientific reviewers.

Who can you contact for further information?

Should you require any further information, please do not hesitate to contact the researcher (Deborah Patton) who is responsible for the day-to-day running of the study, or any other member of the research team, using the contact details below.

Contact details for more information:

Deborah Patton
Postgraduate Researcher
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast BT9 7BL
Telephone: (028) 902097 2033
Email: dpatton08@qub.ac.uk

Prof. Carmel Hughes
Professor of Primary Care Pharmacy
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast BT9 7BL
Telephone: (028) 9097 2147
Email: c.hughes@qub.ac.uk

Dr. Cristín Ryan
Senior Lecturer in Pharmacy Practice
RCSI School of Pharmacy
Royal College of Surgeons in Ireland
123 St. Stephens Green, D2, Ireland
Telephone: (0035) 31 402 8689
Email: cristinryan@rcsi.ie

Appendix 4.13: Community pharmacist consent form

Community Pharmacist Consent Form

Study Title: Feasibility testing of the ID-MAP (IDentification of Medication Adherence Problems) intervention in older adults prescribed polypharmacy in primary care

Please initial the following statements.		**Initials**
1.	I have read the information that I have received in relation to the above study and have asked any necessary questions. I understand what the study involves.	
2.	I agree to take part in any training required to allow me to deliver the intervention to patients recruited from the pharmacy in which I work.	
3.	I agree to provide the research team copies of any materials completed during the study.	
4.	I agree to take part in a feedback telephone interview and give permission for this to be audio recorded.	
5.	I agree to share data with the researchers from recruited patients' medication records at the agreed time points, subject to patient consent.	
6.	I understand that I may withdraw from the study at any time without giving a reason. I understand that any data collected up to this point may be retained by the research team and included in any reports.	
7.	I understand that my personal information will be confidential and stored safely in the School of Pharmacy, QUB. I am aware that any results published from the study will be anonymous.	
8.	I understand that relevant data collected during the study may be looked at by researchers involved in the study, or from QUB, for audit purposes.	
9.	I agree to take part in this study.	

Please write your name, sign and date the form below.

Pharmacist Name (Print):

Signature: Date:

Researcher Name (Print):

Signature: Date:

Appendix 4.14: Continuing professional development certificate

Queen's University Belfast

Certificate of Participation

Title of Event: Feasibility testing of the ID-MAP (IDentification of Medication Adherence Problems) intervention in older adults prescribed polypharmacy in primary care

Date of Event: March 2016 to March 2017

Name of pharmacist:

I hereby certify that the individual named above attended this event.

Signed: _____

Event Organiser: Professor Carmel Hughes

Head of School, School of Pharmacy, Queen's University Belfast

Date:

Appendix 4.15: Eligibility Screening Form

Eligibility Screening Form

Patient name	
Address	
Contact telephone number	
Date of birth	
H&C number	
Carer/relative, if applicable (name, telephone number)	
Patient's regular GP (name, practice, telephone number)	

Screening checklist

IMPORTANT: All blue boxes must be ticked before proceeding to the next stage (recruitment)

Patient meets the following criteria:	Yes	No
- 65 years or older		
- Prescribed four or more regular medications (**excluding** OTC and when required)		
- At least six months' PMR data available from date of screening		
- Attends study site pharmacy **only** for regular medications		
- Lives in their own home		
- Patient is **NOT** prescribed donepezil, rivastigmine, galantamine or memantine		
- Patient is able to provide written informed consent		
Eligibility Screening Questionnaire has been completed		
- Adherence problem(s) identified		

Patient eligible for the ID-MAP intervention (only when all blue boxes above are ticked)

YES ☐ → Proceed with recruitment NO ☐ → Detail reason(s) below

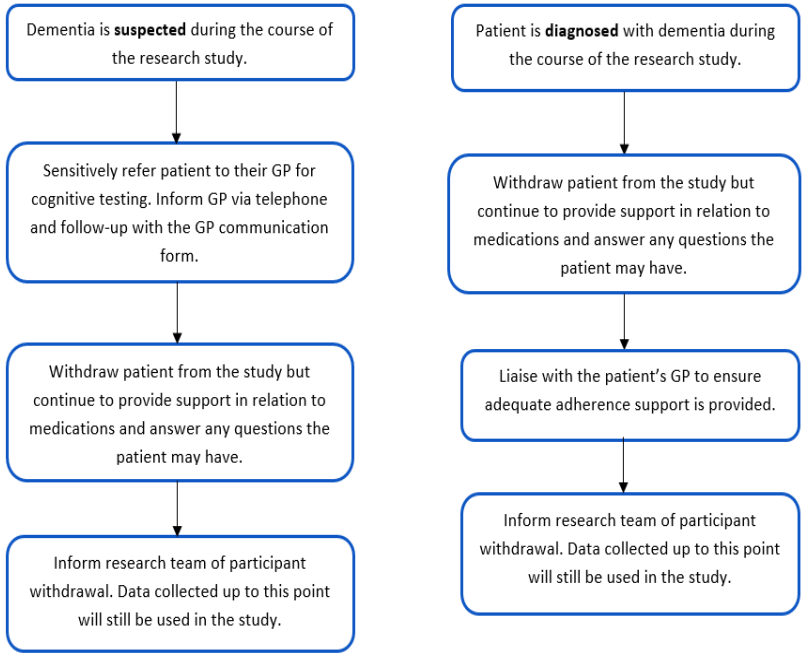
Date of eligibility screening:

	Tick if applicable
Refused at outset (state reason if known_____)	
Did not meet all of the eligibility criteria (please detail_____)	
Did not complete the Eligibility Screening Questionnaire	

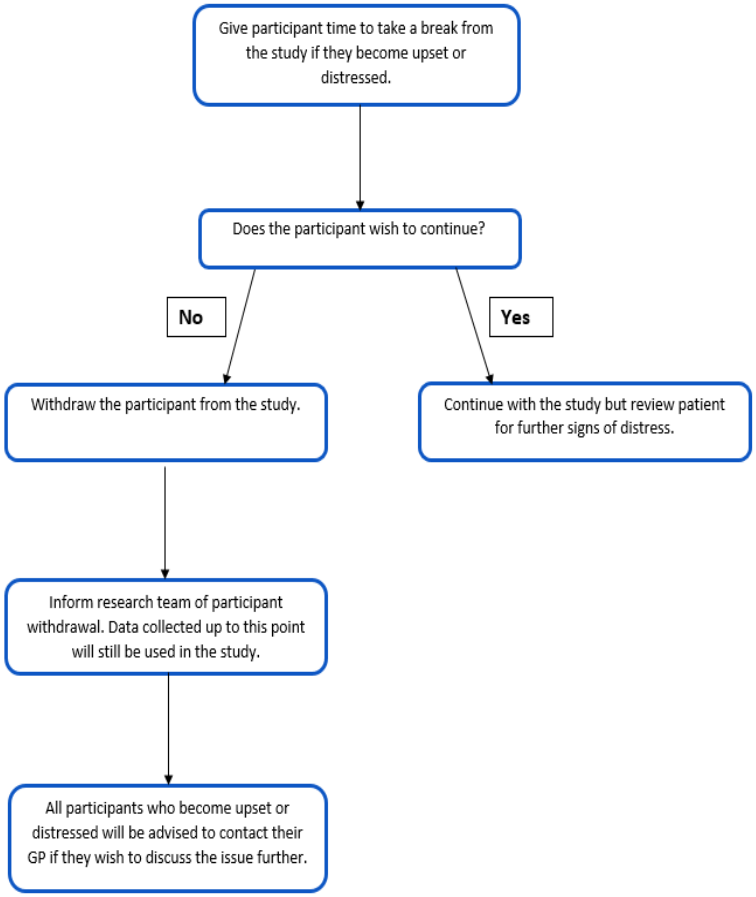
Additional notes:

Patient ID:

Appendix 4.16: Standard Operating Procedure for handling the situation where dementia is suspected or where a patient is diagnosed with dementia during the course of the study



Appendix 4.17: Standard Operating Procedure for handling patients who become distressed during the study



Appendix 4.18: Patient consent form 1

Patient consent for Eligibility Screening Questionnaire completion (Consent Form 1)

Section 1: Information about the questionnaire

This questionnaire focuses on all of the medicines you are prescribed for your medical conditions. This will help your pharmacist identify if you are having any problems with your medicines.

Before you complete this questionnaire, you will be asked to give your consent to do so.

However, if you decide not to complete the questionnaire, your pharmacist will continue to provide advice on your medicines at any time.

If you decide to complete this questionnaire, your pharmacist may provide feedback to your GP or the research team.

You may also be eligible to take part in a larger research study that is currently being conducted by Queen's University Belfast. If you are suitable, your pharmacist will provide further information on this before you decide whether you wish to take part.

Your pharmacist might also need to ask your GP for more information on the medicines that you are prescribed. They will only ask your GP for this information if you later decide that you wish to take part in the larger study.

Section 2: Consent to complete the questionnaire

Please initial the following statements.	**Initials**
I understand the reason for completing the questionnaire and what it will involve.	
I agree to allow my pharmacist to provide feedback on the questionnaire to my GP and the research team.	
I agree to allow my pharmacist to share any information with my GP, or ask my GP for information on my medicines, if necessary.	

Please write your name, sign and date the form below.

Patient Name (Print):

Patient Signature: Date:

Pharmacist Name (Print):

Pharmacist Signature: Date:

Patient ID:

Appendix 4.19: Eligibility Screening Questionnaire (MMAS-8)

Eligibility Screening Questionnaire

Instructions for completing the questionnaire

This questionnaire is about all of the medicines you are prescribed by your GP for your medical conditions. It should take approximately 5 minutes to complete. **Please answer all questions honestly.** You may be taking (or using) a lot of medicines. This can include tablets, capsules, inhalers, creams, eye drops, nasal sprays, patches etc. Try to think about ALL of the medicines that you take (or use) when answering the following eight questions.

For the following questions, please circle either YES or NO

1	Do you sometimes forget to take your medicines?	YES	NO
2	People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past 2 weeks, were there any days when you did not take all of your medicines?	YES	NO
3	Have you ever cut back or stopped taking any of your medicines without telling your doctor because you felt worse when you took it?	YES	NO
4	When you travel or leave home, do you sometimes forget to bring along your medicines?	YES	NO
5	Did you take all of your medicines yesterday?	YES	NO
6	When you feel like your symptoms are under control, do you sometimes stop taking any of your medicines?	YES	NO
7	Taking medicines everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?	YES	NO

For the next question, please tick the option that best applies to you

8	How often do you have difficulty remembering to take all your medicines?	__A. Never/rarely __B. Once in a while __C. Sometimes __D. Usually __E. All the time

Patient ID:

Appendix 4.20: Signed license contract for use of MMAS-8

MMAS-8 License Contract and Copyright Agreement

Please print, sign, and scan (PDF) and email *this agreement to* dmorisky@ucla.edu

Please sign and return this contractual agreement in a PDF format, to Professor Morisky and he will provide you (upon receipt of the payment invoice) with pages listing the MMAS-8 items, scoring and re-coding criteria and signature authorizing full use of this copyrighted scale. I agree to use only the English version of the MMAS-8 unless I purchase a validated translation of the MMAS-8 through Professor Morisky. I understand that it is a violation of international copyright laws to either use your own translation and call it the "MMAS-8" or use an existing MMAS-8 scale that has been translated and used for another study. The validated translation is non-transferrable and is linked to a specific license agreement and cannot be reproduced, copied, distributed, placed on the internet, published, or used by another individual. If the licensee violates any copyright laws contained in this licensing agreement they will be solely responsible for a $5000.00 penalty and any associated legal costs.

Name and Contact Information of Licensee: Deborah Patton (email:dpatton08@qub.ac.uk, telephone: 01144289072033)

Title of Study: Feasibility testing of the ID-MAP (IDentification of Medication Adherence Problems) intervention in older adults receiving polypharmacy in primary care.

Total number of administrations: 20

Signature of developer/owner of the MMAS-8:
Donald E. Morisky, ScD, Developer/Owner of the MMAS-8

Date Signed:

Signature of Licensee: Deborah Patton/ D Patton

Date Signed: 19/01/2016

Appendix 4.21: Patient study information sheet (feasibility study)

Study Title: Testing of a new pharmacy service to help patients who are prescribed several medicines

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important that you understand why this research is being completed and what you will be asked to do. Please take time to read the following information and do not hesitate to ask questions about anything that is unclear to you. Contact details for the researcher can be found at the end of this information sheet.

What is the purpose of this study?

