



The development of a comprehensive medicines management approach for persons with dementia in primary care

FULL ACADEMIC REPORT

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Funded by: HSC R&D Division, Public Health Agency and The Atlantic Philanthropies



ABSTRACT

Background

People with dementia (PwD) face unique challenges in their ability to successfully manage their medicines. However, little is known about these challenges from the perspectives of PwD, their carers, and primary healthcare professionals (HCPs), such as General Practitioners (GPs) and community pharmacists. To date, very few medicines management interventions have been developed which are aimed at community-dwelling PwD (i.e. those living at home and managed within the primary care setting). This project, therefore, sought to develop an intervention (using a theory-based approach) to improve medicines management for PwD in primary care in Northern Ireland (NI).

Methods

This three-phase project used a mixed methods approach. In Phase 1, a retrospective cross-sectional study was conducted using NI prescribing data, in order to investigate prescribing trends for PwD in primary care ($n=6,826$ patients). A subset of the Screening Tool of Older Persons Potentially Inappropriate Prescriptions (STOPP) criteria was also applied to the dataset to assess the appropriateness of prescribing for this patient population. In Phase 2, face-to-face interviews were conducted with PwD ($n=18$), their carers ($n=15$), GPs ($n=15$), and community pharmacists ($n=15$) in order to explore participants' views of medicines management for PwD and their perceptions of the barriers and facilitators to successful medicines management for PwD. The Theoretical Domains Framework (TDF) was used as the underpinning theory, allowing key theoretical domains to be identified and mapped to behaviour change techniques (BCTs) which are considered the 'active ingredients' of an intervention. Draft interventions were developed to operationalise selected BCTs, and were presented to GPs and community pharmacists during task groups. Participants were asked to assess the feasibility of implementing proposed intervention content using the APEASE (Affordability, Practicability, Effectiveness/cost-effectiveness, Acceptability, Side-effects/safety, Equity) criteria. In Phase 3, the intervention was tested for feasibility (usability and acceptability) in three community pharmacies.

Results

The observational pharmacoepidemiology conducted in Phase 1 revealed a high prevalence of both polypharmacy (i.e. use of ≥ 4 regular medicines; 81.5%) and potentially inappropriate prescribing (PIP; 64.4%) amongst this patient population. The most common instance of PIP was the use of anticholinergic/antimuscarinic medications (25.2%). In Phase 2, the role of carers in medicines

management was emphasised. Patients believed themselves to be competent with regard to medicines management, and did not report any issues with medicine-taking or adherence at the time of the interview. HCPs expressed a number of concerns about medicines management for PwD, particularly monitoring adherence to medication regimens and conducting medication review. Two draft interventions comprising selected BCTs ('Modelling or demonstration of behaviour', 'Salience of consequences', 'Information about health consequences', 'Information about social and environmental consequences', 'Action planning', 'Social support or encouragement', 'Self-monitoring of behaviour') were developed, each targeting GPs and community pharmacists. Following the task groups and discussions within the research team, the community pharmacy-based intervention was selected for feasibility testing. The intervention targeted community pharmacists to conduct a medication review and monitor adherence in a PwD, delivered as an online video demonstrating key behaviours. The video included feedback emphasising positive outcomes of performing the behaviours. Action planning and a 'quick reference guide' (QRG) were used as complementary intervention components to facilitate conducting medication review and monitoring adherence in PwD. However, in Phase 3, community pharmacists experienced a number of challenges recruiting PwD and carers to the study, and as a result were unable to complete the study.

Conclusion

A community pharmacy-based intervention has been developed targeting medicines management for PwD in primary care using a systematic, theory-based approach. However, due to difficulties with screening and recruitment of PwD and carers in the feasibility study, it has not been possible to fully determine the usability and acceptability of implementing this intervention in clinical practice. Future work will be needed to refine aspects of the intervention before progressing to a larger pilot study.

Funding

HSC R&D Division of the Public Health Agency and The Atlantic Philanthropies (Commissioned Call – Dementia Care).

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LIST OF ABBREVIATIONS

APEASE	Acceptability, Practicability, Effectiveness/cost-effectiveness, Affordability, Safety/side-effects, Equity
BCT	Behaviour change technique
BMQ	Beliefs about Medicines Questionnaire
BNF	British National Formulary
BPSD	Behavioural and psychological symptoms of dementia
BSO	Business Services Organisation
CI	Confidence interval
CPD	Continuing Professional Development
CPRD	Clinical Practice Research Datalink
EPD	Enhanced Prescribing Database
GCP	Good Clinical Practice
GP	General practitioner
HCP	Healthcare professional
HSC	Health and Social Care
JDR	Join Dementia Research
NI	Northern Ireland
MARS-5	Medication Adherence Reporting Scale – 5 item
MRC	Medical Research Council
MTBQ	Multimorbidity Treatment Burden Questionnaire
MUR	Medicine Use Review
NICE	National Institute for Health and Care Excellence
NICRN	Northern Ireland Clinical Research Network
NPI	Neuropsychiatric Inventory
OR	Odds ratio
OTC	Over the counter
ORECNI	Office for Research Ethics Committees Northern Ireland
PIP	Potentially inappropriate prescribing
PMG	Project management group
PMR	Patient medication record
PPI	Patient and public involvement
PwD	Person/people with dementia

QOL	Quality of life
QRG	Quick reference guide
QUB	Queen's University Belfast
REC	Research Ethics Committee
SD	Standard deviation
STOPP	Screening Tool of Older Person's Prescriptions
TDF	Theoretical domains framework
UK	United Kingdom

CHAPTER 1. Introduction and background

1.1 Introduction

The use of medicines in older people (conventionally designated as those over the age of 65 years) has been described as the ‘single most important health care intervention in the industrialised world’ (Avorn, 2010). A term often associated with the use of medicines is ‘medicines management’, which is defined as ‘encompassing the entire way that medicines are selected, procured, delivered, prescribed, administered, and reviewed to optimise the contribution that they make to producing informed and desired outcomes of patient care’ (Audit Commission, 2001). It can be summarised as the right medicines for the right patient at the right time. In short, the essential components of medicines management are prescribing, dispensing, administration (including adherence) and review of medications.

Medicines management in persons with dementia (PwD) has been the focus of this three-phase project. In 2015, it was estimated that 47 million people worldwide were living with dementia (World Health Organisation, 2017). Due to a growing and ageing population, it is anticipated that this number will rise to 132 million by 2050 (World Health Organisation, 2017). Multimorbidity – which is defined as the presence of two or more chronic health conditions – is highly prevalent in the population with dementia; it has been reported that approximately 95% of those with dementia have another chronic disease (Barnett *et al.*, 2012). Given that much of our healthcare is configured around single-disease frameworks and prescribing guidelines, this can result in potentially complex medication regimens for PwD. A recent cross-sectional analysis of a primary care data set revealed that PwD had significantly more physical medical conditions (an average of 2.9 conditions) than persons without dementia (who had an average of 2.4 conditions) after controlling for age and gender (Clague *et al.*, 2017). Consequently, PwD were significantly more likely to have been prescribed more than five repeat medications [Odds ratio (OR) 1.46, 95% CI 1.40 to 1.52, $p < 0.001$] and had a two-fold increase in the likelihood of receiving 10 or more repeat prescriptions [OR 2.01, 95% CI 1.90 to 2.12, $p < 0.001$] when compared to older persons without dementia (Clague *et al.*, 2017).

There is currently no consensus as to how to define the term ‘polypharmacy’, but the definition most often adopted is ‘four or more regularly prescribed medications’ (Rankin *et al.*, 2018). As well as being associated with higher healthcare costs (Maher *et al.*, 2014), polypharmacy has been identified as a risk factor for potentially inappropriate prescribing (Bradley *et al.*, 2012). Potentially inappropriate prescribing (PIP) refers to the use of medicines that either have no strong evidence base, are

associated with a greater risk of harmful side-effects or are not cost effective (O'Mahony and Gallagher, 2008). In addition to concerns around polypharmacy and PIP, the impaired cognitive and communication skills of PwD can result in accidental non-adherence and medication-related hospital admissions (Elliott *et al.*, 2015). The presence of behavioural and psychological symptoms of dementia (BPSD), which are acknowledged to be difficult to manage both non-pharmacologically and pharmacologically, may also provide a challenge to prescribers, and to those helping with administration of medications (Wood-Mitchell *et al.*, 2008; Alsaeed *et al.*, 2016; Jennings *et al.*, 2018). It has been reported that as a person's cognitive impairment worsens, the amount of assistance with medicines provided by either formal or informal carers increases (Maidment *et al.*, 2017). However, without the support of healthcare professionals (HCPs), informal carers, who might not have received training or have access to evidence-based information, may find it difficult to manage the complicated medication regimens that are typical of so many PwD (Smith *et al.*, 2015; Maidment *et al.*, 2017). Medicines management has the potential to place additional stress on carers, and if carers become unable to cope then additional resources or options, such as admission to residential care, may be required (Maidment *et al.*, 2017).

It has been stated that successful medicines management for PwD could have a number of positive outcomes, which may include reductions in iatrogenic disease and inappropriate medications as well as improvements in quality of life (QOL) for both PwD and their carers (Maidment *et al.*, 2012). However, despite the importance of appropriate medicines management, there remains a paucity of research in this area, particularly for dementia patients who reside in their own homes in the community. This has been confirmed by a recent systematic review conducted by members of the research team (McGrattan *et al.*, 2017a). It has been estimated that 493,000 (61.3%) of people with late-onset dementia in the UK are community-dwelling (Prince *et al.*, 2014), and are managed within primary care. A recent UK-wide study reported that PwD have considerably higher health service usage in terms of primary care consultations and prescribing than those without dementia (Browne *et al.*, 2017). There have been calls for future research to focus on medicines management more broadly in PwD, in order to further understanding as well as to aid the development of interventions to improve outcomes (Maidment *et al.*, 2012). Whilst the current Northern Ireland Dementia Strategy focuses on the inappropriate use of psychoactive drugs in PwD in the context of nursing and residential homes, the Strategy also advocates appropriate prescribing in PwD in both primary and secondary care (Department of Health, Social Services and Public Safety, 2011).

Any intervention to improve and optimise medicines management will need to be multi-faceted, spanning prescribing of the medicines in the first instance, to adherence by the recipient. Furthermore, in line with the UK Medical Research Council's (MRC) complex intervention framework, existing evidence as well as an appropriate theoretical framework should be applied to guide and inform intervention development (Craig *et al.*, 2008; Medical Research Council, 2008). Intervention development should also involve those who deliver and/or receive these interventions, which for this study would include HCPs, carers (informal and formal), and recipients of care (French *et al.*, 2012). The following section lists the aims and objectives of this research.

1.2 Aims and objectives

The overall aims of this mixed methods project were to assess the appropriateness of medicines prescribed for PwD in primary care, to identify the most important aspects of medicines management from the perspectives of PwD, their carers and HCPs, and to develop an intervention that sought to optimise medicines management in PwD. The specific objectives were as follows:

1. To investigate prescribing trends and the appropriateness of medicines prescribed to PwD in primary care in Northern Ireland (NI) using dispensing data from the Health and Social Care (HSC) Business Services Organisation (BSO);
2. To develop a semi-structured interview guide and undertake interviews with PwD and their carers to explore medicines management issues (prescribing, review and administration, adherence) of importance to them;
3. To develop a theoretically informed semi-structured interview guide and undertake interviews with HCPs to include questions about factors that might influence medicines management in PwD;
4. To use the interview analysis to identify key behaviours, barriers and facilitators associated with medicines management in this context;
5. To triangulate the findings from objectives 1-4
6. To develop a suitable intervention to be tested for feasibility with PwD, carers and HCPs in primary care.

1.3 Study overview and structure of the report

The study included three distinct phases, which are outlined in Figure 1. This structure was informed by the MRC guidance on complex interventions (Craig *et al.*, 2008) and preceding research undertaken by members of the research team (Duncan *et al.*, 2012; Cadogan *et al.*, 2015; Cadogan *et al.*, 2016; Cadogan *et al.*, 2018; Patton *et al.*, 2018).