Patients with medical conditions are often prescribed several medicines by their General Practitioner (GP). Other research studies have shown that some patients find it difficult to take all of these medicines. We have identified some solutions that might help patients who are prescribed several medicines and we want to see how these might work. These solutions will be explained to you as part of a new service we are testing in your pharmacy. Together with your pharmacist, you will make a plan to help you get the most from all of the medicines that you take.

Why have you been chosen?

You have been chosen for the study because you are an older adult who is currently taking four or more prescribed medicines every day. The questionnaire you have already completed shows that you might benefit from this new service.

Appendix 4.21 (cont'd): Patient study information sheet (feasibility study)

Do you have to take part?

You do not have to take part in the study. Your decision whether or not to take part will not affect your medical care. If you decide to take part, you will be asked to sign a consent form. You have been given a copy of this consent form to read over at home. Your pharmacist will telephone you after one week to see if you would like to take part.

If you do decide to take part, your pharmacist will schedule an appointment in the pharmacy and ask you to bring along the consent form. You can withdraw from the study at any stage. You are not required to give a reason and it will not affect your normal medical care.

What will happen if you take part?

If you decide to take part, you will be asked to attend three (30 to 40 minute) appointments, in your local pharmacy that you usually go to. At the first appointment, you will be asked to answer questions about your general health. Together with your pharmacist, you will then discuss any problems you may be having in relation to your medicines. Your pharmacist will then arrange a second appointment.

At the second appointment, the pharmacist will provide you with a Medication Diary that you can use to record the medicines you take each day. This will also contain a list of all the medicines that your GP prescribes for you. You will also discuss solutions to problems you may be facing with your medicines. Your pharmacist will then arrange a third and final appointment to find out how you got on with these solutions.

After you have attended all three appointments a member of the research team will telephone you to ask you some questions about the service. You will also be asked to complete a short questionnaire, about your medicines and general health, three months after the appointments. The researcher will post this out to you along with a pre-paid return envelope.

With your permission, the pharmacist will provide us with some feedback on the appointments. This will include information on any problems that you discussed in relation to taking your medicines and any solutions put in place to help you. You will not be identified in any reports or publications. The pharmacist will also provide us with information about the medicines you collect from the pharmacy in the six months before the service and in the three months after the service. We will use all of this information to see if our service is helpful to patients.

Are there any risks or disadvantages of taking part in the study?

There is little risk to you if you take part in the study and you can decide to stop at any time. It is possible that the service may make you think about your health. If you find this distressing, you can stop at any time.

What are the benefits of taking part in the study?

By taking part in this study you will be providing information which will help us test our service. This service aims to help patients who take several medicines every day.

What will happen if you decide you no longer wish to take part?

You are free to withdraw from the study at any time. If you decide to do so, the information recorded up until the time you left the study may still be included in the report. Your normal medical care will not be affected if you decide you no longer wish to take part.

Appendix 4.21 (cont'd): Patient study information sheet (feasibility study)

Will your details be kept confidential?

All information collected, as part of this study, will be kept confidential and will only be accessible to the research team. Your name will not appear in any publications. Your Pharmacist will not be told about anything you say to the researchers when they telephone you after the appointments. Information collected during the study, including your signed consent forms, will be stored securely in the School of Pharmacy, Queen's University Belfast. It will be kept for five years and then destroyed. This is in line with the Data Protection Act (1998).

However, if we find something that suggests that you have been given the wrong treatment or that a health care professional has not acted in the correct way, we may need to report this to the appropriate authority.

In order to ensure that studies involving patients are carried out to a high standard, the University is required to monitor on-going research studies. This means staff from the Queen's University Governance Office may need to review the information collected as part of this research study but you will not be identified in any way.

What will happen to the results of the research?

The results from the study will be used as part of a research project at Queen's University Belfast. The results may be presented at conferences or published in academic journals. All results will be anonymous and you will not be identified. You will be provided with a report of the results at the end of the study.

Who is organising and funding the research?

This research is being organised by the School of Pharmacy at Queen's University Belfast. It is funded by the Harold and Marjorie Moss Charitable Trust Fund.

Who has reviewed the study?

The study has been reviewed by two independent scientific reviewers and approved by the Office for Research Ethics Committees in Northern Ireland.

Who can you contact for further information?

Please do not hesitate to contact the researchers (as detailed below) if you have any questions about the research study:

Deborah Patton
Postgraduate Researcher
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast BT9 7BL
Telephone: (028) 902097 2033
Email: dpatton08@qub.ac.uk

Prof. Carmel Hughes
Professor of Primary Care Pharmacy
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast BT9 7BL
Telephone: (028) 9097 2147
Email: c.hughes@qub.ac.uk

Dr. Cristín Ryan
RCSI School of Pharmacy
Royal College of Surgeons in Ireland
123 St. Stephens Green, D2, Ireland
Telephone: 03531 402 8689
Email: cristinryan@rcsi.ie

Appendix 4.22: Patient study consent form 2 (feasibility study)

Study Title: Testing of a new pharmacy service to help patients who are prescribed several medicines

Please initial the following statements.	Initials
1. I have read (or someone has read to me) the information that I have received in relation to the above study and have asked any necessary questions. I understand what the study involves.	
2. I agree to attend three appointments in my local pharmacy. I understand that I will be asked questions about my general health and medicines during these appointments.	
3. I give permission for my pharmacist to share any information with my GP, or ask my GP for information on the medicines that I take for my medical conditions, if this is necessary.	
4. I agree to take part in a telephone interview with a researcher shortly after my last appointment and complete a short questionnaire after three months. I give permission for the telephone interview to be audio recorded.	
5. I understand that I may withdraw from the study at any time without giving a reason and that this will not affect my medical care. I understand that any information recorded up until this time may still be included in the report.	
6. I understand that my personal information will be confidential and stored safely in the School of Pharmacy, Queens University Belfast (QUB). I am aware that any results from the study will be anonymous.	
7. I understand that relevant sections of information collected during the study may be looked at by researchers involved in the study, or from QUB, for audit purposes.	
8. I agree to take part in this study.	

Please write your name, sign and date the form below.

Participant Name (Print):

Participant Signature: Date:

Pharmacist Name (Print):

Pharmacist Signature: Date:

Appendix 4.23: Recruitment/retention form

Patient Recruitment/retention Form

Recruitment checklist

IMPORTANT: All blue boxes must be ticked before proceeding with Appointment 1

	Yes	No
Purpose of the research study explained		
Patient has been given a study information sheet and Consent Form 2 to read at home		
Patient has verbally consented to taking part in the study when contacted via telephone after one week (date of verbal consent:_____)		
A date for Appointment 1 has been set (Time and date:_____)		
Patient has been contacted the day before Appointment 1 as a reminder		
Consent Form 2 returned and completed together at Appointment 1		
Patient understands what they will be required to do as part of the study		

Patient officially recruited into the research study (only when all blue boxes above are ticked)

YES ☐ → Proceed with Appointment 1 NO ☐ → Detail reason(s) below

Date of official recruitment:

Reason(s) patient was not recruited into the study

(please detail_____)

GP communication during the study

	Tick if applicable/ completed
GP referral required during study period (state reason_____)	
GP communication form completed *(please attach a photocopy to this form)*	

Action taken by GP (if known, please detail):_____

_____

Non-completion of the study

Patient dropped out during the study (date of drop-out: _____)	
Did not attend Appointment 1	
Did not attend Appointment 2	
Did not attend Appointment 3	

Reason known (please provide details_____)

Patient ID:

Appendix 4.24: GP information letter

Queen's University Belfast

Date:

Dear (insert General Practitioner's name),

Re: Feasibility testing of the ID-MAP (IDentification of Medication Adherence Problems) intervention in older adults prescribed polypharmacy in primary care

I am writing to inform you about a research study that is happening in a community pharmacy in your local area (*insert community pharmacy name*). This study will involve testing the above intervention in older adults who are prescribed four or more medications. The ID-MAP intervention has been developed based on findings from research involving discussions with older adults from across Northern Ireland about their medication-taking behaviour. As an outcome of this research, we have developed an intervention to target key adherence problems identified. The background research involved input from a multi-disciplinary team (including academic and practising pharmacists, general practitioners (GPs), a geriatrician and a Health Psychologist).

As part of this intervention, we have developed an adherence assessment tool that will assist pharmacists to identify the main problems faced by individual patients and the best solutions to overcome these. This will allow the intervention to be tailored to the patient's needs. The pharmacist will make every effort to resolve problems faced by patients, but in some instances, it may be more appropriate to refer the patient back to their GP. Should this occur, a communication form will be sent with details of any problems identified and, if appropriate, suggestions for your consideration. If you wish to be kept informed of the recommendations made to your patients during the appointments in the pharmacy, this can be forwarded to you for information. The communication form will clearly indicate whether any action is required on your part or if it is solely for information purposes.

We appreciate the time you have taken to read this letter. If you have any queries, please do not hesitate to contact your local community pharmacist *(insert name)* or any member of the research team using the contact details provided below.

Yours sincerely,

Prof. Carmel Hughes

Professor of Primary Care Pharmacy, Queen's University Belfast.

Appendix 4.24 (cont'd): GP information letter

On behalf of the research team and the participating community pharmacy (insert name):

Deborah Patton, Prof. Carmel Hughes, Dr. Cristín Ryan, (insert pharmacists name)

Contact details for more information:

(Insert community pharmacist details here)

Deborah Patton
Postgraduate Researcher
School of Pharmacy
Queen's University Belfast
97 Lisburn Road, Belfast BT9 7BL
Telephone: (028) 902097 2033
Email: dpatton08@qub.ac.uk

Prof. Carmel Hughes
Professor of Primary Care Pharmacy
School of Pharmacy
Queen's University Belfast
97 Lisburn Road, Belfast BT9 7BL
Telephone: (028) 9097 2147
Email: c.hughes@qub.ac.uk

Dr. Cristín Ryan
Senior Lecturer in Pharmacy Practice
School of Pharmacy
Royal College of Surgeons in Ireland
123 St. Stephens Green, D2, Ireland
Telephone: 03531 402 8689
Email: cristinryan@rcsi

Appendix 4.25: EQ-5D-5L questionnaire

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- I have no problems in walking about ❑
- I have slight problems in walking about ❑
- I have moderate problems in walking about ❑
- I have severe problems in walking about ❑
- I am unable to walk about ❑

SELF-CARE

- I have no problems washing or dressing myself ❑
- I have slight problems washing or dressing myself ❑
- I have moderate problems washing or dressing myself ❑
- I have severe problems washing or dressing myself ❑
- I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

- I have no problems doing my usual activities ❑
- I have slight problems doing my usual activities ❑
- I have moderate problems doing my usual activities ❑
- I have severe problems doing my usual activities ❑
- I am unable to do my usual activities ❑

PAIN / DISCOMFORT

- I have no pain or discomfort ❑
- I have slight pain or discomfort ❑
- I have moderate pain or discomfort ❑
- I have severe pain or discomfort ❑
- I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

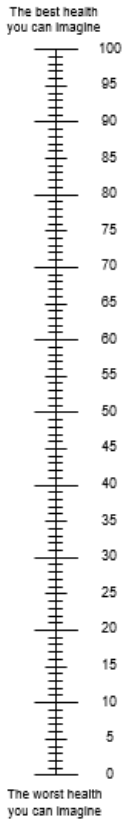
- I am not anxious or depressed ❑
- I am slightly anxious or depressed ❑
- I am moderately anxious or depressed ❑
- I am severely anxious or depressed ❑
- I am extremely anxious or depressed ❑

2

Appendix 4.25 (cont'd): EQ-5D-5L questionnaire

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Appendix 4.26: Permission for use of EQ-5D-5L

RE: Your request to use EQ-5D has been sent

Gerben Bakker <bakker@euroqol.org>

Wed 25/11/2015 10:59

important

To:Deborah Patton <dpatton08@qub.ac.uk>;

Cc:Mandy van Reenen <vanreenen@euroqol.org>;

1 attachments (81 KB)

Effective_UK (English) EQ-5D-5L Paper Self complete v1.0.docx;

Dear Deborah,

I'll merge the 2 requests. Please find the 5L version attached.

Best regards,

Gerben Bakker
User Support Officer
EuroQol Research Foundation

T: + 31 88 4400189
E: bakker@euroqol.org
W: www.euroqol.org

From: Deborah Patton [mailto:dpatton08@qub.ac.uk]
Sent: woensdag 25 november 2015 11:58
To: Gerben Bakker <bakker@euroqol.org>
Cc: Mandy van Reenen <vanreenen@euroqol.org>
Subject: Re: Your request to use EQ-5D has been sent

Dear Gerben,

Thank you for the reply. I seem to have missed that email. Thanks.

Would it be possible to request the use of the EQ-5D-5L instead? I have submitted another request to use this version. Apologies for the confusion.

Many thanks

Deborah Patton

-------- Original message --------
From: Gerben Bakker <bakker@euroqol.org>
Date: 25/11/2015 10:31 (GMT+00:00)
To: Deborah Patton <dpatton08@qub.ac.uk>
Cc: Mandy van Reenen <vanreenen@euroqol.org>
Subject: RE: Your request to use EQ-5D has been sent

Appendix 4.26 (cont'd): Permission for use of EQ-5D-5L

28/07/2017 Mail – dpatton08@qub.ac.uk

Dear Deborah,

You may have missed the following reply sent to you on October 27th.
Attachment: Effective_UK (English) EQ-5D-3L Paper Self complete v1.0 (ID 23961).docx

Subject: EQ-5D registration
Body:
Dear Ms/Mr. deborah patton,

Thank you for registering your research at the EuroQol Reseach Foundation's website.

As the "Feasibility testing of the ID-MAP (IDentification of Medication Adherence Problems) intervention in older adults receiving polypharmacy in primary care" study you registered involves low patient numbers (20) you may use the EQ-5D-3L instrument (Paper version) free of charge. Please note that separate permission is required if any of the following is applicable:

- Funded by a pharmaceutical company, medical device manufacturer or other profit-making stakeholder;
- Number of respondents over 5000
- Routine Outcome Measurement;
- Developing or maintaining a Registry;
- Digital representations (e.g. PDA, Tablet or Web)

Please find attached the English (United Kingdom) EQ-5D-3L Paper version (word format). A brief user guide is downloadable from the EuroQol website (www.euroqol.org)

Kind regards,

Mandy van Reenen
Communications Specialist
EuroQol Research Foundation
T: +31 88 4400190
E: vanreenen@euroqol.org
W: www.euroqol.org

Best regards,

Gerben Bakker
User Support Officer
EuroQol Research Foundation

T: + 31 88 4400189
E: bakker@euroqol.org
W: www.euroqol.org

Appendix 4.27: Semi-structured interview topic guide for community pharmacist feedback interview

Pharmacist (face-to-face) feedback interview guide

Introduction

Good morning/afternoon and thank you for agreeing to take part in this feedback interview. The aim of this interview is to find out about your experience with delivering the ID-MAP intervention to older patients in your clinical practice. During the interview you will be asked about the training you received, the materials used in the intervention, the practicality of delivering such an intervention in your everyday practice and your overall experience with it. Please feel free to share your own views and opinions, both positive and negative. Your feedback will be very important in refining this intervention for future testing.

The interview should last around one hour. I would like to remind you that this interview will be audio-recorded, however, anything that you say during the interview will be kept confidential and will not be attributed to you in any way. We can stop the interview at any time, or if you would prefer not to answer a question then please let me know and we can move onto the next one.

Do you have any immediate questions before we get started with the interview?

[Turn on digital recorder]

1. To start off with, could you tell me how many years you have been practising as a community pharmacist?
2. What is your current job title (e.g. manager, second pharmacist)?
3. How long have been in your current position?

Intervention training and support

4. At the beginning of this research study we held a short on-site training session. What did you think about this training session?
   Prompt: *What did you like or dislike about it?*
5. What could be done to improve the training session?
   Prompt: *Is there anything you would have liked more training or instructions on?*
6. What would your views be on a more in-depth training session, for example at a one-day workshop held at the University? *(Note: Pharmacists would be reimbursed for travel expenses and locum cover)*
7. Can you think of anything that should be covered at a one-day workshop that might be beneficial for pharmacists involved in the future testing of this intervention?
   Prompts: *Role play scenarios with patient actors, opportunity to practise sessions, peer discussions, Q&A sessions*
8. How confident were you in delivering this type of intervention?
   Prompts: *Would your confidence be affected if the patient was resistant to change or intentionally non-adherent?*
9. Do you think it would be beneficial to have an expert in behaviour change e.g. health psychologist involved in training pharmacists to deliver this type of behaviour change intervention?
   Prompts: *For example, training in how to motivate patients to change their behaviour, dealing with resistant patients?*
10. Is there anything the research team could have done to better support you with delivering the intervention?
    Prompts: *More support between sessions, help with screening patients and recruitment, more help with data collection*
11. How have you found the overall level of communication during the research study?
    Prompts: *What is the best way to communicate with community pharmacists involved in this type of research? On-site visits, telephone calls, emails.*

Appendix 4.27 (cont'd): Semi-structured interview topic guide for community pharmacist feedback interview

Intervention manual/example patient scenarios

To supplement the on-site training, we also provided you with an intervention manual outlining the requirements for delivering the ID-MAP intervention.

12. What did you think about the intervention manual?

    Prompts: *Would you recommend any changes to the content/format/type of information covered?*

13. What did you think of the two example patient scenarios provided?

    [Show copies as a reminder if necessary]

    Prompts: *Were they realistic/helpful/useful? Have you any suggestions for improving these?*

Patient screening

For the first part of this study we asked you to approach patients who met the initial eligibility criteria. These patients were then asked to complete the screening questionnaire to see if they could potentially benefit from this type of adherence intervention.

14. How did you find the eligibility screening process?
15. What did you think of the eligibility criteria that we had proposed?

    [Show list of eligibility criteria as a reminder and ask about each one]

    Prompts: *Were the criteria too restrictive/too broad? Did we miss out any criteria that you think might be important?*

16. What did you think of the documentation that you were asked to complete for the screening process (i.e. eligibility screening form with checklist, Consent Form 1)? [Show copies as a reminder]

    Prompts: What improvements are needed?

17. What did you think of the Eligibility Screening Questionnaire which included 8 questions about the patient's medication adherence? [Show copy as a reminder]

    Prompts: *When did you ask patients to complete this?*

18. Do you think anyone else could perform this eligibility screening process?

    Prompts: *For example, pharmacy support staff (e.g. dispensing technicians, medicine counter assistants)? If so, what type of training would they need?*

Patient recruitment

We then asked you to recruit eligible patients into the study and invite them along to a number of appointments in the pharmacy.

19. How did you find the recruitment process?

    Prompts: *Did you experience any problems recruiting eligible patients into the study? Could we do anything to improve the recruitment process or better support you with this?*

20. What did you think of the documentation that was required for the recruitment process (i.e. study consent form 2, Patient information sheet, recruitment form)? [Show copies as a reminder]

    Prompts: What improvements are needed?

21. What did you think of the health-related quality of life questionnaire that you instructed patients to complete at the start of Appointment 1? [Show copy as a reminder]

    Prompts: *Was this the best time to ask patients to complete this? Could pharmacy support staff be involved in collecting this type of information from patients?*

Structure and number of appointments

22. What did you think of the structure and number of appointments we proposed for the intervention?

    Prompts: *Suggested appointment length; time periods between appointments, should this be changed and why?*

23. *If applicable:* What influenced your decision to deliver the intervention over two appointments as opposed to three?

    Prompts: *Do you think two sessions is sufficient for identifying issues, providing solutions and maintaining behaviour change in older patients?*

24. On average how long did the appointments last?

    Prompt: *What proportion of this was delivering the intervention? Should they be longer or shorter?*

ID-MAP Booklet

A separate booklet was completed for each patient who attended appointments in the pharmacy.

25. What did you think of the ID-MAP Booklet?

    [Show copy as a reminder if necessary]

    Prompts: *Was the booklet easy or difficult to complete? Did the booklet help guide the appointments? What did you think of the format/layout/level of information provided?*

26. What did you think of the ID-MAP adherence assessment Tool included in Section 2 of the booklet?

    Prompts: *Did this tool help you to identify adherence problems/guide your selection of adherence solutions? Did you find it too restrictive/too comprehensive? Did you have to re-word any of the questions?*

27. Do you have any suggestions for improving the ID-MAP Booklet or adherence assessment Tool?

    Prompts: *Changes to layout, content, format*

28. What are your views on having an electronic version of the ID-MAP Booklet and adherence assessment Tool, for example on an IPAD app to help reduce the amount of paperwork?

Patient medication diary

As part of this intervention, each patient was offered a Medication Diary. [Show copy as a reminder]

29. What did you think about this diary?

    Prompts: *Was it straightforward or too time-consuming to prepare? Could your pharmacy staff be involved in preparing this solution? Do you think this should be given to patients at their first appointment?*

30. Do you have any suggestions for improving the diary?

    Prompts: *Changes to layout/information/size*

31. In your opinion, how did the patients find the medication diary?

    Prompts: *Should we provide more detailed written/photographic instructions along with the diary?*

32. How did you make use the diary at the follow-up appointment?

    Prompts: *For example, did you discuss missed doses with patients? How comfortable did you feel doing this?*

33. Should the medication diary be offered to all patients with adherence problems?

    Prompts: *Should it be offered as a short-term solution over a few weeks or months or used as an ongoing solution until no longer required by the patient? Should there be an assessment of the patient's ability to use the diary?*

Appendix 4.27 (cont'd): Semi-structured interview topic guide for community pharmacist feedback interview

Other optional adherence solutions

In addition to the medication diary, there were a number of other optional solutions which could be recommended or delivered based on the patient's need, such as practical, reminder and social support strategies or a discussion around medication concerns using the leaflets provided.

[Show copies of Solution Guides as a reminder if necessary]

34. Did you recommend any of these additional solutions to your patients at their first appointment?
    ***Prompts**: What did you think about these solutions? What did you like or dislike about them? Did the patients find them helpful?*
35. How did you go about selecting the best solution(s)?
    ***Prompt**: Did the patients put forward their own ideas or contribute to the selection of solutions?*
36. Did you recommend any of these additional solutions or provide further advice at each patient's follow-up appointment?
37. If applicable…for the solutions that you did not provide (e.g. leaflets, reminder stickers), do you think these might be beneficial for other patients under different circumstances?
38. Could any of the adherence solutions be removed from the intervention?
    ***Prompt**: Why?*
39. Are there any solutions missing from the intervention that you think might be useful?

Goals and action plan

You also completed a goals and action plan sheet for each patient as part of this intervention.

[Show copy as a reminder]

40. What did you think about doing this?
    ***Prompts**: Is there anything you particularly liked or disliked about this?*
41. What did you think of the IF-THEN format that we suggested for creating an action plan?
42. Do you think an overall general health goal should be discussed with all patients, even those who are highly motivated?
43. In your opinion, how did patients find the activity of setting medicine and general health goals and developing an action plan?
    ***Prompts**: Do you think they understood the purpose of it? Do you think this solution is relevant for all patients? Did you think it was useful to write this information down for patients?*
44. How did you get on with reviewing each patient's goals at their follow-up appointment?
45. Is there anything else you think could be improved or changed in relation to this solution?

Overall intervention experience/future implementation

46. Overall, how would you describe your experience with delivering the ID-MAP intervention?
    ***Prompts**: What aspect did you particularly like or dislike? If you could add anything in or change any aspect of this intervention, what would this be?*
47. How often do you think an adherence assessment (i.e. diagnosing adherence issues) should be conducted with older patients who are prescribed four or more medications?
    ***Prompts**: As a one-off intervention; repeated at specified intervals (e.g. annually, six monthly); at each dispensing*
48. How often do you think adherence solutions should be reviewed?
    ***Prompts**: Should patients be followed up again after a specified period of time to check if the solutions are still working or if new ones are necessary e.g. in 6 months, 12 months?*
49. What outcomes do you think are important when assessing whether this type of adherence intervention has been effective?
    ***Prompts**: Patient reported effectiveness of recommended adherence strategies, patient satisfaction, clinical outcomes (e.g. improvements in symptoms), changes in self-reported adherence*
50. In your opinion, is the ID-MAP intervention, including the initial screening process, feasible in the community pharmacy setting?
    ***Prompts**: What modifications would be required? Where and by whom should it be delivered instead? Should another healthcare professional be responsible for supporting older patients with adherence?*
51. How easy or difficult would it be to implement such an intervention in your everyday practice?
    ***Prompts**: Can you think of any potential barriers? What might help to implement this type of intervention into practice?*
52. If this intervention was funded as a community pharmacy service, would you be willing to provide this in your everyday clinical practice?
    ***Prompt**: What level of payment would you expect to be reimbursed for providing this type of intervention?*

Round up

That brings us to the end of this interview. Thank you very much for participating in this research study so far and for all of your feedback on the intervention.