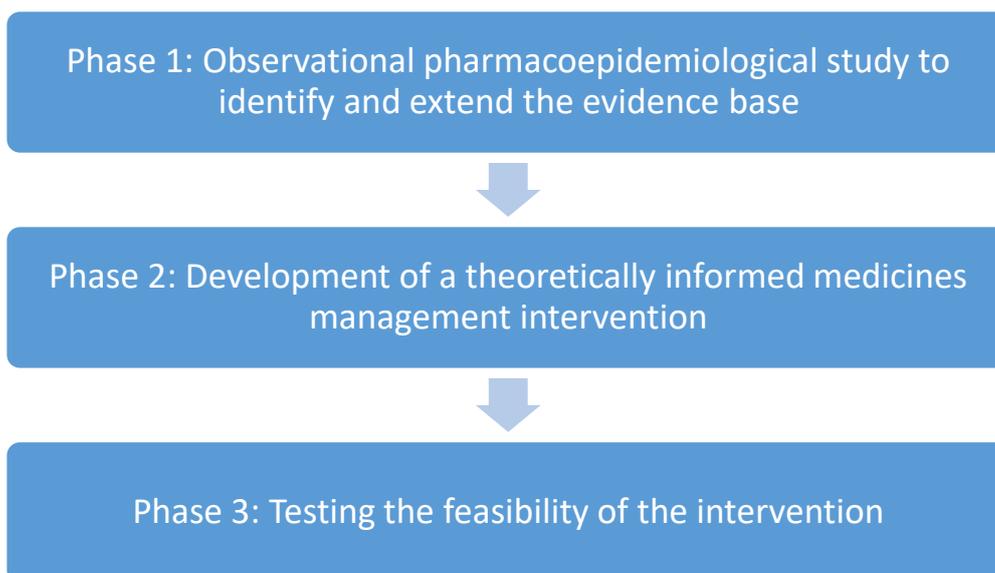


Figure 1. Overview of the three phases of the research project

As each phase of the study included different methodology and types of results, this report is structured as follows:

- *Chapter 1* outlines the background to the project, how the research was organised, and patient and public involvement (PPI) throughout the project;
- *Chapter 2* describes the observational pharmacoepidemiology study (Phase 1) that was conducted to extend the evidence base by investigating prescribing trends and the appropriateness of medicines prescribed to community-dwelling PwD in NI;
- *Chapter 3* details the process by which the intervention was developed (Phase 2). This includes the results of semi-structured interviews conducted with PwD, their carers, General Practitioners (GPs) and community pharmacists, as well as task group work with HCPs to further develop and refine intervention content;
- *Chapter 4* focuses on testing the feasibility of the intervention in two community pharmacies in NI and the collection of associated data (Phase 3);
- *Chapter 5* discusses the key findings from the study, the strengths and limitations of the research, practice and policy implications of the research, proposals for future research, pathway to impact and lists the final conclusions.

1.4 Study organisation and oversight

Queen's University Belfast (QUB) acted as Sponsor for the study and indemnity cover was outlined in the letter received from the Sponsor. The study was led by CH as Chief Investigator and management

of the study was overseen by a multidisciplinary Project Management Group (PMG), which comprised all the authors listed on this report. The PMG met every two months throughout the course of the project using teleconference facilities. Two face-to-face meetings were also held, in November 2014 and March 2017. All meetings were chaired by the Chief Investigator (CH). An agenda was prepared in advance of every meeting and circulated to all group members. Following each meeting, minutes were prepared and disseminated.

The day-to-day running of the project was undertaken by researchers based at the School of Pharmacy, QUB. Additional ad hoc meetings were held between the Chief Investigator and the researchers to address issues as they arose. As requested by the funding body, annual progress reports were submitted, which outlined progress to date, listed any outputs from the research as well as impact, detailed personal and public involvement, and described the proposed work programme for the next twelve months.

1.5 Patient and public involvement (PPI)

Previous research undertaken by members of the PMG had focused on prescribing and medicines use in care homes for older people. These studies highlighted inappropriate prescribing, inadequate review of medicines and problems with adherence. Lay members and practitioners who were members of the steering groups for these projects commented that similar issues may be seen in PwD living in their own homes. These comments formed part of the impetus for the proposed project.

Prior to submitting the grant application, this project was discussed with research volunteers from the Alzheimer's Society, carers and PwD who attended a regional memory clinic in the Belfast HSC Trust (run by Professor Passmore, a member of the research team), GPs and community pharmacists. There was enthusiasm for the project, with one carer stating a widely held view: *"it's a hugely important area of work. I've personally seen the full range in the last year...pills from a blister pack missed, not taken, and a caring GP and local pharmacy who went the extra mile to ensure the right pill or formulations were prescribed and given from a person-centred perspective."* This suggested that research was required to ensure that an intervention could be developed to promote best care. Initially, there had been uncertainty about continuing to a feasibility phase in this project. However, as there was general support for this, particularly from GPs and pharmacists, the decision was made to include a feasibility phase in the study design.

One of the members of the PMG, Dr. Hilary Buchanan, is a retired GP, former carer for a relative with dementia and (at the time of project planning) was a research volunteer with the Alzheimer's Society. Dr. Buchanan was involved in the planning and development of the study from the outset, providing feedback and comment on the research proposal. She gave advice on the study design and provided further input regarding the conduct of the study at the regular PMG meetings. She was able to advise the research team on how best to engage with PwD and their carers, and provided guidance on the development of the participant information sheets that were used during the recruitment process. Moreover, she commented on the topic guides that were developed for the semi-structured interviews, particularly in terms of the language and terminology used. In addition, we sought advice from practising GPs and pharmacists during the development of the interview topic guides for these HCPs. Extensive piloting of the interview guides (and other associated study documentation such as participant information sheets and consent forms) was undertaken prior to commencing data collection.

In addition to the input provided by Dr. Buchanan, it was valuable to have the input of PwD and their carers, GPs and community pharmacists as part of the semi-structured interviews that were conducted during the intervention development process in Phase 2 (Chapter 3). Participants were asked to describe their experiences of medicines management, their perceptions of barriers and facilitators to achieving appropriate medicines management, and their views on potential intervention components and outcome measures. In addition to the interviews, GPs and community pharmacists took part in task groups to help further develop and refine the intervention content. This has helped to ensure that the intervention developed during the project has incorporated the views of all relevant stakeholders. Furthermore, as part of the feasibility study, participating community pharmacists took part in interviews where they discussed their experiences of participating in the study and provided suggestions on how the intervention could be improved. The findings from these interviews have contributed towards the decision as to whether the intervention should progress to further pilot testing.

1.6 Summary

There has been limited research on medicines management in PwD, particularly for those living at home and managed within primary care. This patient group have unique medication needs compared with the general older population and medicines management interventions for community-dwelling PwD are urgently needed. This three-phase project was designed to address this issue by employing a systematic approach to inform the development and feasibility testing of a medicines management

intervention for this patient group. The project was managed by a multidisciplinary research team, with significant patient-public involvement (PPI) input throughout, and had all necessary approvals in place prior to the start of each phase of work.

CHAPTER 2. Observational pharmacoepidemiology

2.1 Introduction

The first chapter of this report outlined some of the complexities of medicines management for PwD. There have been concerns regarding the quality and appropriateness of prescribing for this patient group, particularly with regard to polypharmacy and PIP. However, there has been very limited epidemiological research on prescribing for PwD, especially for those who reside in the community. At the time of project planning, most of the work to date had focused on PwD resident in care homes or those at the end of life (Zuckerman *et al.*, 2005; Ballard *et al.*, 2009; Guthrie *et al.*, 2010; Parsons *et al.*, 2010; Parsons *et al.*, 2012; Thorpe *et al.*, 2012; Parsons *et al.*, 2013). Studies that had specifically investigated inappropriate medication use within the community-dwelling dementia population had been small in size and relied on patient or caregiver reports of medication use (Lau *et al.*, 2010; Fiss *et al.*, 2013; Koyama *et al.*, 2013; Montastruc *et al.*, 2013). Previous work conducted by the Chief Investigator (CH) to investigate the prevalence of PIP amongst older people in NI included some PwD, but the methodology was not specific for this patient group (Bradley *et al.*, 2012). Given the paucity of data in this area, this chapter presents the results of the observational pharmacoepidemiological study that was conducted to extend the evidence base by investigating current prescribing trends and the potential inappropriateness of medicines prescribed to PwD in primary care in NI.

2.2 Aims and objectives

The overall aim of the current study was to assess the appropriateness of prescribing for community-dwelling PwD in NI.

The specific objectives of this study were to:

1. Determine the number and types of medications prescribed to PwD in NI and to estimate the prevalence of polypharmacy (indicated by the use of ≥ 4 regular medications from different drug groups) among this population;
2. Estimate the prevalence of PIP in PwD in NI based on the application of a subset of Screening Tool of Older Person's Prescriptions (STOPP) criteria [a tool developed to assess the appropriateness of prescribing which has been extensively validated in UK settings (Duerden *et al.*, 2013; O'Mahony *et al.*, 2015)];
3. Investigate the association between PIP, polypharmacy, gender, and age in PwD in NI, in order to more precisely characterise those with dementia who might be at risk of PIP.

2.3 Methods

This study used a retrospective and cross-sectional approach.

2.3.1 Data source

Data were extracted from the Enhanced Prescribing Database (EPD), which securely holds information on drugs prescribed, and subsequently dispensed, to patients in primary care in NI. When prescriptions have been dispensed by community pharmacies, they are forwarded to the HSC Business Services Organisation (BSO) each month for reimbursement. Computer-generated prescriptions contain a unique two-dimensional barcode that is scanned by the BSO during the reimbursement process. This barcode links a patient's HSC Number with details of their prescribed medication and prescriber. Approximately 85-90% of all prescriptions forwarded to the BSO result in data of research standard (Bradley *et al.*, 2012). This high proportion of usable data has helped to generate a central database of approximately 1.9 million patients in NI (Bradley *et al.*, 2012). The EPD does not contain any clinical or diagnostic information about patients.

2.3.2 Study population

In order to identify participants, a computerised search of the EPD was undertaken, which was carried out by data custodians from the BSO. The study population consisted of all individuals who had been dispensed a drug for dementia (i.e. donepezil, galantamine, rivastigmine or memantine) between 1st January 2013 and 31st December 2013 (inclusive). These drugs were used as a proxy measure for diagnosis of dementia, as the EPD does not contain any clinical information about patients. Data relating to other medications, which were dispensed to these patients during the study period, were also requested.

In order to apply certain STOPP criteria, patients were required to have at least three months of lead-in data prior to 1st January 2013. Therefore, data were required between 1st October 2012 and 31st December 2013, and patients had to be registered with a GP in NI between these dates. In addition, any patients who entered a care home on or before 31st December 2013, or any patients who died during the study period, were excluded from the dataset. The following information was extracted for all patients from the EPD:

1. Data on all items prescribed from 1st October 2012 to 31st December 2013 (drug name, strength, quantity, directions for use, and date of issue);
2. The month and year in which each prescription was scanned by the BSO;
3. Patients' gender; and

4. Patients' age in years (as at 31st December 2013).

2.3.3 Exposures

Thirty-six of the original 80 STOPP (version 2) indicators were applied to EPD prescription files for study participants. As the EPD does not contain any clinical or diagnostic information about patients, these 36 indicators were considered by the research team to be applicable without access to such information. For example, '*aldosterone antagonists with concurrent potassium-conserving drugs without monitoring of serum potassium*' could not be operationalised due to the absence of data on biochemical monitoring, and therefore was not included. For some criteria, prescription drugs for the treatment of certain conditions were identified in the EPD dataset and used as proxies for diagnosis, where possible, such as for glaucoma and gout (Appendix 1). This approach had been used in other epidemiological studies (Cahir *et al.*, 2010; Bradley *et al.*, 2012; Bradley *et al.*, 2014).

Data on drug use were extracted using British National Formulary codes (Joint Formulary Committee, 2015). Patients were categories into those who received a STOPP criteria drug or drug combination. STOPP criteria which specified a particular duration of use, such as '*benzodiazepines for ≥ 4 weeks*', were assessed by identifying individuals who used the drugs for durations exceeding these appropriate thresholds within the study period (using the month a prescription was scanned by the BSO). STOPP criteria which specified a particular dosage not to be exceeded, such as '*oral elemental iron doses greater than 200mg daily*', were evaluated by calculating the number of daily defined doses (DDDs) for each recipient using the strength and quantity of the dispensed medication for each prescription.

The total number of prescriptions dispensed for each different drug group (according to BNF code) was calculated for each individual, during the one-year study period. A 'repeat medication' was defined as one for which the patient received three or more prescriptions for that agent in the study period. Polypharmacy was examined by the use of four or more repeat medications from different drug groups.

2.3.4 Outcomes

The primary outcome was the overall prevalence of PIP in PwD in primary care in NI in 2013, according to a subset of the STOPP criteria. Secondary outcomes measures were: (i) the prevalence of PIP per individual STOPP criterion, and (ii) the association between PIP and polypharmacy, gender, and age group.

2.3.5 Statistical analysis

All data extraction and analyses were performed using STATA/SE version 13 (StataCorp, College Station, TX, USA). The overall prevalence of PIP in the study population and the prevalence per individual STOPP criterion was calculated as a proportion of all eligible persons in the dataset and reported as percentage estimate and 95% confidence intervals (CIs). Univariate analyses were used to confirm or otherwise if explanatory variables (polypharmacy, age, gender) were significantly associated with PIP (at $p < 0.10$), and these were included in the multivariate model. Adjusted logistic regression analyses were then used to calculate odds ratios (ORs) and 95% CIs to investigate associations between any (versus no) PIP and polypharmacy (categorised as 0-3 versus ≥ 4 repeat drug classes), age group (≤ 44 , 45-64, 65-84, ≥ 85 years), and gender (male, female). There were no missing data for the variables of interest. Statistical significance was set *a priori* at $p < 0.05$.

2.3.6 Ethical considerations and approval

In order to ensure patient confidentiality, data requested as part of this study was non-identifiable in that names, addresses/postcodes, dates of birth, and general practice information were not requested. As the data were extracted from the EPD by the BSO, the data received by the research team were completely anonymised. The dataset was transferred from the BSO to the researcher's computer for analysis via an encrypted CD, which was stored in a locked filing cabinet and destroyed as soon as the transfer had taken place. Data were stored on an encrypted file on the researcher's computer using TrueCrypt®, a free open-source encryption software recommended by QUB. The computer was password-protected and kept in a first floor office in the School of Pharmacy (QUB) that was locked when not occupied. A data access agreement was signed by the primary researcher, Dr. Heather Barry (HBa), and Chief Investigator (CH) as new data custodians, and to indicate a change in custodianship (Appendix 2).

This study was reviewed by the National Research Ethics Service Committee London – City Road & Hampstead (Ref: 14/LO/1891) and was given a favourable opinion in October 2014 (Appendix 3).

2.4 Results

2.4.1 Characteristics of the study population

For the study period, 6,826 persons identified in the EPD were eligible for inclusion. The majority were female ($n=4,393$ patients, 64.4%). Patients ranged in age from 34 to 100 years, with a mean age of 79.6 [\pm standard deviation (SD) 8.0] years. Patients were receiving a mean of 6.8 (SD \pm 3.5) repeat medications. Over three-quarters of patients ($n=5,564$, 81.5%) were receiving four or more regularly

prescribed medications (the definition of polypharmacy adopted for the study), whilst the use of ten or more repeat medications was observed in one fifth of patients ($n=1,427$, 20.9%)

2.4.2 Prevalence of PIP in 2013

The overall prevalence of PIP in the study period was 64.4% (95% CI 63.2-65.5, $n=4,393$ patients). Almost one-quarter of the population ($n=1,571$ patients, 23.0%, 95% CI 22.0-24.0) were prescribed one potentially inappropriate medication, 1,141 patients (16.7%, 95% CI 15.8-17.6) were prescribed two potentially inappropriate medications, and 1,681 patients (24.6%, 95% CI 23.6-25.7) were prescribed three or more potentially inappropriate medications.

The prevalence of PIP according to each individual STOPP criterion is described in Appendix 4. The most common instance of PIP was the use of anticholinergic/antimuscarinic medications ($n=1,718$ patients, 25.2%). The second most frequently prescribed potentially inappropriate medicines were proton pump inhibitors (PPIs) at full therapeutic dosage for >8 weeks ($n=1,561$ patients, 22.9%), followed by acetylcholinesterase inhibitors with concurrent treatment with drugs that reduce heart rate ($n=1,276$ patients, 18.7%), benzodiazepines for ≥ 4 weeks ($n=777$ patients, 11.4%), and use of regular opioids without a concomitant laxative ($n=715$ patients, 10.5%). Duplication of therapy within drug classes was most frequently observed with opioid analgesics ($n=346$, 5.1%) and benzodiazepines ($n=239$, 3.5%). Many other STOPP criteria had a prevalence of less than 1.0%, such as '*thiazide diuretics with a history of gout*' and '*phenothiazines as first-line treatment, since safer and more efficacious alternatives exist*'.

2.4.3 Factors associated with PIP

Results of the logistic regression analyses are presented in Table 1. A strong association between PIP and polypharmacy was observed. Those receiving four or more regularly prescribed medications were seven and a half times more likely to be exposed to PIP compared to those on zero to three medications (adjusted OR 7.6, 95% CI 6.6-8.7). PIP was more likely to occur in females than in males after adjusting for age and polypharmacy (adjusted OR 1.3, 95% CI 1.2-1.4). No association was observed between PIP and age after adjustments for gender and polypharmacy.

Table 1. Logistic regression analyses investigating any PIP criteria

	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Polypharmacy		
<i>Never (ref)</i>	1.0	1.0
<i>Ever</i>	7.5 (6.5 – 8.6)	7.6 (6.6 – 8.7)
Gender		
<i>Male (ref)</i>	1.0	1.0
<i>Female</i>	1.2 (1.1 – 1.4)	1.3 (1.2 – 1.4)
Age group (years)		
<i>≤44 (ref)</i>	1.0	1.0
<i>45-64</i>	0.6 (0.1 – 3.2)	0.8 (0.1 – 4.6)
<i>65-84</i>	0.7 (0.1 – 3.7)	0.7 (0.1 – 4.2)
<i>≥85</i>	0.8 (0.1 – 3.9)	0.7 (0.1 – 4.0)

2.5 Summary

This study revealed a number of common instances of PIP and identified a high level of polypharmacy amongst PwD in primary care in NI. Some of these instances of PIP (for example, the use of proton pump inhibitors at full therapeutic dosage for >8 weeks and benzodiazepines for ≥4 weeks) are unsurprising, and have been reported in other studies exploring PIP amongst older people (Cahir *et al.*, 2010; Bradley *et al.*, 2012; Bradley *et al.*, 2014). The high use of anticholinergic and antimuscarinic medications in this current study population is of concern, especially given the fact that such medications can add to cognitive decline in dementia patients. Further research is therefore required to better understand GPs' prescribing behaviours for community-dwelling PwD as well as to identify the factors that influence prescribing decisions.

CHAPTER 3. Intervention development

3.1 Introduction

The observational pharmacoepidemiological study conducted as part of the first phase of this research (Chapter 2) identified a high prevalence of polypharmacy (81.5%) and PIP (64.4%) amongst PwD in primary care in NI. In addition, as discussed in Chapter 1, the impaired cognitive and communication skills of PwD, together with the presence of BPSD, may generate additional challenges in medication adherence (Maidment *et al.*, 2012; Elliott *et al.*, 2015). It was postulated that challenges such as these may influence doctors' prescribing behaviour and the quality of chronic illness management, for example, adherence to hypertensive guidelines (Imfeld *et al.*, 2013). At the time of project planning, there had been very limited research on prescribing, review, administration and adherence to medicines in PwD, particularly those residing in their own home and managed within the primary care setting. Despite the acknowledged importance of appropriate medicines management for this patient group, two recently published reviews highlighted a lack of developed interventions in this area, particularly for community-dwelling PwD (Aston *et al.*, 2017; McGrattan *et al.*, 2017). One of the reviews, conducted by members of the research team, concluded that well-designed holistic interventions must be developed that utilise a multidisciplinary approach involving different members of the primary healthcare team. Furthermore, interventions should endorse training and/or offer support for carers (McGrattan *et al.*, 2017).

It is widely acknowledged in the literature that carers (either formal or informal) play a key role in managing medicines for PwD (Maidment *et al.*, 2017). Research conducted in Australia noted the importance of routine and strategies to assist with medicines, particularly in terms of administration and adherence, and emphasised the evolving responsibility of carers as the patient's capacity diminishes (While *et al.*, 2013). The authors reported that this may lead to stress for carers and a responsibility that may not be fully recognised by HCPs (While *et al.*, 2013). During project planning, the research team were aware of one medicines management intervention for PwD and their carers which was under development in Germany (Fiß *et al.*, 2013), but due to differences in organisation of healthcare, this would not have been applicable to the NI setting.

Few studies also existed at that time which explored the roles that primary HCPs had to play in medicines management for PwD. A Canadian study had reported that family physicians were aware of the problems around medication management, but felt it was not their concern (Yaffe *et al.*, 2008). It had also been reported that the presence of a family carer may lower a GP's attention to medication-

related issues (While *et al.*, 2013). Previous work conducted by members of the research team had shown that community pharmacists frequently encountered PwD and their carers, dealing with queries about stopping or starting medication and measures to improve adherence most frequently (Barry *et al.*, 2013). Given these gaps in the literature, the research team felt it was important to explore medicines management issues for PwD from the perspectives of all key stakeholders. It was anticipated that extending the evidence base in this way would help to inform the development of an intervention to improve and optimise medicines management for PwD in primary care.

Therefore, the third chapter of this report describes the process of developing an intervention to improve medicines management for community-dwelling PwD (Phase 2). As previously stated, this study was set within the MRC's Complex Intervention Framework (Craig *et al.*, 2008; Medical Research Council, 2008) and therefore involved applying an appropriate theoretical framework, drawing on existing evidence and engaging key stakeholders in the intervention development process. In the context of this project, the main stakeholders were considered to be PwD, their carers, GPs and community pharmacists. In order to incorporate a theory-base into the intervention development phase, the Theoretical Domains Framework (TDF) was applied to identify the barriers and enablers of the behaviour change required to achieve successful medicines management (French *et al.*, 2012). The TDF is not a theory *per se* but rather provides a structure by which the cognitive, affective, social and environmental determinants of a behaviour can be identified (Atkins *et al.*, 2017). In the context of the current project, it allowed the research team to understand the behaviours and processes associated with medicines management amongst PwD, their carers, and primary HCPs. The most recent version of the TDF contains 14 theoretical domains that are relevant to behaviour change: '*knowledge*'; '*skills*'; '*social/professional role and identity*'; '*beliefs about capabilities*'; '*optimism*'; '*beliefs about consequences*'; '*reinforcement*'; '*intentions*'; '*goals*'; '*memory, attention and decision processes*'; '*environmental context and resources*'; '*social influences*'; '*emotions*'; and '*behavioural regulation*' (Cane *et al.*, 2012).

TDF-based interview studies can identify beliefs, which reflect barriers to and enablers of behaviours change, which then guide intervention design (Francis *et al.*, 2012). In line with the process for intervention development, target behaviours are specified and key theoretical domains are identified and then mapped to corresponding behaviour change techniques (BCTs), which can then be incorporated into an intervention (Michie *et al.*, 2014). BCTs are considered to be the 'active ingredients' of the intervention and have been defined as 'an observable, replicable and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour'

(Michie *et al.*, 2013). Examples of BCTs include ‘social support or encouragement’, ‘self-monitoring of behaviour’, ‘feedback on behaviour’, and ‘habit formation’. This systematic approach to intervention development is illustrated in Figure 2, and has been used by members of the research team in a number of previous studies (Duncan *et al.*, 2012; Cadogan *et al.*, 2015; Cadogan *et al.*, 2016; Patton *et al.*, 2018).

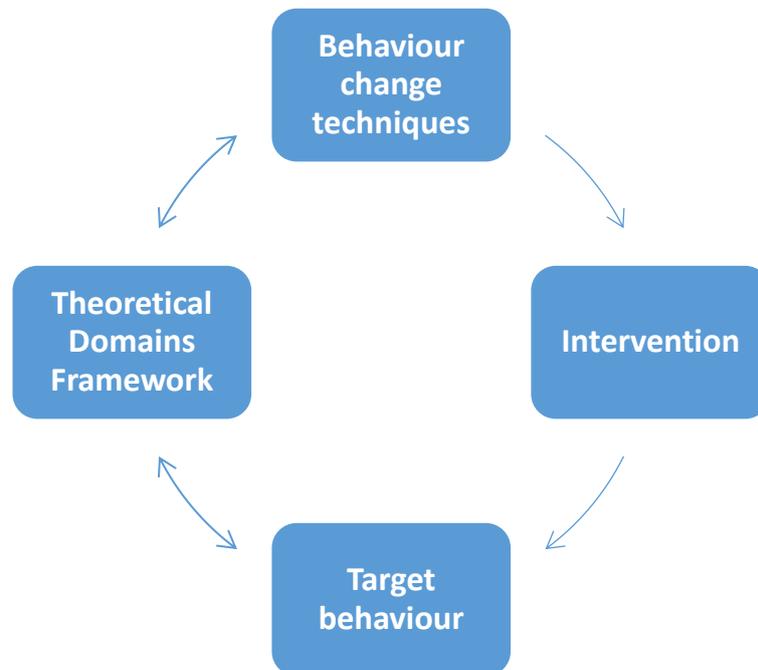


Figure 2. Systematic process of theory-based intervention development

3.2 Aims and objectives

The overall aim of the current study was to develop an intervention targeting medicines management for PwD in primary care in NI.

The specific objectives of this study were to:

1. Identify barriers and facilitators of successful medicines management from the perspectives of GPs, community pharmacists, PwD and their carers;
2. Identify target behaviours and key theoretical domains (barriers and enablers of the behaviour change required);
3. Map key domains to corresponding BCTs;
4. Develop an intervention incorporating identified BCTs.

3.3 Methods

This study used a qualitative approach, and focused on the ‘development’ phase of the MRC’s Complex Intervention Framework (Craig *et al.*, 2008; Medical Research Council, 2008).

3.3.1 Design

Semi-structured interviews were conducted with PwD, their carers, GPs and community pharmacists using a topic guide based on the TDF in order to identify key theoretical domains which would then be mapped to BCTs.

3.3.2 Sampling and recruitment of participants

As four different participant groups were sampled, a number of approaches were taken to identify potential participants. Two sub-groups of the Northern Ireland Clinical Research Network (NICRN) – Dementia and Primary Care – assisted with sampling and recruitment (See Appendix 5 for the letter of support from the Network Co-ordinating Centre). The Research Fellow (HBa) also had previous experience of recruiting and conducting interviews with PwD and their carers.

Sampling and recruitment of patients and carers

From the previous experience of members of the research team, we knew that successful recruitment of PwD and their carers should involve a number of different approaches to ensure a maximum variation sample (Iliffe *et al.*, 2014; Barry *et al.*, 2015; Barry *et al.*, 2016a). These approaches are outlined forthwith.

Memory clinics

Recruitment of patient/carer dyads took place through two regional memory clinics in the Belfast HSC Trust (located at Belfast City Hospital and Musgrave Park Hospital). PwD from across NI are referred to memory clinics for diagnosis and regular review by consultant geriatricians. Research nurses from the NICRN screened patients and their carers against a list of inclusion and exclusion criteria. Patients were eligible to participate in the study if they met the following criteria:

- A confirmed diagnosis of dementia (of any type);
- Lived in their own home;
- Prescribed four or more regular medications;
- Considered to be capable of undertaking an interview with a researcher.