Is there anything that you feel has not been covered? Do you have any further comments that you would like to make?

Thanks very much for taking the time out to talk to me today.

[Turn off digital recorder]

Appendix 4.28: Semi-structured interview topic guides for patient feedback interview (Site 01 and Site 02)

Patient feedback interview guide (Site 01)

Introduction

Good morning/afternoon Mr/Mrs/Ms (insert full name). My name is Deborah Patton and I am a researcher at the School of Pharmacy, Queen's University Belfast. I am telephoning in relation to a research study that you have been taking part in at your community pharmacy, X pharmacy, X. I was speaking with your pharmacist (X) and he said you were happy for me to give you a call to get some feedback on the service. Is now a good time for you to talk?

Thank you very much for taking part in this research study so far and for agreeing to speak to me to today. Would you prefer me to call you Mr/Mrs/Ms (insert surname) or (insert forename)? The aim of this interview is to find out about your experiences of the service you received from your pharmacist as part of the research study. During the interview you will be asked about the appointments you attended in the pharmacy and the advice you received to help you get the most from your medicines. Please feel free to share your own views and opinions, both positive and negative. There are no right or wrong answers. Your feedback is very important in making sure that this service will be helpful for other patients who are taking several medicines in the future. Anything that you say during this interview will be strictly confidential and your name will not appear on any reports or publications from this research.

I have prepared a list of questions to help guide the interview. It should take about 45 minutes and it will be audio-recorded to make sure that I don't miss anything important. If you would prefer not to answer a particular question or would like to stop the interview at any time, then please let me know. Are you happy for me to start the audio-recording and begin the interview?

[Start audio-recording]

To start us off, would you mind telling me how long you have been attending your current community pharmacy?

Patient screening/recruitment

Before you took part in this research study, your pharmacist asked you to complete a short questionnaire about the medicines that you take every day. The purpose of this was to find out if you might benefit from the new service. This questionnaire included eight questions about your medicines, for example 'Do you sometimes forget to take your medicines?'.

1. Can you tell me what you thought about this questionnaire?
   Prompts: Were you given enough information about the questionnaire before completing it? Did you understand all of the questions? How easy or difficult was this to complete? Did you feel comfortable answering the questions?

After you completed this questionnaire, your pharmacist invited you to take part in the full research study and gave you an information sheet to take home and read.

2. What did you think about this information sheet?
   Prompts: Was this easy or difficult to understand? Would you have liked more or less information?

3. Did you have any additional questions about the research study that weren't answered in the information sheet?
   Prompts: Was the pharmacist able to answer any additional questions that you had?

Appointment 1

You were then asked to attend the pharmacy for your first appointment of the service. At the start of this appointment your pharmacist asked you to fill-in another short questionnaire. This was about your general health and how you were feeling. For example, it included questions about your mobility and how you get about and your level of pain or discomfort.

4. What did you think about this questionnaire?
   Prompts: Did you understand all of the questions? How easy or difficult was this to complete? Did you feel comfortable answering the questions?

You then went on to discuss how you manage your medicines when you are at home.

5. How did you feel about discussing your medicines with your pharmacist?
   Prompts: Did you understand all of their questions? Did you feel comfortable answering their questions?

6. Was there anything about your medicines that you wanted to discuss but didn't get the opportunity to talk about at this first appointment?
   Prompts: Did you have enough time to discuss all of the issues that were important to you?

Appointment 2

Patient medication diary

You were then invited along to a second appointment in the pharmacy. At this appointment your pharmacist provided you with a medicines diary that included a list of all of your regular medicines.

7. Can you tell me what you thought about this diary?
   Prompts: What did you particularly like or dislike about the diary?

8. Were you given instructions on how to use the diary?
   Prompts: Were these instructions helpful or unhelpful? Were these instructions easy or difficult to understand?

9. How did you get on with using this diary when you were at home?
   Prompts: Were you able to use the diary every day? Did it help you with taking your medicines?

10. Do you have any suggestions for improving the diary?
    Prompts: How did you find the layout/size of writing?

11. Could you see yourself using this type of diary on a long-term basis?

12. Would you recommend the diary to other patients who are prescribed several medicines?

Appendix 4.28 (cont'd): Semi-structured interview topic guide for patient feedback interview (Site 01 and Site 02)

Other adherence solutions [Only ask questions 13-15 if Solution B and/or C were delivered]

13. *(If applicable)...* Did the pharmacist provide or recommend anything else at this appointment to help you take your medicines?
    Prompts: Did they give you any leaflets or reminder sticker? Did they have any other suggestions about what might help you? Did the pharmacist suggest any changes to your medicines or how you take them?
14. *(If applicable)...* What did you think of the reminder sticker/advice/suggestion?
    Prompts: Did you find this useful? Did this help you to take your medicines every day? What did you like or dislike about this?
15. *(If applicable)...* What did you think of the leaflet on 'Voicing concerns about your medicines'/'Generic medicines'?
    Prompts: What did you think of the information provided? Was this easy or difficult to understand? How did you find the layout/size of writing?
16. Were you able to discuss any concerns or worries you had about your medicines at this first appointment?
17. Is there anything else that you would have liked that your pharmacist did not recommend or offer?

Goals and action plan

Together with your pharmacist, you then set a medicine goal(s) and agreed on an action plan to help you get the most from your medicines. Your pharmacist wrote this information on a sheet for you to take home.

18. What did you think about setting a medicine goal (or goals) and making an action plan to help you take your medicines?
    Prompts: Was this helpful or unhelpful? Was this task easy or difficult to understand?
19. What did you think of the written sheet given to you to take home?
    Prompts: Was this easy or difficult to understand? How did you find the layout/size of writing?

Summary of Appointment 2

20. Overall, how would say you found this second appointment?
    Prompts: Was it too long or too short? Did you find it helpful or unhelpful?

Appointment 3 (follow-up)

You were then asked to come in for a final follow up appointment in the pharmacy to find out how you got on with the diary and everything else you discussed at the previous appointment.

21. How did you get on at this final appointment with your pharmacist?
    Prompts: Was it too long or too short? Did you find it helpful or unhelpful?
22. Can you tell me a bit about what you talked about at this final appointment?
    Prompt: Did the pharmacist take a look at the diary and ask you how you got on with this? Did you talk about the reminder sticker/advice/suggestions from the last appointment? Did the pharmacist ask how you got on with your medicine goal(s) and action plan?
23. Was there anything you wanted to discuss during this final appointment but did not get the opportunity to?

Overall service experience

24. Overall, how would you describe your experience of the service?
    Prompts: What parts of the service did you particularly like? What parts of the service did you dislike?
25. What did you think about the number of appointments you were asked to attend? (i.e. three appointments)
    Prompts: Would you have preferred to attend more or less appointments? Would you have preferred a number of shorter appointments?
26. How did you feel about receiving this service from your pharmacist?
    Prompts: Were you happy to discuss your medications with your pharmacist? Would you have preferred to receive this service from a different healthcare professional involved in your care e.g. doctor, nurse?
27. Do you think this service has influenced how you take your medicines? If so, how do you think it has helped?
    Prompts: Has it reduced how often you miss taking your medicines? Has it helped to address your worries or concerns?
28. Would you recommend this service to other patients?
29. What do you think would be the best way to advertise or promote the service to other patients?
30. Finally, have you any further suggestions for improving the service that you would like to add?

Round up

That brings us to the end of this interview. Thank you very much for participating in this research study and for all of your feedback on the service. The final thing that we will ask you to do for this study is to complete one last questionnaire in approximately three months' time. I will post this out to you and include a free postage return envelope so that you can return this to me without charge. The questionnaire should take no longer than 10-15 minutes to complete and will ask you again about your medicines and general health. A copy of the results from this research study will be posted out to you once all of the interviews and telephone calls have been completed. Have you any questions that you would like to ask me before we finish the interview? **[End audio-recording]**

Appendix 4.28 (cont'd): Semi-structured interview topic guide for patient feedback interview (Site 01 and Site 02)

Patient feedback interview guide (Site 02)

Introduction

Good morning/afternoon Mr/Mrs/Ms (insert full name). My name is Deborah Patton and I am a researcher at the School of Pharmacy, Queen's University Belfast. I am telephoning in relation to a research study that you have been taking part in at your community pharmacy, X. I was speaking with your pharmacist (X) and they said you were happy for me to give you a call to get some feedback on the service. Is now a good time for you to talk? Thank you very much for taking part in this research study so far and for agreeing to speak to me to today. Would you prefer me to call you Mr/Mrs/Ms (insert surname) or (insert forename)?

The aim of this interview is to find out about your experiences of the service you received from your pharmacist as part of the research study. During the interview you will be asked about the appointments you attended in the pharmacy and the advice you received to help you get the most from your medicines. Please feel free to share your own views and opinions, both positive and negative. There are no right or wrong answers. Your feedback is very important in making sure that this service will be helpful for other patients who are taking several medicines in the future. Anything that you say during this interview will be strictly confidential and your name will not appear on any reports or publications from this research.

I have prepared a list of questions to help guide the interview. It should take about 45 minutes and it will be audio-recorded to make sure that I don't miss anything important. If you would prefer not to answer a particular question or would like to stop the interview at any time, then please let me know. Are you happy for me to start the audio-recording and begin the interview?

[Start audio-recording]

To start us off, would you mind telling me how long you have been attending your current community pharmacy?

Patient screening/recruitment

Before you took part in this research study, your pharmacist asked you to complete a short questionnaire about the medicines that you take every day. The purpose of this was to find out if you might benefit from the new service. This questionnaire included eight questions about your medicines, for example 'Do you sometimes forget to take your medicines?'.

1. Can you tell me what you thought about this questionnaire?
   Prompts: Were you given enough information about the questionnaire before completing it? Did you understand all of the questions? How easy or difficult was this to complete? Did you feel comfortable answering the questions?

After you completed this questionnaire, your pharmacist invited you to take part in the full research study and gave you an information sheet to take home and read.

2. What did you think about this information sheet?
   Prompts: Was this easy or difficult to understand? Would you have liked more or less information?

3. Did you have any additional questions about the research study that weren't answered in the information sheet?
   Prompts: Was the pharmacist able to answer any additional questions that you had?

Appointment 1 and 2 (combined by Site 02)

You were then asked to attend the pharmacy for your first appointment of the service. At the start of this appointment your pharmacist asked you to fill-in another short questionnaire. This was about your general health and how you were feeling. For example, it included questions about your mobility and how you get about and your level of pain or discomfort.

4. What did you think about this questionnaire?
   Prompts: Did you understand all of the questions? How easy or difficult was this to complete? Did you feel comfortable answering the questions?

You then went on to discuss how you manage your medicines when you are at home.

5. How did you feel about discussing your medicines with your pharmacist?
   Prompts: Did you understand all of their questions? Did you feel comfortable answering their questions?

6. Was there anything about your medicines that you wanted to discuss but didn't get the opportunity to talk about?
   Prompts: Did you have enough time to discuss all of the issues that were important to you?

Patient medication diary

During the first appointment your pharmacist provided you with a medicines diary that included a list of all of your regular medicines.

7. Can you tell me what you thought about this diary?
   Prompts: What did you particularly like or dislike about the diary?

8. Were you given instructions on how to use the diary?
   Prompts: Were these instructions helpful or unhelpful? Were these instructions easy or difficult to understand?

9. How did you get on with using this diary when you were at home?
   Prompts: Were you able to use the diary every day? Did it help you with taking your medicines?

10. Do you have any suggestions for improving the diary?
    Prompts: How did you find the layout/size of writing?

11. Could you see yourself using this type of diary on a long-term basis?

12. Would you recommend the diary to other patients who are prescribed several medicines?

Appendix 4.28 (cont'd): Semi-structured interview topic guide for patient feedback interview (Site 01 and Site 02)

Other adherence solutions

[Only ask questions 13-15 if Solution B and/or C were delivered]

13. *(If applicable)…* Did the pharmacist provide or recommend anything else to help you take your medicines?
    Prompts: Did they give you any leaflets or reminder sticker? Did they have any other suggestions about what might help you? Did the pharmacist suggest any changes to your medicines or how you take them?
14. *(If applicable)…* What did you think of the reminder sticker/advice/suggestion?
    Prompts: Did you find this useful? Did this help you to take your medicines every day? What did you like or dislike about this?
15. *(If applicable)…* What did you think of the leaflet on 'Voicing concerns about your medicines'/'Generic medicines'?
    Prompts: What did you think of the information provided? Was this easy or difficult to understand? How did you find the layout/size of writing?
16. Were you able to discuss any concerns or worries you had about your medicines at this first appointment?
17. Is there anything else that you would have liked that your pharmacist did not recommend or offer?