Carers were eligible if they had contact with the patient at least three times a week and provided assistance to them with their medicines.

Eligible patient/carer dyads were approached by the clinician, given brief verbal information about the study, and provided with written invitation letters (Appendices 6 and 7) and information sheets (Appendices 8 and 9) to take away and read. With the patient and/or carer's permission, telephone contact details were taken and passed on to a member of the research team (HBa or MM), who then made contact after one week to ascertain patient and carer interest in the study. If patients and carers agreed, arrangements were made for the researcher(s) to visit them at home to conduct the interviews.

Primary care

It was anticipated that the second approach, which had been used successfully by a member of the research team (LR; Iliffe *et al.*, 2014), would allow us to identify dementia patients who may be living on their own. These patients may or may not have been attending an outpatient memory clinic.

General practices were purposively sampled to ensure practices were recruited from a range of geographical locations across NI. A computer-generated random sample of practices from each of the five HSC Trust areas were contacted by telephone by a research nurse from the NICRN. The practice manager/lead GP in each practice was given a brief verbal overview of the project, followed by written information about the study (comprising an invitation letter and information sheet; Appendices 10 and 11) via email or post if interest was expressed. Practices were followed up after one week to determine their agreement to take part in the study, and participating practices signed a research governance form (Appendix 12). The research nurse aimed to recruit two practices (one urban, one rural) per HSC Trust area.

Research nurses undertook screening and recruitment of patients only in each practice. The research nurse screened practice records, asking the lead GP to review the list of potentially eligible patients to confirm their eligibility and suitability of each individual to undertake an interview. Patients were eligible to participate in the study if they met the following criteria:

- A confirmed diagnosis of dementia (of any type);
- Living alone in their own home;
- Prescribed four or more regular medications;
- Considered to be capable of undertaking an interview with a researcher.

An invitation letter (Appendix 13), accompanied by an information sheet (Appendix 14), was posted out to all eligible patients. The research nurse returned to the practice after one week in order to follow up patients by telephone to ascertain their interest in taking part in the study. For patients willing to participate in an interview, arrangements were made for the researcher (HBa) to conduct the interview at the patient's home.

Recruitment of participants was guided by data saturation. However, previous work had indicated that data saturation would be achieved following 30-40 interviews encompassing both PwD and carers (While *et al.*, 2013). Therefore, we sought to recruit up to 15 patient/carer dyads from the memory clinics, and up to 10 PwD from GP practices (i.e. one patient per practice).

Join Dementia Research database

Following a period of slow recruitment through general practices, the research team also tried recruiting patients using the Join Dementia Research (JDR) database (www.joindementiaresearch.nihr.ac.uk). This is a service within the United Kingdom (UK) that allows people to volunteer to participate in all types of dementia research (Smith *et al.*, 2017). Researchers log in to the database, 'set up' their study stipulating the inclusion and exclusion criteria, and the service can then connect researchers with potential participants. Following a period of study set-up, the researcher (HBa) was able to access the database to find a list of potential participants matched with the study. Contact details were available for each person (usually either the PwD or a carer/representative). The researcher made telephone contact with each individual and confirmed their eligibility against the inclusion criteria, which were the same criteria as for patients recruited through primary care outlined above. A brief verbal overview of the study was then provided, followed up by written information (comprising invitation letter and information sheet; same as before) sent by email/post for those who expressed interest. As with the other recruitment methods, the researcher made follow-up contact by telephone after one week, and if the patient was agreeable to participating in the study, the researcher arranged a convenient time to visit the patient at home to conduct the interview.

Sampling and recruitment of General Practitioners (GPs)

GPs from each of the recruited practices were invited to take part in an interview. Written information (comprising an invitation letter and information sheet; Appendices 15 and 16) was provided to potential participants, and the researcher (HBa) liaised with the practice manager/lead GP to

determine which GPs wished to participate in an interview, and to arrange to visit the practice to conduct the interview(s). We sought to recruit between 15-20 GPs, as previous research had indicated that this number was sufficient for data saturation (Hughes and McCann, 2003; Francis *et al.*, 2010; Cadogan *et al.*, 2015).

Sampling and recruitment of Community Pharmacists

Recruited GP practices were asked to identify the community pharmacies which dispensed most of the prescriptions they issued. A previous study conducted by the CI (CH) showed that up to three community pharmacies dispensed >75% of all prescriptions from one practice (Hughes *et al.*, 2000). These pharmacies were contacted by telephone by the researcher (HBa) who provided a brief verbal overview of the project, followed up with a written invitation letter (Appendix 17) and information sheet (Appendix 18) sent via email or post, to those who expressed interest. Follow-up telephone contact was made with each pharmacy after one week, and if pharmacists were agreeable to participating in the study the researcher (HBa and/or MM) arranged to visit the pharmacy to obtain consent and to conduct the interview. Most community pharmacies have one pharmacist on staff, so we anticipated that we would recruit representatives from 15-20 community pharmacies. Previous work had found that if a general practice agrees to participate in a research study, associated community pharmacies will also agree (Hughes and Goldie, 2009; Rubio-Valera *et al.*, 2012).

3.3.3 Data collection

Data collection took place between October 2015 and November 2016. Interviews with participants were conducted by the researchers (HBa and MM) either in the patient's home (for patient and carer interviews) or their place of work (for HCP interviews). Written informed consent was obtained from all participants prior to commencing each interview (Appendices 19-21). Before taking consent from participants with dementia, the researcher followed a process used during previous research studies (Barry *et al.*, 2015; Barry *et al.*, 2016a), and in line with local legislation (Lynch *et al.*, 2017), to assess their capacity to provide consent (Appendix 22). Each participant was offered an honorarium of £50 in recognition of their time; HCPs were also awarded a certificate of participation for their Continuing Professional Development (CPD) portfolios (Appendix 23).

Interview topic guides were based on the 14 domains of the TDF (Cane *et al.*, 2012) and developed following discussions within the research team. Whilst a separate topic guide was developed and piloted for each participant group (Appendices 24-27), each topic guide followed a similar format covering three main areas. Participants were firstly provided with an explanation of the term

medicines management (in this context prescribing, dispensing, administration, including adherence, and review), and asked to reflect upon their own experiences and what they felt their roles/responsibilities were in relation to medicines management for PwD. For example, PwD were asked about how decisions were made about their medicines and if they were involved; carers were asked about their responsibility for the medicines for a PwD. Participants were then asked more focused questions guided by the 14 TDF domains in order to explore their perceptions of the barriers and facilitators to achieving successful medicines management for PwD; prompts were used to encourage participants to elaborate on their responses where necessary. Lastly, participants were asked their views about potential intervention components and outcomes measures for inclusion in future intervention studies.

Furthermore, in order to gauge the relative importance that participants placed upon medicines, the Beliefs about Medicines Questionnaire (BMQ; Horne *et al.*, 1999) was administered to patient participants where possible (Appendix 28). This enabled assessment of patients' beliefs regarding the necessity for, concerns about, and perceptions of harm from medicines, and how these beliefs affected their adherence. The BMQ contains 18 items, ten of which make up the BMQ-Specific subscale, and eight which make up the BMQ-General subscale. The BMQ-Specific subscale contains five items that measure a participant's beliefs about the necessity of the medication they are prescribed and five items that assess concerns about the potential negative consequences of taking their prescribed medicines. The BMQ-General subscale measures views towards overuse of medicines (four items) and perceptions of possible harms (two items) and benefits (two items) from taking medicines in general. Responses for all 18 items are recorded on a five-point Likert scale, from 1 (strongly agree) to 5 (strongly disagree). Higher scores for each scale indicate stronger beliefs (Horne *et al.*, 1999).

3.3.5 Data analysis

With participants' permission, all interviews were audio recorded and transcribed verbatim. Each transcript was proof-read and checked against the original digital recording for accuracy. All identifiers (e.g. names, locations) were removed from transcripts to ensure participant anonymity. Codes were assigned to denote if a participant was a patient (PT), carer (CA), general practitioner (GP) or community pharmacist (CP), together with a two-digit identification number. The data were managed and analysed using NVivo® software (QSR International Pty Ltd. Version 11, 2015).

Each dataset was analysed separately and all transcripts were analysed independently by at least two members of the research team (HBa, MM, CH or CR). Initially the researchers spent time familiarising and immersing themselves in the data, by reading through transcripts and listening back to interview recordings. Data analysis comprised a number of stages, and was modelled on approaches used by other members of the research team in previous studies utilising the TDF (Duncan *et al.*, 2012; Cadogan *et al.*, 2015; Patton *et al.*, 2018). The primary focus of the analysis was the TDF-related data. The framework method (Gale *et al.*, 2013) was used to systematically index and chart the data. Data was indexed by two researchers working independently (HBa and MM) using the 14 domains of the TDF (Cane *et al.*, 2012; Michie *et al.*, 2014) as the coding categories (Appendix 29). Indexed data were then charted and summarised by one of the researchers (HBa or MM) in a Microsoft Excel spreadsheet to generate a framework matrix (available on request). The matrix comprised one row per participant and an individual column for each TDF domain. Each spreadsheet cell contained summarised content for each individual participant and TDF domain. A separate Excel worksheet was used for each participant group (i.e. PwD, carers, GPs, community pharmacists). References to illustrative quotes were also included.

Content analysis (Ritchie and Spencer, 1994; Francis *et al.*, 2009) of the framework matrix was performed to identify factors perceived to influence the achievement of successful medicines management for PwD (i.e. barriers and facilitators) within each TDF domain. An interpretative summary of findings was then produced for each participant group outlining the subthemes/specific beliefs within each domain. Due to the complex interaction between a number of different behaviours involved in the medicines management process, the research team spent time focusing on each of the 'target behaviours' (Michie *et al.*, 2014) identified by HCPs during the interviews. They specified each of these in the form of 'narratives' concentrating on answering the following questions (Michie *et al.*, 2014): *Who* needs to perform the behaviour? *What* does the person need to do differently to achieve the desired change? *When, where, how often* and *with whom* will they do it? In addition to the target behaviours, the summaries for each participant group included problems/priorities, barriers and facilitators discussed under each theoretical domain. The summaries were reviewed and discussed by members of the research team and key theoretical domains identified (see below).

Identification of key theoretical domains

The approach to identifying key theoretical domains was guided by previous research (Francis *et al.*, 2009; Duncan *et al.*, 2012; Cadogan *et al.*, 2015; Patton *et al.*, 2018), whereby the extent to which sections of interview transcripts were coded to each domain was reviewed as a crude indicator of

relevance, and the summary documents were then used to determine whether participants related the domain to the target behaviour (Francis *et al.*, 2009). This process involved discussion within the research team to reach consensus on the selection of domains. Consideration was also given to the barriers and facilitators within relevant domains that could feasibly be targeted as part of a future intervention based upon the available project resources.

Triangulation

Data source triangulation (Patton, 1999) was conducted, using the evidence gathered from the different participant groups during the course of the study. The research team compared and contrasted participants' perceptions of barriers and facilitators within each of the theoretical domains, which helped to inform decision-making as to how selected BCTs could be operationalised as part of a future intervention.

Mapping of key theoretical domains to BCTs

The process used to map key theoretical domains to BCTs was guided by methods used by members of the research team in previous studies (Cadogan *et al.*, 2015; Patton *et al.*, 2018). The research team made reference to guidance within the literature and established taxonomies (Michie *et al.*, 2008; Cane *et al.*, 2015) which map BCTs to the behavioural determinants (domains) they are effective in changing. The mapping table published by Cane *et al.* (2015) was used in the first instance, however the research team also referred to the matrix by Michie *et al.* (2008) because in some instances, there were no BCTs linked to domains within the Cane *et al.* matrix, e.g. 'Social/professional role and identity' and 'memory, attention and decision processes'. The BCT mapping and selection process involved discussion within the research team to reach a consensus-based decision. Decisions were informed by the summary of findings from the content analysis of the interview data. Other factors considered during the selection process included the applicability of the BCT to the target population, the feasibility of operationalising the BCT in a future intervention to be delivered within the primary care setting, and the feasibility of implementing the BCT within the scope of the project.

Draft intervention development

Following identification of BCTs, consideration was given as to how the BCTs could be applied in practice. The analysis of patient and carer behaviours did not identify any barriers to, or issues concerning, adequate medicines management (see later). Therefore, following discussions within the research team, the decision was made not to proceed with developing an intervention for patients and carers. Two draft intervention outlines were developed for HCPs; one for community pharmacists

and one for GPs. In accordance with previously published guidance, the mode of delivery and content of the interventions were determined (French *et al.*, 2012). Both were informed by the results of the qualitative study described above, preceding research (Cadogan *et al.*, 2015; Barry *et al.*, 2016b; Cadogan *et al.*, 2016) and the experience and expertise of the multidisciplinary research team.

Task group work and selection of final intervention components

In order to progress and refine the draft interventions, task groups were conducted with GPs and community pharmacists to obtain their views and recommendations. Task groups are a hybrid focus group intended to generate both 'conventional' qualitative data and sets of principles or proposals for action grounded in the experience of the group members (Mort and Finch, 2005; May *et al.*, 2011). In order to recruit participants, a member of the research team (HBa) contacted the general practices and community pharmacies from which participants who took part in the interviews were originally recruited. Two task groups were conducted: one for GPs and one for pharmacists, during December 2017. The first task group included GPs only and took place at a single GP practice. Community pharmacists took part in the second task group, which was conducted at the School of Pharmacy, QUB. Similar to previous activities, participants were offered an honorarium of £50 and awarded a certificate of participation.

Task group content was developed based on previous studies that have used this approach (Mort and Finch, 2005; May *et al.*, 2011). Participants were first provided with an overview of the project and a brief summary of the work conducted to date (Appendix 30). In order to begin an open conversation, and to establish a degree of consensus regarding key concerns and issues, participants were presented with samples of statements collected during the interviews and asked to categorise them according to the following labels: 'true', 'false', 'interesting'. Following this discussion, participants were given written material where the identified target behaviours were structured around the following questions (Michie *et al.*, 2014): *Who* needs to perform the behaviour? *What* does the person need to do differently to achieve the desired change? *When, where, how often* and *with whom* will they do it? Participants were asked to provide any comments or suggestions for change (Appendices 31 and 32). Finally, participants appraised the draft intervention outlines developed by the research team using the APEASE criteria (Affordability, Practicability, Effectiveness/cost-effectiveness, Acceptability, Side-effects/safety, Equity; Michie *et al.*, 2014; Atkins, 2016). In order to do this, each participant was asked to complete a form (Appendix 33) containing the following questions: Can it be delivered to budget? Can it be delivered as designed? Does it work (ratio of effect to cost)? Is it appropriate? Does it have

any unwanted side-effects or unintended consequences? Will it reduce or increase the disparities in health/wellbeing/standard of living? Forms were collected at the end of each task group.

Task group discussions were audio recorded and analysed using thematic analysis (Braun and Clarke, 2006) to identify overarching themes and subthemes in relation to the proposed intervention components that were discussed by participants. Three members of the research team (CH, HBa, LB) met to agree on final intervention components (e.g., intervention content, mode of delivery). The discussion was guided by the task group data as well as what was feasible to implement within the scope of the project (e.g. time and resource restrictions).

3.3.8 Ethical considerations and approval

All personal information obtained about participants for the purposes of recruitment or data collection was kept confidential, and held in accordance with the Data Protection Act 1998. Electronic data (e.g. audio files) were held on a password-protected computer at the School of Pharmacy, QUB, and any paper-based information (e.g. consent forms) was held in a locked filing cabinet in the research team office. Access to data was restricted to members of the research team. The NICRN (Primary Care) Research Nurses who worked with GP practices provided copies of their Good Clinical Practice (GCP) certificates and Confidentiality Agreements providing evidence of training and responsibility regarding contact with confidential information. The participating GP practices and memory clinics were supplied with a study file, which was kept in a secure location at the practice/clinic and contained the study protocol and all relevant study information. No identifiable patient data was removed from GP practices/memory clinics at any time during the conduct of the study. Anonymity was ensured in the analysis of the transcripts and no published data could be attributed to individuals involved.

Written informed consent was obtained from all participants prior to commencing data collection. Seeking informed consent from PwD can be problematic as their mental capacity can fluctuate, and their ability to understand information, reason effectively, and make judgements can be affected by their cognitive functioning (Hotopf, 2005). As previously stated, each PwD's capacity to consent was assessed prior to taking part in an interview, following a process that has been used successfully in other studies (Barry *et al.*, 2015; Barry *et al.*, 2016a).

Although there was little risk associated with this study, there was a risk that participants (patients, carers and/or HCPs) might disclose examples of poor practice during the interviews. In the unlikely

event of this occurring, it was agreed that any cases would be reported to the Chief Investigator (CH) who would, in the first instance, refer it to the HCPs concerned and if necessary, to the appropriate regulatory authority. This procedure was outlined to all participants in the information sheet prior to participating in the study. Furthermore, participating in an interview could potentially cause PwD and/or their carers to become upset or distressed by prompting thoughts related to their health or experiences of care. Risk was minimised through provision of the study information sheet. During the interview, the researcher monitored participants for signs of distress. If a participant became upset or distressed, a protocol was followed and the patient's GP was informed by letter.

This study was reviewed by the East of England – Cambridge and Hertfordshire Research Ethics Committee (Ref: 15/EE/0103) and given a favourable opinion in February 2015 (Appendix 34).

3.4 Results

The data presented below is categorised initially as patient and carer data or HCP data. The data is then presented sequentially by each step leading to intervention development.

3.4.1 Data collected from patients and carers

Patient and carer characteristics

Thirty-three participants ($n=18$ patients, $n=15$ carers) took part in an interview. Data relating to the number of patients screened, excluded and consented by each of the sampling strategies is provided in Table 2; most patients were recruited through memory clinics, and very few through primary care or the JDR database.

Table 2. Patient recruitment by sampling strategy

	Memory clinic	Primary care	JDR database
Patients screened	24	529	23
<i>Did not meet inclusion criteria</i>	1	462	17
<i>Excluded by GP</i>	-	12	-
<i>Unable to make contact</i>	4	-	5
Contacted after one week by researcher/research nurse	19	55	1
<i>Consented to participate in study</i>	15*	5+	1
Patients interviewed	14	3	1

*One patient refused to be interviewed during data collection

+Two patients deemed unsuitable to interview as did not meet inclusion criteria

The gender split was equal in patients, whereas most carers ($n=13$) were female. Interviews lasted 27 minutes, on average, and ranged between 10-62 minutes.

Summary of findings from TDF analysis for patients and carers

Patients felt their responsibility was to ensure they took their medicines as prescribed and adhered to their medication regimen, whilst carers talked about their role in supporting the patient to do this and ensuring that patients had, in fact, taken their medications ('Social/professional role and identity'). Carers' roles varied depending upon the extent of community pharmacy input with ordering/collecting prescriptions and medication delivery and the severity of the patient's condition.

"To remember to take them every day! In the morning and then the evening. I don't mind, it's just part of life." [PT_10]

"Well I'm one hundred percent responsible, that's how I feel now. And I just wonder if there have been mistakes made in the past..." [CA_02]

"If she [patient] forgets, I have to say 'Did you take that one?' and I have to be there because she might say 'I did' and she didn't." [CA_07]

Patients described their competence and confidence with regard to medicine-taking, and reported not having any problems or issues with this at the current time ('Beliefs about capabilities'). Patients identified that having input from a family member or formal carer was a facilitator in this regard.

"I can take my medicines without any bother, I feel very confident. I just take them because I know the people that give me them, I know who they are...so I don't worry." [PT_02]

"I can no longer deal with it by myself...so I'm confident that my wife will do the right thing. I'm not confident that I would be doing the right thing."
[PT_04]

Patients and carers talked about the importance of medicine-taking as part of a routine, linked to other tasks such as mealtimes or bedtime. Most patients reported having strategies in place to help them remember to take their medicines ('Memory, attention and decision processes') such as a weekly compliance aid ('Environmental context and resources') or by using a checklist, and all patients received assistance from a carer, either informal (e.g. family member) or formal (linked to 'Social influences'). It was apparent that carers played an important role in prompting patients to take their medicines, checking to ensure medicines adherence ('Behavioural regulation') and in one case rewarding the patient for taking their medicines ('Reinforcement'), and would therefore be an integral part of a future intervention.

"They are all separate, and in wee slots [compliance aid], you just spilt the slot open and get what you want for that morning, and then there's a different one for the night." [PT_01]

"Well it's just a routine I do first thing in the morning. He [husband] makes me my breakfast and I take my medications then." [PT_05]

"I know I shouldn't but late at night, when he's taken the two of these [tablets] I give him two squares of chocolate. It's just a wee thing. I say 'Once you have these down now you can have this.'" [CA_05]

In addition, many patients made use of, and benefited from, community pharmacy services such as prescription ordering and delivery ('Environmental context and resources'). It was evident that patients and carers placed great trust in HCPs such as their GP and community pharmacist, and had confidence in their knowledge and judgement ('Social influences').

"They're [GP and pharmacist] the experts, and there's nothing to suggest that what I'm getting is doing me harm rather than helping me." [PT_07]

"Oh the pharmacist is excellent, isn't he? They're very kind you know, if you run out of anything, if you rang down they would send it up to you." [CA_03]

Patients appeared to have little or limited knowledge about their medicines ('Knowledge'), but were content with this due to the support they had from carers and their GP. Carers, on the other hand, were much more knowledgeable about patients' medications although the level of knowledge varied amongst carers. Some indicated that they would welcome more information from a HCP, particularly about medication indications.

“Don’t ask me what kinds of medicines. Like all I know is they are all tablets... I don’t know what they’re for.” [PT_02]

“...So for someone to sit down and say ‘This is what they’re for, there may be side effects’ and name a few...I think that is a good idea. A very good idea.” [CA_13]

Carers reported concern about the progression of cognitive impairment in the patient, and how this would impact upon their medicine-taking ability in the future (‘Beliefs about consequences’). Most acknowledged that while the situation was manageable currently, they could foresee issues with medicines management becoming more apparent over time, as the condition progressed. This was linked to a perceived lack of confidence in how they would be able manage the patient’s medicines and ensure their adherence as dementia worsened (‘Beliefs about capabilities’), and heightened anxiety around this issue (‘Emotion’).

“What happens in the future...I start to worry about that.” [CA_05]

“Well I would get anxious if he got to the stage where he didn’t want to take them [tablets].” [CA_11]

While carers talked about the positive relationships they had with HCPs (‘Social influences’), they also discussed difficulties around GP accessibility, lack of continuity in GPs, and the limited time they had to discuss patient medication issues in a ten-minute appointment slot (‘Environmental context and resources’). Whilst this was perceived to be a barrier, the accessibility of community pharmacists was viewed as a facilitator and a way around this.

“It’s hard to get through to the GP, they’re very, very busy.” [CA_05]

“I mean, all you have to do is stand there for five minutes, and in between dispensing they [pharmacist] will come out and have a chat.” [CA_06]

The ‘Optimism’ and ‘Skills’ domains were seldom discussed by participants. It was particularly difficult to determine how individual TDF domains impacted upon patients’ and carers’ behaviour as explicit links were not made between their beliefs and behaviour. For example, both patients and carers discussed that medicine-taking and adherence of the patient to their medication regimen was a high priority (‘Goals’), but no links were made between their goals/priorities and medicine-taking behaviour. The lack of problems identified by patients and carers also made it difficult for the research team to identify how a potential future intervention could be aimed at patients and carers. Therefore, it was decided that the remainder of the analysis would focus on the HCP data, with some key decisions made during the intervention development process being informed by the data collected from patients and carers.

The domains found to be relevant to patient and carer behaviours related to medicines management (i.e. obtaining prescriptions/medicines from the GP/pharmacist and medication administration/adherence) are summarised in Appendices 35 and 36.

Beliefs about Medicines Questionnaire (BMQ) data

Of the 18 patients who participated in an interview, $n=15$ completed a BMQ survey. In three cases, due to fatigue after the interview the researcher left the survey with the PwD, together with a stamped addressed envelope, so that they could complete it in their own time and return it to the School of Pharmacy. However, these surveys were never received. The data is presented in Table 3 below.

Table 3. Dementia patients' responses to the Beliefs about Medicines Questionnaire (BMQ)

	N (%)			
	Strongly agree/ Agree	Neither agree nor disagree	Disagree/ Strongly disagree	Missing
BMQ Specific				
<i>My health, at present, depends on my medicines</i>	15 (83.3)	-	-	3 (16.7)
<i>Having to take medicines worries me</i>	2 (11.1)	-	13 (72.2)	3 (16.7)
<i>My life would be impossible without my medicines</i>	9 (50.0)	4 (22.2)	2 (11.1)	3 (16.7)
<i>Without my medicines I would be very ill</i>	11 (61.1)	3 (16.7)	1 (5.5)	3 (16.7)
<i>I sometimes worry about long-term effects of my medicines</i>	2 (11.1)	4 (22.2)	9 (50.0)	3 (16.7)
<i>My medicines are a mystery to me</i>	5 (27.8)	3 (16.7)	7 (38.9)	3 (16.7)
<i>My health in the future will depend on my medicines</i>	14 (77.8)	1 (5.5)	-	3 (16.7)
<i>My medicines disrupt my life</i>	2 (11.1)	-	13 (72.2)	3 (16.7)
<i>I sometimes worry about becoming too dependent on my medicines</i>	3 (16.7)	2 (11.1)	10 (55.5)	3 (16.7)
<i>My medicines protect me from becoming worse</i>	14 (77.8)	-	1 (5.5)	3 (16.7)
BMQ General				
<i>Doctors use too many medicines</i>	2 (11.1)	6 (33.3)	7 (38.9)	3 (16.7)
<i>People who take medicines should stop their treatment for a while every now and again</i>	-	4 (22.2)	11 (61.1)	3 (16.7)
<i>Most medicines are addictive</i>	2 (11.1)	7 (38.9)	6 (33.3)	3 (16.7)
<i>Natural remedies are safer than medicines</i>	2 (11.1)	6 (33.3)	7 (38.9)	3 (16.7)
<i>Medicines do more harm than good</i>	-	1 (5.5)	14 (77.8)	3 (16.7)
<i>All medicines are poisons</i>	1 (5.5)	2 (11.1)	12 (66.7)	3 (16.7)
<i>Doctors place too much trust in medicines</i>	-	5 (27.8)	10 (55.6)	3 (16.7)
<i>If doctors had more time with patients they would prescribe fewer medicines</i>	2 (11.1)	9 (50.0)	4 (22.2)	3 (16.7)

3.4.2 Data collected from healthcare professionals (HCPs)

HCP characteristics

Fifty-two general practices and 18 community pharmacies were contacted about the study. Thirty HCP participants ($n=15$ GPs, $n=15$ community pharmacists) were recruited from nine general practices and 15 community pharmacies across the five HSC Trust areas in NI. Whilst 10 general practices were recruited to the study initially, and assisted with recruitment of PwD, GPs from one of the practices later refused to take part in an interview. Demographic characteristics of HCPs are shown in Table 4. The duration of interviews varied amongst GP (range 35-60 minutes) and pharmacist (range 33-80 minutes) participants.