Goals and action plan

Together with your pharmacist, you then set a medicine goal(s) and agreed on an action plan to help you get the most from your medicines. Your pharmacist wrote this information on a sheet for you to take home.

18. What did you think about setting a medicine goal (or goals) and making an action plan to help you take your medicines?
    Prompts: Was this helpful or unhelpful? Was this task easy or difficult to understand?
19. What did you think of the written sheet given to you to take home?
    Prompts: Was this easy or difficult to understand? How did you find the layout/size of writing?

Summary of Appointment 1 and 2

20. Overall, how would say you found this first appointment?
    Prompts: Was it too long or too short? Did you find it helpful or unhelpful?

Appointment 3 (follow-up)

You were then asked to come in for a final follow up appointment in the pharmacy to find out how you got on with the diary and everything else you discussed at the previous appointment.

21. How did you get on at this final appointment with your pharmacist?
    Prompts: Was it too long or too short? Did you find it helpful or unhelpful?
22. Can you tell me a bit about what you talked about at this final appointment?
    Prompt: Did the pharmacist take a look at the diary and ask you how you got on with this? Did you talk about the reminder sticker/advice/suggestions from the last appointment? Did the pharmacist ask how you got on with your medicine goal(s) and action plan?
23. Was there anything you wanted to discuss during this second appointment but did not get the opportunity to?

Overall service experience

24. Overall, how would you describe your experience of the service?
    Prompts: What parts of the service did you particularly like? What parts of the service did you dislike?
25. What did you think about the number of appointments you were asked to attend?
    Prompts: Would you have preferred to attend more or less appointments? Would you have preferred a number of shorter appointments?
26. How did you feel about receiving this service from your pharmacist?
    Prompts: Were you happy to discuss your medications with your pharmacist? Would you have preferred to receive this service from a different healthcare professional involved in your care e.g. doctor, nurse?
27. Do you think this service has influenced how you take your medicines? If so, how do you think it has helped?
    Prompts: Has it reduced how often you miss taking your medicines? Has it helped to address your worries or concerns?
28. Would you recommend this service to other patients?
29. What do you think would be the best way to advertise or promote the service to other patients?
30. Finally, have you any further suggestions for improving the service that you would like to add?

Round up

That brings us to the end of this interview. Thank you very much for participating in this research study and for all of your feedback on the service. The final thing that we will ask you to do for this study is to complete one last questionnaire in approximately three months' time. I will post this out to you and include a free postage return envelope so that you can return this to me without charge. The questionnaire should take no longer than 15-20 minutes to complete and will ask you again about your medicines and general health. A copy of the results from this research study will be posted out to you once all of the interviews and telephone calls have been completed. Have you any questions that you would like to ask me before we finish the interview? [End audio-recording]

Appendix 4.29: Summary of patients form

Summary of patients

Instructions for pharmacists: Please complete this table at the end of the study for all patients who were **successfully recruited** into the study

Patient ID	Patient Name	Address	Date of birth	Gender (M or F)	Number of prescribed medicines* (excluding PRN)

*regular medications

Summary of patients (continued)

Instructions for pharmacists

At the end of the study period please complete this table using the individual eligibility screening and recruitment forms completed for **all patients who were approached** to take part, regardless of whether they were successfully recruited or not.

	Total
Number of patients who refused on initial approach	
Number of patients approached that also attended other pharmacies for regular medications	
Number of patients approached that did not live in their own home	
Number of patients who did not complete all aspects of the Eligibility Screening Questionnaire	
Number of patients with high adherence (identified form the Eligibility Screening Questionnaire)	
Number of patients who did not attend Appointment 1	
Number of patients who did not attend Appointment 2	
Number of patients who did not attend Appointment 3	
Number of patients who did not return the medication diary	
Number of patients who completed all aspects of the service	
Overall number of patients approached	

Appendix 4.30: Completed TIDieR checklist

TIDieR item number	Description of item	Location where relevant information can be found
1.	**BRIEF NAME:** Provide the name or a phrase that describes the intervention.	Page 98
2.	**WHY:** Describe any rationale, theory, or goal of the elements essential to the intervention.	Theoretical basis described in Chapter 3. Content outlined on pages 102-107.
3. **4.**	**WHAT** **Materials:** Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL). **Procedures:** Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Pages 118-110 and Appendices 4.1 to 4.6. Pages 114-116 and Appendix 4.8 (training manual).
5.	**WHO PROVIDED:** For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Pages 111-112 and Appendices 4.8- 4.10.
6.	**HOW:** Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Page 94.
7.	**WHERE:** Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Page 94.
8.	**WHEN and HOW MUCH**: Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Page 106-107.
9.	**TAILORING:** If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Page 105.
10.	**MODIFICATIONS:** If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Yes CPs at one site delivered the intervention over two appointments instead of three: see pages 122-123.
11. **12.**	**HOW WELL** **Planned:** If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them. **Actual:** If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Self-reported fidelity assessed: see page 118 and results on pages 134-136.

Appendix 5.1: Approval letter from School of Pharmacy ethics Committee

Queen's University Belfast

School of Pharmacy

Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL
Tel 028 90972086
Fax 028 90247794

Deborah Patton
School of Pharmacy
MBC
Lisburn Road
Belfast

10 August 2016

Dear Deborah

Re: Application for approval by the School of Pharmacy Ethics Committee

Title: An exploration of community pharmacists' (CPs) experience of, and attitudes towards providing medication adherence support to older adults prescribed polypharmacy: a mixed methods approach

Project type: PhD

Staff: Professor Carmel Hughes / Dr Cristin Ryan

School Ref: 017PMY2016

The Committee reviewed the above application and raised no major ethical concerns and therefore ethical approval has been granted.

Yours sincerely,

Dr Heather Anderson
Chair, School of Pharmacy Ethics Committee

Copy: Professor Carmel Hughes

The Queen's Anniversary Prizes for Higher and Further Education 2011

Athena SWAN Silver Award

Appendix 5.2: Study invitation letter for community pharmacists (Phase 1: Interviews)

Queen's University Belfast

School of Pharmacy
Medical Biology Centre
97 Lisburn Rd
Belfast BT9 7BL
Tel: 028 90972033

Date

Dear (insert pharmacist's name),

Re: An exploration of community pharmacists' experience of, and attitudes towards providing medication adherence support to older adults prescribed polypharmacy

I am writing to invite you to take part in an interview as part of the above research study. This study is contributing to a PhD research project that is exploring medication adherence in older adults who are prescribed several medications (i.e. polypharmacy). Medication non-adherence is common in older adults, with approximately 50% failing to take medications as prescribed. Improved medication adherence has the potential to improve clinical outcomes for patients and reduce hospital/GP visits, as well as providing cost savings for the NHS. Community pharmacists are well-placed to support older adults with medication adherence but their views and attitudes in relation to this have not yet been explored in great detail.

The aim of this interview is therefore to gather information on pharmacists' experiences in relation to providing adherence support to older adults and views on a novel community pharmacist-led intervention that has been developed as part of an ongoing research project at Queen's University Belfast. We also want to identify what factors might hinder or facilitate your involvement in providing this type of adherence support to older patients.

The interview should last no longer than one hour and you will be offered £50 in recognition for taking the time out of your schedule to take part. I have enclosed a study information sheet which provides further details on the study.

We appreciate the time you have taken to read this letter and the enclosed information sheet. Please do not hesitate to contact any member of the research team (using the details provided in the information sheet) if you have any questions regarding the study. The researcher (Deborah Patton) will be in contact with you within one week of receiving this information to discuss if you would like to participate.

Yours sincerely,

Prof. Carmel Hughes (Chief Investigator/Head of School)

Appendix 5.3: Study information sheet for community pharmacists (Phase 1: Interviews)

Queen's University Belfast

Study Title: An exploration of community pharmacists' experience of, and attitudes towards providing medication adherence support to older adults prescribed polypharmacy

You are being invited to take part in a research study. Before you decide whether or not you would like to take part, it is important that you take time to understand why this research is being completed and what will be asked of you should you agree to participate.

Please read the following information and contact the researcher (Deborah Patton) or any other member of the research team if you have any queries. Contact details can be found at the end of this information sheet.

What is the purpose of this study?

Older adults commonly suffer from two or more long-term conditions and are routinely prescribed four or more medications (polypharmacy) to take on a regular basis. Approximately 50% of older patients do not take (or use) their medications as prescribed by their GP, and are therefore considered to be non-adherent. This non-adherent behaviour has been linked to poor clinical outcomes for patients, as well as increased attendance at GP practices, increased hospital admissions and rising healthcare costs. As the population of older patients continues to increase, improving medication adherence is a global challenge that requires the combined support of policy makers, healthcare professionals and researchers alike. Community pharmacists are recognised as the most accessible healthcare professional in the primary care setting who are well-placed to provide adherence support to older adults. The purpose of this study is to gather information on what pharmacists are currently doing in practice to support older patients with medication adherence and explore pharmacists' views on a novel intervention that includes a structured adherence assessment.

Why have you been chosen?

You have been asked to participate in this study because you are a pharmacist working in the community setting and are therefore ideally placed to support older adults with medication adherence. You are also part of the Community Pharmacy Placement Network at the School of Pharmacy, Queen's University Belfast (QUB) ***(include only if applicable)***.

Do you have to take part?

It is your decision whether or not you would like to take part in this study. Please read this information sheet and do not hesitate to contact the researcher or any other member of the research team, should you have any questions. If you do decide to take part, you will be asked to sign a consent form. You will be given a copy of this consent form. The original form will be stored securely in the School of Pharmacy, Queen's University Belfast (QUB). If you agree to take part, you are free to withdraw from the study at any time and are not required to give a reason.

What will happen if you take part?

The researcher (Deborah Patton) will contact you a minimum of one week after you receive this information sheet to discuss if you are interested in participating in the study. If you wish to participate in the study, you will be asked to take part in an interview that should last no longer than one hour. The interview can be arranged at a time and place that is convenient for you.

During the interview you will be asked about your experiences of supporting older patients with medication adherence, what factors influence the provision of this type of adherence support and your views on a novel intervention that includes a structured adherence assessment tool.

You will also be asked to provide details about yourself and your current position to give us an overview of the pharmacists who participate in the study. With your permission, the interview will be audio-recorded and transcribed by the researcher.

On completion of the interview, you will be offered a certificate of participation which can be added to your Continuing Professional Development (CPD) portfolio. You will also be offered an honorarium of £50 by way of compensation for your time.

Are there any risks or disadvantages of taking part in the study?

There is a small risk that poor practice may be identified during this study. In the unlikely event that this occurs, any cases will be reported to the Chief Investigator (Professor Carmel Hughes) who will take appropriate action on a case-by-case basis. This may involve informing the appropriate professional regulatory body (e.g. Pharmaceutical Society of Northern Ireland).

What are the benefits of taking part in the study?

There are no direct benefits to you for taking part in this research study. However, the findings will inform the ongoing development of strategies to improve medication adherence in older patients, for example, interventions aimed at patients and training packages for pharmacists.

What will happen if you decide you no longer wish to take part?

You are free to withdraw from the study at any time. However, any data collected prior to your withdrawal may still be used in the final results.

Appendix 5.3 (cont'd): Study information sheet for community pharmacists (Phase 1: Interviews)

Will your details be kept confidential?

All information collected as part of the study will be treated in a confidential manner. Your name or community pharmacy will not appear in any reports or publications. Any identifiable information collected during the study (e.g. consent forms) will be stored securely in the School of Pharmacy, QUB. In line with the Data Protection Act (1998), these documents will be kept for five years and then destroyed.

In order to ensure that research studies involving human participants are carried out to a high standard, the University is required to monitor ongoing studies. As a result, staff from the Queen's University Governance Office may need to review the information collected as part of this research study.

What will happen to the results of the research?

The results from the research will be used as part of a research project being carried out at the School of Pharmacy, QUB. Data may be presented at conferences or published in academic journals. All data obtained as part of this study will be anonymised. You will be provided with a report of the results on completion of the study.

Who is organising and funding the research?

This research is being organised by the School of Pharmacy at Queen's University Belfast. It is funded by the Harold and Marjorie Moss Charitable Trust Fund and the Department for Employment and Learning (DEL).

Who has reviewed the study?

The study has received ethical approval from the School of Pharmacy Ethics Committee, QUB.

Who can you contact for further information?

Should you require any further information, please do not hesitate to contact the researcher (Deborah Patton) who is responsible for the day-to-day running of the study, or any other member of the research team, using the contact details below.

Contact details for more information:

Deborah Patton

Postgraduate Researcher

School of Pharmacy

Queen's University Belfast

97 Lisburn Road

Belfast BT9 7BL

Telephone: (028) 9097 2033

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Appendix 5.4: Semi-structured topic guide (Phase 1: Interviews)

Community Pharmacists' interview schedule (Phase 1)

Study title: Community pharmacists' experience of, and attitudes towards, providing medication adherence support to older adults prescribed polypharmacy

Introduction

Thank you for taking the time to talk to me today. To start off, can I check that you have had the opportunity to read through the information sheet that was emailed/posted out to you?

The aim of this study is discuss your experiences and views on providing medication adherence support to older adults who are prescribed polypharmacy. For the purposes of this interview we will define polypharmacy as four or more medications. During the interview, I hope to gather information on what you think might help or hinder you when providing medication adherence support to older patients prescribed polypharmacy. I would also like to hear your views on a novel community pharmacist-led intervention that has been developed as part of an ongoing research project at Queen's University Belfast.

I would like to remind you that this interview will be audio-recorded, however, anything that you say during the interview will be kept confidential and will not be attributed to you in any way. We can stop the interview at any time, or if you would prefer not to answer a question then please let me know and we can move onto the next one. There are no right or wrong answers to any of the questions so please feel free to share your honest views and opinions.

Before we begin with the interview, I need to get written consent from you to indicate that you have read all of the information provided and understand what you are being asked to do. If you don't mind, could you please read each statement and initial the boxes to indicate that you understand and agree.

Do you have any immediate questions before we get started with the interview?

[Turn on digital recorder]

Demographics

[Complete pharmacist demographic data sheet]

1. To start off with, could you tell me how many years you have been practising as a community pharmacist?
2. What is your current job title (e.g. manager, second pharmacist)?
3. How long have been in your current position?
4. Have you any additional qualifications (e.g. non-medical prescribing, clinical diploma, additional postgraduate masters)?
5. Have you recently completed any training or participated in any research projects on medication adherence?

Definitions

The patients in whom we are interested as part of this research project are older adults and by this I mean those aged 65 years or older.

6. Could you give me a rough estimate of the percentage of patients who attend this pharmacy who would fall into this age category (65 years or older)?

As I have mentioned, we are interested in medication adherence in older adults, particularly those who are prescribed polypharmacy or four or more medications. The term medication adherence has been defined by the World Health Organisation (WHO) as: 'The extent to which a person's behaviour [in terms of taking medication] corresponds with agreed recommendations from a health care provider.'

Previous experience of supporting older adults with medication adherence

7. How often would you say you encounter older adults prescribed polypharmacy who are experiencing difficulties with taking medications as prescribed?

   Prompts: On a daily/weekly/monthly basis, rarely. How often would you personally engage with these patients?

8. How do you identify older adults who are experiencing difficulties with taking multiple medications as prescribed?

   Prompts: When counselling patients, during MURs, when checking the PMR

9. When speaking to older patients about their medicines, what kinds of problems or difficulties do you commonly come across with regards to taking medications as prescribed?

   Prompts: Physical difficulties, side effects, memory problems, lack of understanding, reducing or increasing medication doses/stopping medications without consulting their prescriber

10. What advice do you give or what solutions do you currently recommend to older patients who are experiencing difficulties taking their medications as prescribed?

    Prompts: Education on medicines, supply medicines in Monitored Dosage Systems (MDS), self-filled pill boxes, reminder strategies, physical aids (pill cutters, inhaler aids)

Example of a non-adherent patient

I am now going to show you an example of an older patient who is experiencing difficulties taking her medications as prescribed and, according to the World Health Organisation's definition, is considered to be non-adherent. Please take your time to read the example. It is not intended as a test in any way. The sole purpose of this is to encourage you to think about similar patients who you may have come across in your own practice.

[Hand participant laminated sheet with example patient on it]

Patient name: Mrs Veronica Smith

Age: 75

Medical conditions: Osteoporosis, hypercholesterolaemia, hypertension, depression, osteoarthritis

Number of regular medications: Eight (as below)

Repeat medication list (name/strength/form)	Directions
Adcal® D3 caplets (calcium carbonate 750mg/colecalciferol 200 units)	Take TWO caplets TWICE daily
Risedronate sodium 35mg tablets	Take ONE tablet each WEEK on Wednesdays
Simvastatin 20mg tablets	Take ONE tablet at night
Ramipril 10mg capsules	Take ONE capsule in the morning
Felodipine M/R 2.5mg tablets	Take ONE tablet in the morning
Citalopram 10mg tablets	Take ONE tablet in the morning
Paracetamol 500mg tablets	Take TWO tablets FOUR times daily (every four to six hours)
Ibuprofen 5% gel	Apply THREE times daily (to knee)

Adherence issues:

1. Mrs Smith has difficulty swallowing her Adcal® D3 caplets and so only takes this medication once daily as opposed to twice daily
2. She doesn't take her risedronate sodium tablet every week as she is worried about oesophageal side effects
3. She regularly forgets to take her simvastatin tablet at night

[Check digital recorder]

Behavioural elicitation

For the remainder of the interview, when we talk about medication non-adherence in older adults prescribed polypharmacy, it might be helpful to think of similar patients who you may have encountered in your own practice.

11. If you were to think about the term 'medication adherence support', how would you describe this?
    Prompts: What kinds of activities would this include?

For the purposes of this interview we will define 'medication adherence support' as any activity or intervention aimed at assessing or improving a patient's adherence to medications. The latest guidance from the National Institute of Health and Care Excellence (NICE) considers this to include:

- Simply asking patients about their adherence
- Providing information and talking to patients about adherence issues and answering questions
- Providing or recommending practical strategies
- Encouraging adherence and involving others to support patients' adherence
- Specific interventions to address patient-reported barriers to adherence

Nature of the behaviours

12. In relation to older adults who have been prescribed polypharmacy, is there anything that you do routinely in your everyday practice to support them in adhering to their medicines?
    Prompts: Apart from the provision of Monitored Dosage Systems, is there anything else that you routinely do?

Knowledge

13. As a community pharmacist, what knowledge do you have that would help you to provide medication adherence support to an older adult who is prescribed polypharmacy?
    Prompts: Clinical knowledge; knowledge of patients' medical history/clinical conditions; knowledge from guidelines (e.g. NICE guidance on medication adherence); other written resources; knowledge of devices to support adherence
14. What do you think should be included in educational packages to enable community pharmacists to provide medication adherence support to older adults who are prescribed polypharmacy?
    Prompts: Education on: why patients are non-adherent; resources currently available to support medication adherence; latest evidence on the best way to improve adherence.
15. How do you think this type of educational package should be delivered?
    Prompts: Online training, face-face training

Skills

16. What skills do you currently have as a community pharmacist that would enable you to provide medication adherence support to an older adult who is prescribed polypharmacy?
    Prompts: What about skills that might help you engage or interact with patients/other healthcare professionals (e.g. communication skills, persuasion skills, time management skills, problem solving skills)
17. Can you think of any specific skills training that would help you in providing medication adherence support to an older adult who is prescribed polypharmacy?
    Prompts: Training in how to: identify non-adherent patients; communicate with patients/other HCPs; motivate/persuade patients; make decisions with regards to the best actions to take

Social/professional role and identity

18. What would you consider your responsibilities within the multidisciplinary primary health care team to be if you were to think about providing medication adherence support to older adults prescribed polypharmacy?
    Prompts: Do you consider it to be part of your responsibility; whose responsibility do you think it is or should be; is there anything that you would consider to be beyond your responsibility?

Beliefs about capabilities

19. Under what circumstances would you feel confident about providing medication adherence support to an older adult who is prescribed polypharmacy?
    Prompts: Perhaps try to think of a time in your own practice where you have discussed medication adherence with an older patient
20. Are there any circumstances under which you would not feel confident about providing medication adherence support to an older adult who is prescribed polypharmacy?
    Prompts: Multiple adherence issues, multiple medical conditions, complex patients. Perhaps try to think of a time when you did not feel confident in discussing medication adherence with an older patient.

Beliefs about consequences

21. What do you think are the potential benefits of providing medication adherence support to older adults prescribed polypharmacy?
    Prompts: Perhaps try to think of positive short or long-term consequences for patients/ yourself/ NHS/carers?
22. Can you think of any potential disadvantages or problems associated with providing medication adherence support to older adults prescribed polypharmacy?
    Prompts: Perhaps try to think of negative short or long-term consequences for patients/ yourself/ NHS/ carers?

[Check digital recorder]

23. What would encourage you to provide medication adherence support to older adults prescribed polypharmacy?
    Prompts: Perhaps try to think of benefits for patients, yourself or the pharmacy (e.g. evidence of benefit to patients, job satisfaction/professional recognition, rewards/ income from service profession)
24. What would discourage you from providing medication adherence support to older adults prescribed polypharmacy?
    Prompts: A lack of incentives/rewards/income from services, no professional recognition, no evidence of benefit to patients

Motivation and goals

25. To what extent is providing medication adherence support to older adults prescribed polypharmacy a priority for you?
    Prompts: Perhaps try to think of it in terms of your other priorities as a community pharmacist– where on your list of priorities would this be?
26. Are there any circumstances under which it would be less important for you to provide medication adherence support for an older adult prescribed polypharmacy?
    Prompts: What other priorities might be more important?

Memory, attention and decision processes

27. Can you tell me how you would go about making a decision on the most appropriate actions to take when providing medication adherence support to an older adult prescribed polypharmacy?
    Prompts: What factors would you consider when making a decision?
28. How would you remember to address any adherence problems identified when providing medication adherence support to an older adult prescribed polypharmacy?
    Prompts: What do you currently do in practice (e.g. note on PMR, written records)?
29. Under what circumstances might you forget to address these adherence problems?
    Prompts: Lack of reminder systems, distraction from other tasks.

Environmental context and resources

30. Are there any resources or anything in your work context that would help you to provide medication adherence support to an older adult prescribed polypharmacy?
    Prompts: Adequate staffing levels, rewards/incentives, income from services
31. What factors such as resources or your work context might prevent you from providing medication adherence support to an older adult prescribed polypharmacy?
    Prompts: Work culture/environment, inadequate staffing levels, lack of rewards/incentives, lack of income from services

[Check digital recorder]

Social influences

32. Who would influence your decision to provide medication adherence support to an older adult prescribed polypharmacy?

    Prompts: Patients, carers, other staff/management, other healthcare professionals. What would their influence be?

Emotion

33. How would providing medication adherence support to an older adult prescribed polypharmacy make you feel?

    Prompts: Intimidated by the complexity of such cases, encouraged by potential benefit to patients

34. How would your own work-related stress or emotional engagement with an older patient influence your decisions around providing medication adherence support?

Behavioural regulation

35. Having decided on the best approach to take to provide medication adherence support to an older adult prescribed polypharmacy, are there any ways in which you could monitor that this activity has been done?

    Prompts: Try to think of systems already in place that you could make use of (such as PMR systems); written records; electronic records

36. What strategies could you use to monitor the outcomes of providing medication adherence support to older adults prescribed polypharmacy?

    Prompts: Outcomes may include patient reported effectiveness of recommended adherence strategies, patient satisfaction, clinical outcomes (e.g. improvements in symptoms). Follow-up appointments, liaison with GPs, PMR systems.

Views on a novel adherence intervention

For the final part of this interview I would like to ask you about your views on a novel intervention that has been developed by our research team to help support medication adherence in older adults prescribed polypharmacy. This has been developed based on the most up-to-date evidence in the literature and from group discussions with older patients from across NI.

The intervention that we have developed includes a structured adherence assessment tool which consists of a pre-defined list of questions to help community pharmacists identify specific adherence problems faced by each patient.

[Hand participant a laminated piece of card with an example question from the ID-MAP adherence assessment tool on it]

As you can see from this example, each type of adherence problem has been linked to recommended adherence solutions.

[Show participant example adherence solution: medication diary for self-monitoring medication use]

This tool aims to guide pharmacists in selecting the best adherence solutions using a comprehensive and structured approach whilst still maintaining some flexibility to allow recommendations to be tailored to the individual patient.

As part of a community pharmacist-led intervention, we propose that patients would attend three appointments in the pharmacy. At the first appointment the pharmacist would assess the patients' adherence using this structured tool and identify the nature of any problems faced. At the second appointment the pharmacist would provide or recommend adherence solutions. At a third and final appointment, the pharmacist would follow-up with the patient to find out if the recommended solutions were helpful. These appointments would last on average 20-30 minutes each.