Table 4. Healthcare professional participant characteristics

	General practitioners ^a ($n=15$)	Community pharmacists ($n=15$)
Participant gender		
Male	7	8
Female	8	7
Years of professional practice (range)	5-30	1-27
HSC Trust area		
Belfast	3	4
Northern	4	3
Southern	5	2
South Eastern	2	3
Western	1	3

^a>1 GP participant was recruited from four general practices

Summary of findings from the TDF analysis for HCPs

GPs discussed medicines management for PwD in terms of the two main responsibilities (i.e. target behaviours) they felt they had in the process: prescribing and conducting medication review ('Social/professional role and identity').

"The good practice of prescribing is to ask yourself 'Do I need to prescribe at all?' The second [thing] is to monitor the polypharmacy side of things, to periodically assess whether the patient needs to remain on X, Y or Z. It's so easy to add in and it can be very difficult to put a pen through something..."
[GP_02]

"Then it is just reviewing them and checking that when other drugs are added that they're not adding to their problems in term of...adding things that will confuse them further." [GP_09]

Community pharmacists, however, predominantly discussed conducting medication review and monitoring adherence in this patient population ('Social/professional role and identity').

"[My role is] to ensure they're getting the correct medication at the correct dose... That it's doing what it's supposed to with no adverse effects. But actually what we're doing on top of that is policing...to ensure they are actually taking the medication. And we would review...it might not be very structured, it could be more ad-hoc." [CP_07]

Whilst each HCP group acknowledged the good working relationship they had with the other HCP group, professional boundaries were discussed ('Social/professional role and identity'). Some of the GPs talked about the boundaries they had encountered between themselves and consultants in secondary care, whereas some of the community pharmacists talked about professional boundaries with GPs:

"And the other thing is that there's a bit of a cut off between GPs and consultants, certainly in this Trust, I don't feel like there's a very sort of natural... I think we could work in improving that..." [GP_07]

"Maybe GPs feel that [medicines management] is their job and that we're encroaching on their territory." [CP_07]

Both HCP groups recognised the clinical knowledge they needed when contributing to medicines management for this particular patient group. In addition to this, a holistic knowledge of patients' personal and social circumstances was considered to be important by both HCP groups ('Knowledge'):

"Whenever you prescribe for an individual, you're looking at the whole situation." [GP_01]

"I also find in community that it's very good to understand their family situation and who is looking in on them... Just checking the patient isn't becoming isolated and that there are people out there who can support them." [CP_03]

However, community pharmacists did feel that their knowledge of patients' medical and clinical history was limited by their lack of access to patients' medical records (which links to the 'Environmental context and resources' domain), whilst some of the GPs discussed their own personal lack of knowledge of the drugs used for dementia (linking to the 'Beliefs about capabilities' domain):

“I’m never quite sure what combination of dementia drugs can be used together...” [GP_06]

“I think because the specialist dementia drugs are secondary care initiated, I am a little bit, I wouldn’t say unhappy about it, but I’m just... A bit more hesitant because they how do I measure whether they’re working or not?” [GP_10]

Both HCP groups acknowledged the benefits of optimising medicines management for PwD, predominantly in terms of slowing disease progression and improving patients’ quality of life (‘Beliefs about consequences’). However, there was a strong concern amongst the HCPs that adherence, in particular, was poor amongst this patient group:

“So then there’s compliance, I just think you have to assume it’s not going to be very good. They’re [PwD] always at risk aren’t they? Even if it’s in a weekly dispensing pack, there’s many ones that open up the wrong day and take two lots [of tablets].” [GP_13]

“I think sometimes it’s a bit risky if there’s a whole pile of bottles of medications and you don’t know who is taking them or what they’re taking and maybe they’re [the PwD] not 100% clear themselves as to what they’re actually taking as well.” [GP_15]

“Because you don’t know if they’re going to not use, or if they’re going to overuse... My concern of it would also be the overdosing on medicines as well.” [CP_13]

One community pharmacist talked about the lack of control they felt once the PwD had left the community pharmacy and was managing their medicines at home:

“What is the total unknown is when you give out medication what really is happening.” [CP_02]

Some GP participants discussed the practice of deprescribing medicines as a facilitator to improve patient outcomes (‘Beliefs about consequences’):

“So if somebody comes in and they are on Natecal® [calcium and vitamin D] twice a day, and they’re sick to the stomach of it, and you look at them and you think “OK, realistically is this benefiting you or is it making you miserable?”, you know, you’re going to feel for them and say look... If you’ve someone with very advanced dementia and you’ve known them a long time and you know what their feelings and thoughts are towards how they want the rest of their life to go, and if you know that being on 16 tablets a day is not doing them the world of good, you’re more inclined to probably withdraw some of the ones that are maybe not essential.” [GP_03]

“Often I feel that patients might benefit from coming off tablets, maybe in the future that will happen more?” [GP_15]

GPs and pharmacists both discussed a number of barriers to optimising medicines management for PwD. Lack of time, for example to check up on changes to patients’ medication or to conduct comprehensive reviews of patients’ medication, was frequently cited and linked to the increasing complexity of patients’ needs (‘Environmental context and resources’):

“To properly do [medication] reviews, rather than go through a quick box ticking, takes time.” [GP_01]

“I think time is the thing... protected time. General practice has changed from a job whereby twenty years ago we were seeing minor self-limited illnesses that took five minutes to sort out. Primary care has now changed whereby the patients that we are seeing tend to be complex, they tend to be elderly, to try and sort these patients in ten minutes is now becoming impossible.” [GP_12]

“In recent years we haven’t done very many formal medicines management or medicines use reviews. Time being the main issue. We have great desire to do them, great intention to do them, but we just haven’t found ourselves with an awful lot of time to do them.” [CP_05]

At the time of data collection, the new pilot scheme to embed pharmacists in general practices in NI was in its early stages, and many of the GP participants could see how these pharmacists could contribute to this area in the future (‘Environmental context and resources’):

“There is certainly a role which needs to be developed for an actual pharmacist or prescribing pharmacist in surgeries to review all [dementia] patients, but particularly the patients who are on repeat prescribing of numerous drugs, say five, say ten or more items.” [GP_01]

“It’s a daily chore and again there’s all this stuff about practice pharmacists, which we were promised in July. Here we are again... a pinch of salt of course... “When will it happen?” but that will be a big boom. When we have a pharmacist attached to us so much of this, you know, if this was identified as a need then it will be... she or he will be used to try and bring things to us.” [GP_02]

“Those [patients] would be good ones for, you know, the practice pharmacist to have a look at those medications in detail to see exactly if all of the medications are appropriate or need reviewed. But I would probably think that a lot of them would need reviewing; probably all of them; and that is a large amount of time and effort.” [GP_08]

“I think an in-practice pharmacist is the way forward for lots of areas and dementia would be one area certainly.” [GP_10]

Both community pharmacists and carers were acknowledged by GPs as being valuable resources to them, in making them aware of medication-related issues that otherwise they would be unaware of ('Social influences'):

"I suppose you're relying a lot on the person who is caring for the patient. Most patients at home really we're talking about here. If the patient is supposed to be taking the drugs themselves and we find there's an issue, quite often it's family and friends we will go to first to ask them to check the medication." [GP_06]

"We've got a couple of good community pharmacists who sometimes ring us who say such and such hasn't picked up their blister packs for two weeks or such and such is only asking for this and saying we've plenty of that." [GP_07]

"More often than not I think it's the pharmacist that would flag up a lot of these things to us, you know, or if these patients are getting their medications delivered, the person delivering the medication might notice, you know, it's just information from various sources in the community, I think." [GP_15]

Appendices 37 and 38 summarise the range of barriers and facilitators that were identified by GPs and community pharmacists within each theoretical domain, together with illustrative quotes. As stated earlier, the remainder of the analysis focused on the HCP interview data.

3.4.3 Identification of key theoretical domains

The narratives produced for each HCP group and each identified target behaviour (GPs: prescribing and conducting medication review; community pharmacists: conducting medication review and monitoring adherence) are provided in Appendix 39. Overall, twelve of the 14 domains were considered relevant to achieving appropriate medicines management for PwD – the domains 'Optimism' and 'Intentions' were not considered to be important because explicit links could not be made between beliefs expressed by HCPs and their behaviour(s). The key theoretical domains identified against each identified target behaviour for GPs (i.e. prescribing and conducting medication review) and community pharmacists (i.e. monitoring adherence and conducting medication review) are shown in Table 5. It became clear during the analysis that a number of domains were interlinked. For example, barriers identified under the 'Environmental context and resources' domain for GPs (such as time and workload) were found to negatively impact on other domains such as 'Memory, attention and decision processes'. Facilitators identified under the 'Knowledge' domain (such as clinical knowledge) were also found to positively impact 'Beliefs about capabilities'. There was also

overlap between the domains ‘Social/professional role and identify’ and ‘Social influences’, largely due to the overlap in theoretical constructs between these domains.

Table 5. Key theoretical domains identified by medicines management target behaviour for each healthcare professional (HCP) group

Theoretical domain	GP		Community pharmacist	
	Prescribing	Conducting medication review	Monitoring adherence	Conducting medication review
<i>Knowledge</i>	✓		✓	
<i>Skills</i>		✓	✓	✓
<i>Memory, attention and decision processes</i>		✓	✓	
<i>Behavioural regulation</i>	✓	✓	✓	
<i>Social/professional role and identity</i>				✓
<i>Beliefs about capabilities</i>	✓		✓	
<i>Beliefs about consequences</i>	✓		✓	✓
<i>Goals</i>	✓	✓	✓	
<i>Reinforcement</i>	✓	✓	✓	
<i>Emotion</i>	✓		✓	
<i>Environmental context and resources</i>	✓	✓	✓	✓
<i>Social influences</i>	✓	✓	✓	✓

3.4.4 Mapping of theoretical domains to BCTs

Using previous work on mapping BCTs to the TDF as already outlined, the research team identified 107 BCTs from the two reference sources (Michie *et al.*, 2008; Cane *et al.*, 2012). Further detail on the mapping process is provided in Appendix 40. Seven BCTs were subsequently selected for inclusion in a future intervention involving GPs and/or community pharmacists to improve medicines management for PwD in primary care: ‘Action planning’, ‘Health consequences’, ‘Modelling or demonstrating the behaviour’, ‘Salience of consequences’, ‘Self-monitoring of behaviour’, ‘Social and environmental consequences’, and ‘Social support or encouragement’/‘Social process of encouragement, pressure, support’. Table 6 presents the seven selected BCTs mapped to key TDF domains. No BCTs were selected for three of the key domains; ‘Reinforcement’, ‘Emotion’, and ‘Environmental context and resources’. Whilst a number of BCTs were identified against each of these domains, the BCTs were not considered to be feasible to target within the confines of the project,

given the time and resources available and the primary care settings in which the intervention was potentially to be implemented.

Table 6. Final selection of BCTs to target each key domain and include as components of an intervention to improve medicines management for people with dementia (PwD) in primary care

Key TDF domain	Behaviour change techniques (BCTs) selected to target the TDF domain
<i>Knowledge</i>	Health consequences ¹
<i>Skills</i>	Modelling/demonstration of behaviour by others ²
<i>Memory, attention and decision processes</i>	Self-monitoring ² Planning, implementation ² (equivalent to 'Action planning')
<i>Behavioural regulation</i>	Self-monitoring of behaviour ¹ Planning, implementation ² (equivalent to 'Action planning')
<i>Social/professional role and identity</i>	Social processes of encouragement, pressure, support ²
<i>Beliefs about capabilities</i>	Self-monitoring ² Social processes of encouragement, pressure, support ²
<i>Beliefs about consequences</i>	Saliency of consequences ¹ Social and environmental consequences ¹ Self-monitoring ²
<i>Goals</i>	Action planning (including implementation intentions) ¹ Social processes of encouragement, pressure, support ²
<i>Reinforcement</i>	None selected ³
<i>Emotion</i>	None selected ³
<i>Environmental context and resources</i>	None selected ³
<i>Social influences</i>	Modelling or demonstrating the behaviour ¹ Social process of encouragement, pressure, support ² Modelling/demonstration of behaviour by others ²

¹Identified from Cane *et al.* (2012) mapping tables

²Identified from Michie *et al.* (2008) mapping tables

³None of the BCTs mapped to these domains were considered to be feasible to target within the confines of the current project

3.4.5 Draft intervention development

Based on the discussions of the research team, two draft interventions that operationalised selected BCTs were developed for potential feasibility testing (Table 7). The draft interventions targeted GPs and community pharmacists respectively, and focused on prescribing and conducting medication review (GPs) or monitoring adherence and conducting medication review (pharmacists) in the context of a consultation with a PwD and their carer. In developing each draft intervention, we considered the local context (as identified from the qualitative interviews) and attempted to ensure that each

intervention would be time-efficient and relatively easy to incorporate into routine clinical practice. The rationale underpinning our chosen mode of BCT delivery for each intervention was guided by the professional experience of the multidisciplinary research team, as well as being informed by members' prior experience of operationalising BCTs in previous intervention development studies (Duncan *et al.*, 2012; Cadogan *et al.*, 2015; Cadogan *et al.*, 2016; Patton *et al.*, 2018).