We are interested in hearing your views on how you think this intervention could work in everyday clinical practice.

37. How do you think this type of structured adherence assessment could fit into your current practice?

    Prompts: Extension of a current service (e.g. MURs), as part of a completely new service

38. What would be the best way to identify non-adherent patients who might benefit most from the intervention?

    Prompts: identified by patient/carer/pharmacy staff (e.g. from PMR/informal discussion with patients); referrals from other HCPs (e.g. GPs, hospital pharmacists, consultants); advertisements; patient completed screening questionnaire

39. What are your views on the use of a preliminary screening questionnaire to identify whether a patient might benefit from this type of intervention?

[Hand participant a laminated piece of card with Morisky 8-item adherence screening questionnaire on it]

Prompts: When would be the best time to ask patients to complete this screening questionnaire?

Appendix 5.4 (cont'd): Semi-structured topic guide (Phase 1: interviews)

40. What do you think about the number of appointments that we have proposed for this type of intervention?

    Prompts: Too many or too few? Do you think you would need time to prepare adherence solutions after identifying problems faced by the patient (i.e. between Appointments 1 and 2)? How many follow-up appointments do you think would be necessary?

41. How often do you think an adherence assessment should be conducted with older patients prescribed polypharmacy?

    Prompts: As a one-off intervention; repeated at specified intervals (e.g. annually, six monthly); at each dispensing

42. Can you think of any potential barriers to implementing this type of adherence intervention into practice?

    Prompts: Environmental constraints, work culture

43. What might help to implement this type of intervention into practice?

    Prompts: Adequate staffing levels, rewards/incentives, professional recognition, education/skills training

Closing statements

That brings us to the end of the interview.

Is there anything about the topic of medication adherence in older adults prescribed polypharmacy that you feel has not been covered?

Do you have any further comments that you would like to make?

Thanks very much for taking the time out to talk to me today.

[Turn off digital recorder]

Appendix 5.5: Community pharmacist consent form (Phase 1: interviews)

Community Pharmacist Consent Form

Study Title: An exploration of community pharmacists' experience of, and attitudes towards providing medication adherence support to older adults prescribed polypharmacy

Please initial the following statements.	**Initials**
1. I have read the information that I have received in relation to the above study and have asked any necessary questions.	
2. I understand what the study involves.	
3. I agree for the interview to be audio-recorded.	
4. I understand that I may withdraw from the study at any time without giving a reason.	
5. I understand that my personal information will be confidential and stored safely in the School of Pharmacy, QUB. I am aware that any results published from the study will be anonymous.	
6. I understand that relevant data collected during the study may be looked at by researchers involved in the study.	
7. I agree to take part in this study.	

Please write your name, sign and date the form below.

Pharmacist Name (Print):

Signature: Date:

Researcher Name (Print):

Signature: Date:

Appendix 5.6: Continuing professional development certificate

Queen's University Belfast

Certificate of Participation

Title of Event: Interview to explore community pharmacists' experience of, and attitudes towards providing medication adherence support to older adults prescribed polypharmacy

Date of Event:

Name of pharmacist:

I hereby certify that the individual named above attended this event.

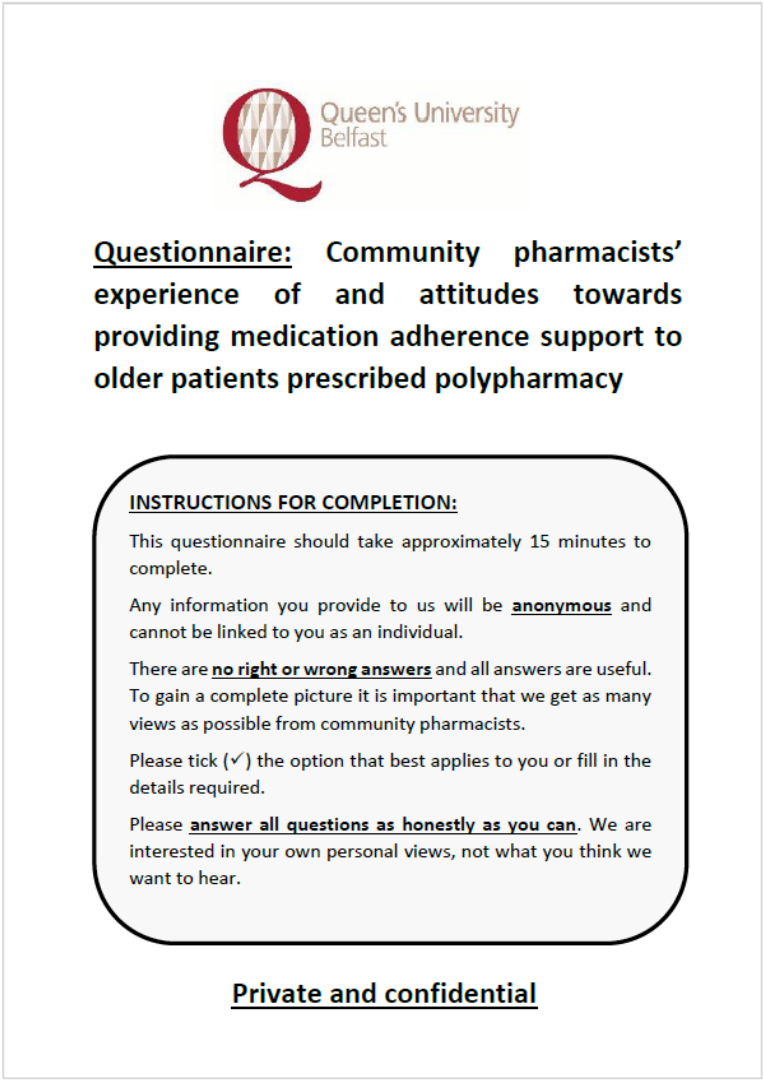
Signed: _____

Event Organiser: Professor Carmel Hughes

Head of School, School of Pharmacy, Queen's University Belfast

Date:

Appendix 5.7: Questionnaire for community pharmacists



Queen's University Belfast

Questionnaire: Community pharmacists' experience of and attitudes towards providing medication adherence support to older patients prescribed polypharmacy

INSTRUCTIONS FOR COMPLETION:

This questionnaire should take approximately 15 minutes to complete.

Any information you provide to us will be **anonymous** and cannot be linked to you as an individual.

There are **no right or wrong answers** and all answers are useful. To gain a complete picture it is important that we get as many views as possible from community pharmacists.

Please tick (✓) the option that best applies to you or fill in the details required.

Please **answer all questions as honestly as you can**. We are interested in your own personal views, not what you think we want to hear.

Private and confidential

Appendix 5.7 (cont'd): Questionnaire for community pharmacists

SECTION 1: DEMOGRAPHIC INFORMATION

Please tell us some details about yourself and where you work:

1. Gender: Male ☐ Female ☐

2. Age (years): <25 ☐ 25-34 ☐ 35-44 ☐ 45-54 ☐ 55-64 ☐ 65+ ☐

3. How many years have you been practising as a community pharmacist? _____

4. Do you have any postgraduate qualifications (e.g. independent prescriber, clinical diploma, PhD)?

   Yes ☐ No ☐

   If yes, please provide details below:

   _____

5. Which type of community pharmacy are you currently working in?

   Large chain (10+ stores) ☐ Small/medium chain (2-9 stores) ☐ Independent ☐

6. How would you best describe the location of your pharmacy?

   Rural ☐ Suburban ☐ Urban ☐

7. What is your current job title (e.g. manager, proprietor, second pharmacist)? _____

8. How many pharmacists (apart from yourself) work in your store on an average day? _____

9. How many support staff (i.e. non-pharmacists) work in your store on an average day? (including dispensary staff and medicines counter assistants) _____

10. On average, how many prescription items would your pharmacy dispense on a typical weekday?

    <100 ☐ 100-199 ☐ 200-299 ☐ 300-399 ☐

    400-499 ☐ 500-599 ☐ 600 + ☐

11. Approximately what percentage of patients who attend your community pharmacy are aged 65 years or over?

    <25% ☐ 25-49% ☐ 50-74% ☐ 75% + ☐

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12. Approximately what percentage of older patients (65 years +) who attend your community pharmacy are prescribed polypharmacy (4+ regular medications)?

    <25% ☐ 25-49% ☐ 50-74% ☐ 75% + ☐

13. In the previous month, approximately how many older patients (65 years +) did you supply Monitored Dosage Systems (MDS) to?

    None ☐ 1-25 ☐ 26-50 ☐ 51-75 ☐ 76-100 ☐ >100 ☐

14. Do you currently provide any of the following services?

    Managing Your Medicines (MYM) service

    Yes ☐ No ☐

    If yes, please indicate approximately how many you completed in the previous year: _____

    Medicines Use Review (MUR) service

    Yes ☐ No ☐

    If yes, please indicate approximately how many you completed in the previous year: _____

15. In the past 5 years, have you undertaken any formal or informal training (e.g. online training, workshops, seminars) on providing medication adherence support?

    Yes ☐ No ☐

    If yes, please provide details below:

    _____

    _____

16. In the past 5 years, have you participated in any research projects, service evaluations or audits that focused on medication adherence?

    Yes ☐ No ☐

    If yes, please provide details below:

    _____

    _____

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SECTION 2: EXPERIENCE OF PROVIDING MEDICATION ADHERENCE SUPPORT

The following questions are about your personal experiences with providing medication adherence support to **older patients** (65 years+) who are **prescribed polypharmacy** (4+ regular medications):

BOX 1: Please consider NICE[1] guidance on 'Medication Adherence Support' provided below:

'**Medication adherence**' (previously known as compliance) is defined by NICE as *'the extent to which the patient's behaviour matches agreed recommendations from the prescriber'.*

'**Medication adherence support**' is a clinical activity undertaken by healthcare professionals that involves:

Step 1: Identification and assessment of non-adherence:

- Using pharmacy-held records or returned unused medications to identify non-adherence
- Asking patients if they have missed any doses of medications in a non-judgemental way
- Exploring underlying reasons for non-adherence such as:
  - Unintentional reasons *(e.g. practical barriers such as difficulties opening packaging, forgetfulness)*
  - Intentional reasons *(e.g. misinformed beliefs, concerns over side effects)*

Step 2: Delivery of tailored strategies to improve adherence:

- Considering options to improve adherence in discussion with the patient
- Selecting strategies based on the underlying reason(s) for non-adherence such as:
  - Practical or reminder strategies
  - Changes to medication(s)/regimen *(e.g. simplification)*
  - Information/advice
  - Support/encouragement
  - Techniques to increase motivation *(e.g. setting goals, developing action plans)*

*This definition has been adapted from: **NICE[1] guidance** (CG 76). 2009. Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence.*
[1]National Institute of Health and Care Excellence

In relation to older adults who are prescribed polypharmacy, please indicate how often you undertake the following 'medication adherence support' activities by placing a tick in the appropriate box ☑:

Step 1: Identification and assessment of non-adherence	*Very frequently*	*Frequently*	*Occasionally*	*Rarely*	*Never/not at all*
I use pharmacy-held records to identify non-adherent older patients	☐	☐	☐	☐	☐
I identify non-adherent older patients through returned unused medications	☐	☐	☐	☐	☐
I ask older patients in a non-judgemental way if they have missed any doses of medications	☐	☐	☐	☐	☐
I explore older patients' underlying reasons for non-adherence *(e.g. intentional, unintentional)*	☐	☐	☐	☐	☐

Step 2: Delivery of tailored strategies to improve adherence	*Very frequently*	*Frequently*	*Occasionally*	*Rarely*	*Never/not at all*
I consider options to improve adherence in discussion with older patients	☐	☐	☐	☐	☐
I **tailor** adherence support strategies to the underlying reason(s) for non-adherence	☐	☐	☐	☐	☐
I recommend and supply MDS (Monitored Dosage Systems) to older patients	☐	☐	☐	☐	☐
I supply MDS to older patients when requested by others *(e.g. GP, patients, carers, hospital pharmacists)*	☐	☐	☐	☐	☐
I recommend that the GP issues multiple dispensing prescriptions *(e.g. weekly, daily)*	☐	☐	☐	☐	☐
I refer patients to their GP or alert GPs to non-adherence	☐	☐	☐	☐	☐
I provide tailored education/advice to older patients	☐	☐	☐	☐	☐

Appendix 5.7 (cont'd): Questionnaire for community pharmacists

Step 2 (continued): Delivery of tailored strategies to improve adherence	*Very frequently*	*Frequently*	*Occasionally*	*Rarely*	*Never/not at all*
I provide older patients with medication lists	☐	☐	☐	☐	☐
I recommend reminder strategies to older patients *(e.g. visual cues, links to other daily routines)*	☐	☐	☐	☐	☐
I recommend that GPs make changes to older patients' medication(s)/ regimen *(e.g. simplification)*	☐	☐	☐	☐	☐
To support adherence I provide the following service(s): • Prescription ordering • Prescription collection • Deliveries to patients' homes	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
I offer older patients support, encouragement and reassurance about their medications	☐	☐	☐	☐	☐
I recommend that older patients use self-monitoring strategies *(e.g. diary, Medication Administration Record Sheets)*	☐	☐	☐	☐	☐
I provide additional information on dispensing labels for older patients *(e.g. indication)*	☐	☐	☐	☐	☐
I provide older patients with alternative packaging *(e.g. non-child resistant bottles)*	☐	☐	☐	☐	☐
I recommend that older patients seek additional support from family/carers	☐	☐	☐	☐	☐
I recommend that older patients purchase adherence aids *(e.g. self-fill pill organisers)*	☐	☐	☐	☐	☐
I use techniques to increase older patients' motivation *(e.g. setting goals, developing action plans)*	☐	☐	☐	☐	☐

Do you undertake any <u>additional</u> adherence support activities other than those listed above?