The decision to use an online video to deliver the BCT 'Modelling or demonstrating of behaviour' as part of both HCP-based interventions was informed by a recent project undertaken by members of the research team (Cadogan *et al.*, 2015; Cadogan *et al.*, 2016). As part of this project, a video was used to demonstrate how GPs can prescribe appropriate polypharmacy for older patients. This mode of delivery was considered to be both usable and acceptable by the GPs who took part in a study assessing the feasibility of the intervention (Cadogan *et al.*, 2018). In addition, HCPs interviewed as part of the current project (both GPs and community pharmacists) highlighted the time pressures they faced when trying to adequately manage medicines for PwD. It was envisaged by the research team that videos would not take up too much time and would be readily accessible to HCPs working in busy primary care settings (or could be viewed from home if they wished). The content of the video would be informed by the findings from the earlier pharmacoepidemiological work conducted by the research team in Phase 1 of the project (Barry *et al.*, 2016b).

The inclusion of a mentoring system or online discussion forum was also informed by our qualitative interviews with HCPs, and their potential isolation from other colleagues, particularly for community pharmacists (Cooper *et al.*, 2009; Magola *et al.*, 2018). It was envisaged that this may allow HCPs to discuss difficult cases in a confidential manner, and receive guidance from their peers.

Table 7. Description of draft interventions to improve medicines management for PwD in primary care

GENERAL PRACTICE-BASED INTERVENTION
<p>Target group: GPs</p> <p>Target behaviours: Prescribing and conducting medication review</p> <p>Intervention description: The intervention would be delivered through a short online video (or series of videos) demonstrating how GPs can prescribe appropriately during a typical consultation with a PwD and their carer ('Modelling or demonstrating of behaviour'). Elements of a medication review conducted by the GP would also be incorporated in the video (or as a separate video). Each video would include feedback from the GP, the PwD and their carer emphasising the positive outcomes of the consultation ('Health consequences', 'Salience of consequences', 'Social and environmental consequences').</p> <p>As complementary intervention components, GPs would be provided with an action planning template to help them make an explicit plan of when, where, and how they would carry out each behaviour, and with whom ('Action planning'). GPs would be encouraged to regularly review this to ensure their behaviour is monitored and recorded ('Self-monitoring of behaviour'). A one-to-one mentoring system would be implemented to facilitate action planning and to provide GPs with the opportunity to discuss challenging clinical cases with GP colleagues ('Social processes of encouragement, pressure, support').</p>
COMMUNITY PHARMACY-BASED INTERVENTION
<p>Target group: Community pharmacists</p> <p>Target behaviours: Monitoring adherence and conducting medication review</p> <p>Intervention description: The intervention would be delivered through a short online video (or series of videos) similar to the GP-based intervention described above. The video would operationalise a number of BCTs ('Modelling or demonstrating of behaviour', 'Health consequences', 'Salience of consequences', 'Social and environmental consequences') by demonstrating how a pharmacist could monitor adherence and conduct a medication review during a scheduled consultation with a PwD and their carer. The video would include feedback from the pharmacist, PwD and their carer emphasising the positive outcomes of this consultation.</p> <p>Patients would be identified by the pharmacist from a search of the pharmacy patient medication record (PMR) and pharmacists would plan to approach PwD and their carers when they would next present at the pharmacy. If agreeable, pharmacists would schedule an appointment to conduct the adherence check and medication review ('Action planning'). Upon completion of this, pharmacists would ensure that any changes they had recommended to patients' medications were communicated to GPs, and recorded on the PMR ('Self-monitoring of behaviour').</p> <p>In order to provide the opportunity for confidential discussion with other community pharmacists, a one-to-one mentoring system or online discussion forum would be incorporated as a complementary intervention component ('Social processes of encouragement, pressure, support').</p>

3.4.6 Task group work and selection of final intervention components

The key strengths and limitations discussed by task group participants regarding the respective draft interventions are summarised in Table 8.

Table 8. Summary of strengths and limitations of draft interventions as identified by task group participants (guided by the APEASE criteria; Michie *et al.*, 2014)

	GP-based intervention	Community pharmacy-based intervention
<i>Strengths</i>	<ul style="list-style-type: none"> • Likely to be an acceptable intervention • One video preferred to multiple versions 	<ul style="list-style-type: none"> • Likely to be a practicable and acceptable intervention • Presence of carer helpful to reduce patient anxiety/reliance on patient report of information • Links with local practice-based pharmacist would be useful
<i>Limitations</i>	<ul style="list-style-type: none"> • Video may need to be tailored depending upon prescribing/medication issues at different stages of dementia • Action planning document not considered to be acceptable • Mentoring system already in place, particularly in large practices 	<ul style="list-style-type: none"> • Time constraints if only one pharmacist on staff

A video format by which to deliver aspects of the intervention was considered acceptable to both GPs and pharmacists. However, it was felt that one video, of no more than 15 minutes, which captured identified target behaviours was practical, and as it could reach a wider audience, would also be cost-effective. The action plan component of the intervention was considered unnecessary by GPs. As an alternative, GPs recommended that a ‘protocol’ should be developed to complement the video, which should include information on contra-indications as well as drug interactions, and be referred to when prescribing or conducting a medication review for a PwD. The concept of a ‘protocol’ was presented to community pharmacists during their task group; this idea was well received and additional suggestions were provided for content (e.g. red flag interactions, list of resources to which PwD and carers could be signposted, guidance on assessing capacity to provide informed consent). The proposed mentoring system was discussed with GPs who did not feel it was practical as regular practice meetings already took place, as well as informal discussions with practice colleagues. Instead, GPs discussed the possibility of webinars or online discussion forums with multidisciplinary input. However, at the pharmacist task group, the idea of a mentoring system was welcomed due to feelings

of isolation experienced by community pharmacists. It was agreed that a mentoring system or online forum may help to address this, particularly if the mentor was a practice-based pharmacist as this would help to establish a link between the community pharmacist and local GP practice. Finally, it was suggested by task group participants that the intervention should be tailored to a particular stage of dementia due to differences in required treatment and support (e.g. deprescribing may be a more pertinent issue for patients with severe/advanced dementia).

Selection of intervention for feasibility testing

Following further discussion within the research team, the community pharmacy-based intervention was selected for further feasibility testing. The GP-based intervention was not considered for further evaluation for a number of reasons. Firstly, in the intervening time between qualitative data collection (which had taken place during late 2015/ early 2016) and the task group work (in late 2017) there had been a number of staff changes (both GPs and practice managers) within the recruited GP practices, and it had been difficult to re-engage with these practices for their participation in the task groups. In addition, it was felt that the current challenges faced within primary care and general practice in NI at that particular time would create additional difficulties in securing the participations of GP practices in a future feasibility study.

Modification of the final intervention selected for feasibility testing

The community pharmacy-based intervention was modified slightly to reflect the feedback provided by pharmacists during the task groups. The final intervention comprised the following:

1. A video which demonstrated how a community pharmacist would conduct a medication review and incorporate adherence checking with a PwD and their carer (stills from the video are included in Appendix 41). A clinical case study was developed, incorporating relevant data from the first phase of the project (e.g. patient demographic characteristics, number of repeat medications, instances of PIP; Barry *et al.*, 2016b) as well as drawing upon the clinical experience of the research team. A script was then written to ensure that the positive consequences of performing the behaviour are reinforced from the perspectives of the pharmacist, PwD and carer. In line with recently published clinical guidance, the principles of a patient-centred approach were applied by including the involvement of the PwD and their carer in decision-making throughout the medication review and adherence check (National Institute for Health and Care Excellence, 2018). The video was filmed and edited over four days by the Video Production team at QUB; filming took place within the simulated community pharmacy premises located in the School of Pharmacy. Two actors were recruited

to play the roles of the PwD and carer, and the postgraduate researcher for this project (MM) played the part of the pharmacist.

(Embedded BCTs: 'Modelling or demonstration of behaviour'; 'Health consequences'; 'Salience of consequences'; Social and environmental consequences')

2. A complementary 'quick reference guide' (QRG) to which pharmacists could refer for top-line information in relation to conducting the medication review and adherence check. The QRG listed common instances of PIP in this patient population (Barry *et al.*, 2016b), pharmacokinetic drug interactions with acetylcholinesterase inhibitors (drugs commonly prescribed for dementia), guidance regarding antipsychotic drug use in PwD, useful tips on communicating with PwD, practice points on monitoring adherence in PwD, and useful sources of further information.

(Embedded BCT: 'Modelling or demonstration of behaviour')

3. After the pharmacist had watched the video and read the complementary QRG, they identified suitable dementia patients from the pharmacy PMR and scheduled an appointment for a PwD and their carer to attend the pharmacy for a medication review and adherence check.

(Embedded BCT: 'Action planning')

4. Following the review, the pharmacist completed a clinical record form outlining any changes to the patient's medication regimen that they recommended. These recommendations were then shared with the patient's GP and recorded on the pharmacy PMR so that the pharmacist could clearly see if their recommendations had been implemented by the patient's GP.

(Embedded BCT: 'Self-monitoring of behaviour')

3.5 Summary

This chapter describes the systematic development of an intervention to improve medicines management for PwD in primary care and serves to address the lack of theory-based and adequately described interventions in the literature (McGrattan *et al.*, 2017). The detailed analysis of the target behaviours that was undertaken using the TDF (Cane *et al.*, 2012) as the underpinning theoretical framework enabled us to identify key mediators (i.e. barriers and facilitators) of behaviour change to target as part of the intervention. Key stakeholders have informed the intervention development process, which is a key strength of the study. However, the lack of medicines management issues identified by patients and carers at the time of data collection informed the research team's decision to focus the remainder of the analysis on the HCP data. The intervention development process and final choice of intervention components involved a degree of pragmatism to be applied, and the use

of HCP task groups were useful in achieving this. Future feasibility testing will help us to determine if further refinements to the intervention are required before progressing to a larger scale evaluation in a randomised study.

CHAPTER 4. Testing the feasibility of the intervention

4.1 Introduction

The previous chapter reported on the development of a complex intervention targeted at community pharmacists to improve medicines management for PwD in primary care. The intervention consisted of a video demonstrating the conduct of a medication review and adherence check with a PwD and their carer. There was also a QRG to complement the video, containing key information that pharmacists may need during the conduct on the medication review and adherence check. Next, the pharmacist was required to schedule an appointment with a PwD and their carer to conduct a medication review and adherence check, after which a clinical record form would be completed and any recommendations communicated to the patient's GP. This chapter reports on the testing of the feasibility of the intervention (usability and acceptability) and study procedures (recruitment methods and data collection).

4.2 Aims

The overall aim of the current study was to assess the feasibility of a community pharmacist-targeted intervention to improve medicines management for PwD in primary care.

The specific objectives of this study were to:

1. Recruit two community pharmacies;
2. Deliver the intervention to community pharmacists in each pharmacy who would then perform medication reviews and adherence checking with PwD and their carers (five patient/carer dyads per community pharmacy);
3. Assess the feasibility and acceptability of the intervention to community pharmacists, PwD and their carers.

4.3 Methods

The study was registered with the ISRCTN registry (Ref: ISRCTN94143260; <http://www.isrctn.com/ISRCTN94143260>).

4.3.1 Recruitment of community pharmacies

A convenience sampling approach was used to recruit two community pharmacies (one urban/sub-urban and one rural) into the study. Pharmacies were sampled from the five community pharmacies

that had participated in the earlier task group work described in Chapter 3. The main reason for approaching these pharmacies initially was because they had participated in the earlier phase of the study during which the intervention had been developed to target specific theoretical domains that were reported to be affecting the management of medicines by community pharmacists within these pharmacies. These pharmacists had displayed enthusiasm for, and engagement with the project to date, and were therefore considered to be well placed to test the usability and acceptability of the intervention in addressing the specific challenges they (and/or their colleagues) reportedly faced in clinical practice.

An expression of interest letter and form was sent to the five community pharmacies that had participated in the pharmacist task group (and, by extension, had also participated in the earlier qualitative interview study). Once expressions of interest were received, and following receipt of ethical approval, the researcher (LB) contacted pharmacists by telephone or email to discuss the study further. If a pharmacist was interested in taking part, an invitation letter (Appendix 42) and study information sheet (Appendix 43) was posted or emailed to them. One week after the documents were sent, the researcher telephoned the pharmacist again to confirm that they would like to participate. If the pharmacist agreed, a meeting was arranged. During this meeting, an overview of the feasibility study was presented and there was a discussion of what participation would involve for the pharmacist. At this stage, the pharmacist was asked to provide written, informed consent (Appendix 44) and given a study folder containing all necessary documentation (e.g. participant information sheets, consent forms, written instructions and login details for accessing the intervention's online video component, etc.).