Yes ☐ No ☐

***If yes**, please provide details below:*

_____

_____

_____

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SECTION 3: ATTITUDES TOWARDS PROVIDING MEDICATION ADHERENCE SUPPORT

Please indicate the extent to which you agree or disagree with the following statements by placing a tick in the appropriate box ☑:

	Strongly agree	*Agree*	*Neither Agree or Disagree*	*Disagree*	*Strongly disagree*
I know how to provide medication adherence support to older patients in line with NICE guidance	☐	☐	☐	☐	☐
I know the <u>appropriate questions</u> to ask older patients to determine the underlying reasons for non-adherence	☐	☐	☐	☐	☐
I have sufficient knowledge of the <u>range of adherence strategies</u> that are available to support older patients	☐	☐	☐	☐	☐
I have been trained to provide medication adherence support to older patients in line with NICE guidance	☐	☐	☐	☐	☐
I have the communication skills required to provide medication adherence support to older patients	☐	☐	☐	☐	☐
I require additional training on techniques that can be used to increase older patients' motivation to adhere *(e.g. setting goals)*	☐	☐	☐	☐	☐
I find it difficult to discuss medication adherence with older patients	☐	☐	☐	☐	☐
I am <u>confident</u> that I can: • address any medication adherence problems that I encounter with older patients • provide adherence support to older patients even when they are not motivated • provide adherence support to older patients even when I am unfamiliar with their medical conditions	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
I worry about giving the wrong advice to older patients when providing medication adherence support	☐	☐	☐	☐	☐
Talking to older patients about medication adherence makes me feel uncomfortable	☐	☐	☐	☐	☐

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	Strongly agree	*Agree*	*Neither Agree or Disagree*	*Disagree*	*Strongly disagree*
I have sufficient **pharmacist staff** levels to allow me to provide medication adherence support to older patients	☐	☐	☐	☐	☐
I have sufficient **support staff** levels to allow me to provide medication adherence support to older patients	☐	☐	☐	☐	☐
I have sufficient space in the pharmacy to allow me to provide medication adherence support to older patients	☐	☐	☐	☐	☐
I **do not** have enough time to provide medication adherence support to older patients	☐	☐	☐	☐	☐
I receive sufficient reimbursement for providing medication adherence support to older patients	☐	☐	☐	☐	☐
Lack of access to patients' medical notes is a barrier to providing medication adherence support	☐	☐	☐	☐	☐
Providing adherence support to older patients: • gives me job satisfaction • improves the profile of community pharmacy • leads to health benefits for patients and cost-savings for the NHS	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Seeing the benefits of providing adherence support to older patients helps me to overcome barriers such as lack of time and reimbursement	☐	☐	☐	☐	☐
Providing medication adherence support to older patients is a low priority for me in daily practice	☐	☐	☐	☐	☐
I want to support more older patients with medication adherence in the future	☐	☐	☐	☐	☐
It is important to always offer medication adherence support to older patients	☐	☐	☐	☐	☐
Providing adherence support to older patients is part of my current role as a community pharmacist	☐	☐	☐	☐	☐

	Strongly agree	*Agree*	*Neither Agree or Disagree*	*Disagree*	*Strongly disagree*
It is my responsibility to provide medication adherence support to older patients	☐	☐	☐	☐	☐
Older patients **do not** consider the provision of adherence support to be part of my role as a community pharmacist	☐	☐	☐	☐	☐
Others *(e.g. GPs, carers)* decide which adherence support strategies are required by older patients	☐	☐	☐	☐	☐
Colleagues in senior positions support me in providing adherence support to older patients	☐	☐	☐	☐	☐
I face resistance from GPs when trying to provide medication adherence support to older patients	☐	☐	☐	☐	☐
I face resistance from patients when trying to provide medication adherence support	☐	☐	☐	☐	☐
Providing medication adherence support is easy for me to remember	☐	☐	☐	☐	☐
I try to be proactive by planning how I can identify and support older patients with medication adherence	☐	☐	☐	☐	☐
Deciding on the best adherence support strategies for older patients is sometimes difficult	☐	☐	☐	☐	☐
I monitor and record the type of medication adherence support that I provide to older patients	☐	☐	☐	☐	☐
Receiving negative feedback from a patient regarding adherence support advice would prevent me from offering this advice to others	☐	☐	☐	☐	☐

Do you have any additional comments related to the provision of 'medication adherence support' by community pharmacists to older adults who are prescribed polypharmacy?

_____

_____

_____

Thank-you for taking the time to complete this questionnaire. Your response is very much appreciated.

Appendix 5.8: Invitation letter to community pharmacists (questionnaire)

School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL
Tel 02890972086
Fax 02890247794

Date

Dear Pharmacist,

Re: An exploration of community pharmacists' experience of and attitudes towards providing medication adherence support to older adults prescribed polypharmacy

I am writing to invite you to complete a questionnaire as part of a PhD research project in the School of Pharmacy at Queen's University Belfast on medication adherence in older adults prescribed several medications (i.e. polypharmacy). The purpose of this questionnaire is to gather information on your experiences of providing medication adherence support to older adults and your views on what helps and hinders you in providing this.

I can assure you that all responses will remain anonymous and will not be attributed to you. Your participation in this study is voluntary and by submitting a completed questionnaire, this will indicate your consent.

I would be grateful if you could take the time to complete the questionnaire and return it using the pre-paid envelope that has been enclosed. The questionnaire should take no longer than 15 minutes to complete. **The deadline for returning completed questionnaires is (insert date)**. We very much appreciate your help with this research study.

If you have any questions or concerns about any aspect of the study, please do not hesitate to contact the researcher, Deborah Patton, (Email: dpatton08@qub.ac.uk; Tel: 02890972033) or the Chief Investigator, Prof. Carmel Hughes, (Email: c.hughes@qub.ac.uk; Tel: 02890972147) who will be happy to discuss these with you.

Yours sincerely,

Deborah Patton — Postgraduate Researcher

Prof. Carmel Hughes — Chief Investigator/Head of School

Appendix 5.9: Reminder letter for community pharmacists (questionnaire)

School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL
Tel 02890972086
Fax 02890247794

Date

Dear Pharmacist,

NOTE: IF YOU HAVE ALREADY COMPLETED AND RETURNED THIS QUESTIONNAIRE, PLEASE IGNORE THIS LETTER AND ENCLOSED DOCUMENTS. WE THANK YOU FOR YOUR PARTICIPATION.

Re: An exploration of community pharmacists' experience of, and attitudes towards providing medication adherence support to older adults prescribed polypharmacy

I am writing to remind you of the deadline for completion of a questionnaire that is part of a PhD research project in the School of Pharmacy at Queen's University Belfast on medication adherence in older adults prescribed several medications (i.e. polypharmacy). The purpose of this questionnaire is to gather information on your experiences of providing medication adherence support to older adults and your views on what helps and hinders you in providing this.

I can assure you that all responses will remain anonymous and will not be attributed to you. Your participation in this study is voluntary and by submitting a completed questionnaire this will indicate your consent.

I would be grateful if you could take the time to complete the questionnaire and return it using the pre-paid envelope that has been enclosed. The questionnaire should take no longer than 15 minutes to complete. **The deadline for returning completed questionnaires is Friday 12th May 2017**. We very much appreciate your help with this research study.

If you have any questions or concerns about any aspect of the study, please do not hesitate to contact the researcher, Deborah Patton, (Email: dpatton08@qub.ac.uk; Tel: 02890972033) or the Chief Investigator, Prof. Carmel Hughes, (Email: c.hughes@qub.ac.uk; Tel: 02890972147) who will be happy to discuss these with you.

Yours sincerely,

Deborah Patton — Postgraduate Researcher

Prof. Carmel Hughes — Chief Investigator/Head of School

Appendix 5.10: Completed COREQ checklist (interviews) (Tong et al. 2007)

Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Interviewer/ facilitator	Which author/s conducted the interview or focus group?	DP carried out all 15 interviews.
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	DP had an MPharm degree and was a PhD candidate.
3. Occupation	What was their occupation at the time of the study?	DP was a PhD research student and registered pharmacist working in the community setting on a part-time basis (MPSNI).
4. Gender	Was the researcher male or female?	Female.
5. Experience and training	What experience or training did the researcher have?	DP had attended training in qualitative research methodologies and had previous involvement in conducting focus groups.
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Pharmacists were contacted via telephone prior to participation to discuss taking part in the study. All community pharmacists were part of the QUB School of Pharmacy Undergraduate Placement Network and had links with QUB. Some participants were known to the researcher through personal pharmacy networks/contacts.
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Participants were aware that the researcher was a PhD student at QUB with an interest in medication adherence. Participants were aware that the research was ethically approved and funded by the Harold and Marjorie Moss Charitable Trust Fund and by the Department of Employment and Learning.
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	The interview topic guide was underpinned by the TDF. Framework analysis was conducted, followed by inductive content analysis.
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Purposive and snowball sampling strategies were employed to identify pharmacists working in both urban and rural areas and different types of community pharmacies (e.g. independently owned and chains).
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Participants were initially contacted via telephone and if interested at this stage they were emailed a letter of invitation and study information sheet.
12. Sample size	How many participants were in the study?	Fifteen participants took part in the study.
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Eleven pharmacists refused to participate, one pharmacist cancelled a scheduled interview due to time constraints.
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Data was collected at the participant's place of work (e.g. consultation room) or other convenient location (local café, pharmacist's own home, School of Pharmacy QUB).
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No others were present at the time of each interview.
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Information about the participant's professional background (e.g. years qualified, job title, training on medication adherence) was collected (see Table 5.1 in thesis).
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	A topic guide with prompts guided interview sessions. The topic guide was piloted before use with two practising community pharmacists.
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No repeat interviews were required.
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	All interviews were audio-recorded.
20. Field notes	Were field notes made during and/or after the interview or focus group?	No notes were made during interviews. All audio recordings were checked after interviews to ensure all information had been captured.

Appendix 5.10 (cont'd): Completed COREQ checklist (interviews) (Tong et al. 2007)

Data collection (cont'd)		
21. Duration	What was the duration of the interviews or focus group?	Interviews ranged in duration from 30 minutes to 72 minutes (total duration 698 minutes).
22. Data saturation	Was data saturation discussed?	Data saturation was reached by the fifteenth interview as no new themes were emerging.
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Transcripts were not returned to interview participants.
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	Three researchers (DP, CR, CH) independently coded the data (two researchers per transcript).
25. Description of the coding tree	Did authors provide a description of the coding tree?	Codes represented barriers and facilitators expressed by participants that were assigned to each domain of the TDF.
26. Derivation of themes	Were themes identified in advance or derived from the data?	Themes arising from each of the TDF domains were informed by the content of the focus groups.
27. Software	What software, if applicable, was used to manage the data?	NVivo® QSR 11.
28. Participant checking	Did participants provide feedback on the findings?	Participants did not provide feedback on the findings.
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number	Quotations have been presented in Section 5.4.1 of this thesis with identifiers removed. Each participant was given an anonymous code (e.g. CP01).
30. Data and findings consistent	Was there consistency between the data presented and the findings?	See Section 5.4.1 of this thesis. We have endeavoured to report the study findings in a clear, consistent manner in order to accurately reflect the data that has been collected.
31. Clarity of major themes	Were major themes clearly presented in the findings?	
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	