Due to unforeseen circumstances with one of the recruited pharmacists (which involved a move to a different community pharmacy within the business to take up a pharmacy manager position), this pharmacist was unable to complete subsequent stages of patient and carer recruitment and data collection, and withdrew from the study. Therefore, an alternative pharmacy was recruited from within the same pharmacy chain.

On completion of the study, community pharmacists would be awarded a certificate of participation, which they could use for their CPD portfolios. Each pharmacist was also offered £500 for the time and resources they allocated to study participation, £100 for each patient/carer dyad recruited (i.e. potential for £500 if five patients and carers were recruited), and £50 to take part in an interview with the researcher (LB or HBa) at the end of the study. Therefore, pharmacists could receive up to a total

of £1,050 for their participation in the study. This was based on incentives provided in previous research studies conducted within primary care (Cadogan *et al.*, 2018).

4.3.2 Sampling and recruitment of PwD and carers

Eligibility criteria

Each participating community pharmacy was asked to recruit five PwD/carer dyads meeting the following inclusion criteria:

- A formal diagnosis of mild-moderate dementia (to be confirmed by their GP)
- Prescribed four or more regular medications (excluding 'when required' medications)
- Have at least twelve months' dispensing data available on the pharmacy Patient Medication Record (PMR) at the time of screening;
- Resident in their own home in the community;
- Have a carer (see below for carer inclusion criteria).

Patients with severe dementia were excluded from the study as these patients were considered to have an increased likelihood of not having the capacity to undertake a medication review. In addition, the medication management issues for PwD at more advanced stages of the disease may require a longer and more comprehensive review with the patient's GP (e.g. due to possible withdrawal or deprescribing of medicines).

In order to be eligible to participate in the study, carers had to have contact with the PwD at least three times a week, and had to provide assistance to the PwD with their medicines. These inclusion criteria were similar to what had been used in Phase 2 of the project.

Screening to assess patient eligibility

A two-stage screening process was implemented (upon the request of the Research Ethics Committee who reviewed the study) to assess patients' eligibility to participate in the study.

The first stage of this process involved the community pharmacist screening and approaching PwD and their carers:

1. Before patients were approached, the community pharmacist used the pharmacy PMR to identify patients who were prescribed a drug for dementia (i.e. donepezil, galantamine, rivastigmine or memantine; this was used as a proxy for a dementia diagnosis at this initial stage), were prescribed ≥ 4 regular medications, and had at least 12 months' of dispensing data available

2. The pharmacist then approached the PwD and their carer when they next attended the pharmacy to tell them about the study (our previous qualitative work with pharmacists revealed that PwD and their carers regularly attended their local pharmacy to collect compliance aid medication packs). If they showed interest, the pharmacist would provide the patient with a study information sheet (Appendix 45), discuss what taking part would involve for the patient and carer, and what the second stage of the eligibility screening process would entail. If patients and carers were interested in taking part, the pharmacist would assess the patient's capacity to provide informed consent using a checklist (Appendix 46), and ask the patient to complete and sign a consent form (Appendix 47) to confirm that the pharmacist could then approach their GP.

The second stage of the screening process involved the community pharmacist making contact with the patient's GP to obtain confirmation that the patient had a diagnosis of mild-moderate dementia. The pharmacist would send a letter to the patient's GP (using a template supplied by the research team; Appendix 48) describing the purpose of the study, along with a copy of the patient's signed consent form and an eligibility checklist (Appendix 49), which the GP would then use to confirm that the patient met the outlined study inclusion criteria.

Patient and carer recruitment

If the patient's GP confirmed their eligibility, the pharmacist would contact the patient and/or carer by telephone to inform them of this, and to ask if they would still like to participate in the study. If so, the pharmacist would post an invitation letter (Appendix 50), two participant information sheets (Appendices 51 and 52), and a supplementary information sheet describing what a medication review would involve (Appendix 53). A week after this information would be posted, the pharmacist would call the patient and/or carer to formally recruit them to the study, and to arrange a mutually convenient date and time for the medication review appointment (which would take place in the community pharmacy).

4.3.3 Intervention delivery

The content of the intervention was described in detail in Chapter 3, and is available to view upon request. The video (approximately 16 minutes duration) and QGR were made accessible to community pharmacists through Articulate® (<https://articulate.com/>) software, which is used to develop and deliver e-learning. This enabled the multimedia-rich educational material (video and text) to be delivered to users via a secure online platform. Community pharmacists recruited to the study were

sent detailed instructions (containing a URL along with a username and password) for accessing and using the software.

After watching the video and reading the accompanying material on Articulate®, pharmacists were expected to screen patients and carers using the two-stage screening process outlined above, in order to meet the recruitment target of five PwD/carer dyads per community pharmacy.

At the start of the review appointment, the pharmacist was to assess the patient's capacity to provide written informed consent for the medication review to be conducted (using the same assessment of capacity checklist that was used previously during screening; Appendix 46), and consent would have been taken from both the PwD and their carer (Appendices 54 and 55). The researcher would have arranged to also be present at the time of the appointment in order to administer a series of outcome measures (described below). Once the outcome measures would have been completed, the pharmacist was to conduct the medication review and adherence check with the PwD and their carer.

After the review, the pharmacist was to complete a clinical record form (Appendix 56) and communicate any recommended medication changes to the patient's GP using a letter (Appendix 57) and pro forma document (Appendix 58). In addition, the pharmacist was to extract data from the pharmacy PMR as soon as possible after the appointment. This was to include details of the patient's prescribed medications. A generic data extraction form (Appendix 59) was provided to pharmacists to ensure the appropriate information would have been extracted.

4.3.4 Outcomes

The primary feasibility outcomes were the usability and acceptability of the intervention to community pharmacists. Feedback from PwD and carers regarding the acceptability of the medication review and adherence check with their community pharmacist was also to be included in the overall evaluation.

As secondary feasibility outcomes, study parameters were to be investigated that would ultimately help to inform the design of a future larger pilot study (i.e. recruitment of pharmacies/pharmacists, PwD and carers, and data collection procedures). For example, we had planned to evaluate the feasibility of applying the STOPP criteria to patients' pharmacy record data to assess the appropriateness of prescribing. We had also hoped to test the feasibility of the administration of questionnaires to PwD and carers to assess outcome measures such as adherence and QOL (see

below). Outcome selection was also informed by a Core Outcome Set, which had been developed by members of the research team (McGrattan *et al.*, 2018).

4.3.5 Data collection and analysis

In assessing the feasibility study outcomes, the following data were to be collected from recruited community pharmacists, PwD, their carers and pharmacy records as described below.

Feedback from community pharmacist, patient and carer participants

In order to obtain a rich and in-depth picture of the usability and acceptability of the intervention, semi-structured interviews were conducted with community pharmacists. These interviews were conducted in the community pharmacy and should have taken place once all medication reviews were completed. However, due to difficulties encountered by the pharmacists with recruitment of PwD and carers (see later), the interviews took place once the study ended. Therefore, the interview topic guide (Appendix 60) was amended to include only questions relating to study documentation, difficulties they experienced with the screening and recruitment process, communication with the research team, what they liked about the intervention, and suggestions they had about how the intervention could be improved in the future. Topic guides for individual pharmacists had to be slightly amended depending on what stage they had reached in attempting to undertake the feasibility study. Interviews were audio recorded, transcribed verbatim, checked for accuracy and anonymised. Originally it was planned to undertake a thematic analysis of this qualitative data (Braun and Clarke, 2006), conducted independently by two members of the research team. However, due to the small number of interviews undertaken, and the limited discussion that could take place, a narrative description of this data is presented in the results section.

PwD and their carers were also to be interviewed between one and two weeks after the medication review and adherence check had taken place with the community pharmacist. These interviews were to have taken place in the patient's home. An interview topic guide had been developed for these interviews (Appendix 61), and questions would have covered what participants thought about the study information they had received, the medication review appointment, the questionnaires they would have had to complete before and after the medication review, and their suggestions for how the intervention could be improved in the future. However, as there were no PwD or carers recruited to the feasibility study (see later), no patient or carer interviews took place.

Recruitment data

In order to assess the feasibility of recruitment procedures, the following data were to be collected:

- The numbers of community pharmacists approached, recruited and consented (to be collected by the researcher);
- The number of patients/carers screened, approached, recruited and consented (to be collected by the participating pharmacists);
- Patient retention rates (to be collected by the researcher).

Pharmacy PMR data

The recruited community pharmacists were to extract data from the pharmacy PMR, at baseline and then two weeks after the medication review and adherence check had taken place. Originally it had been proposed that follow-up data would be collected four weeks after the review had taken place. However, due to delays in recruiting patient/carer dyads, the follow-up data collection point was moved back by two weeks in order to ensure that the feasibility study could be completed on time. Data extraction was to be conducted to assess the appropriateness of medication prescribed for PwD, psychotropic drug use, clinically significant drug interactions, and anticholinergic burden. The extracted data was to include details of the patient's prescribed medications (both acute and repeat items). A generic data extraction form (Appendix 59) was provided to pharmacists to ensure that the appropriate information was extracted. In terms of analysis, the same sub-set of the STOPP criteria, which had been used in the observational pharmacoepidemiological study in Phase 1 ($n=36$ indicators), was to be applied using the same standard methodology as described previously (Barry *et al.*, 2016b).

Questionnaire data

The feasibility of collecting data via a range of questionnaires was to be assessed. Data analysis for each of the measures listed below was to be undertaken using STATA/SE version 13 (StataCorp, College Station, TX, USA). Scores (calculated from standard methodology for each of the measures) were to be compared descriptively and graphically for participants at both time-points (i.e. baseline and two-week follow-up).

Adherence

Adherence was to be measured using the validated Medication Adherence Reporting Scale-5 item (MARS-5; Thompson *et al.*, 2000) and one item from the Lu *et al.* (2008) instrument (Appendix 62). Both measures were to be administered at the medication review appointment and at two weeks'

post medication review. The MARS-5 consists of up to five statements that assess different types of non-adherent behaviour (e.g. “*I forget to take them*”; “*I decide to miss out a dose*”). One of the five statements relates to unintentional non-adherence and the other four statements refer to intentional non-adherence. Responses are recorded on a 5-point Likert scale, from 1 (always) to 5 (never). Scores range from 5 to 25 and higher scores indicate higher adherence. In order to administer the measure, the researcher (LB) was to read each item and the different response options to the PwD (permission for use of MARS-5 in this study was granted by the developer). The item from the Lu *et al.* (2008) instrument asks participants to “*rate your ability to take ALL of your prescribed medicines in the last months.*” There are six response categories: very poor, poor, fair, good, very good, excellent.

Quality of life (QOL)

As recommended in a recently published Core Outcome Set for disease modification trials for mild to moderate dementia (Webster *et al.*, 2017), QOL was assessed by the Dementia Quality of Life (DEMQOL) system. This consists of a patient self-report measure (DEMQOL) and a carer proxy-report measure (DEMQOL-Proxy; Smith *et al.*, 2005).

The DEMQOL was to be administered to the PwD at the medication review appointment and two weeks’ post-medication review (Appendix 63). The measure contains 28 items and responses were to be recorded on a four-point Likert scale, from 1 (not at all) to 4 (a lot). Scores range from 28 to 112 and higher scores would have indicated better QOL. In order to administer the measure, the interviewer was to read each item to the participant and show them a response card. The first 13 items assess positive affect (e.g. confident, full of energy) and negative affect (e.g. worried or anxious, lonely). Participants were to be asked to indicate the extent to which they had felt each emotion over the past week. For items 14 to 19, participants were to be asked to indicate how often over the past week they had been worried about different aspects of their memory and cognition (e.g. forgetting who people are, thoughts being muddled). Finally, items 20 to 28 were to assess worries about daily living over the past seven days (e.g. concerns about getting help when required, overall health). A general QOL item is listed at the end of the measure but was not to be included in the overall score.

The DEMQOL-Proxy was to be administered in addition to the DEMQOL. The DEMQOL-Proxy consists of 31 items, which were to measure the carer’s perception of the patient’s QOL (Appendix 64). Responses were to be recorded on a four-point Likert scale, and scores range from 31 to 124. Higher scores would have indicated better QOL. Eleven items were to assess positive and negative affect, nine were to assess memory and 10 were to measure activities of daily living. The final item was to

assess QOL overall and was not to be included in the overall score. As with the DEMQOL, all items refer to the previous week. The items were to be read out to the carer and responses were to be presented on a response card.

Behavioural and psychological symptoms of dementia (BPSD)

The Neuropsychiatric Inventory Questionnaire (NPI-Q) was to be administered to the carer only at the medication review appointment and two weeks' post-medication review to assess BPSD in the patient (Cummings, 1997; Appendix 65). The NPI-Q measures 12 different symptoms (e.g. delusions, agitations, appetite/eating). The initial response to each item is whether the symptom is present (yes/no). If the patient had experienced the symptom, the carer was to be asked to rate the severity of the symptom (how it had affected the patient) as either 'mild' (score 1), 'moderate' (score 2) or 'severe' (score 3). The carer was then to be asked to rate the distress they had experienced due to the symptom. Responses were to be recorded on a six-point Likert scale, ranging from 0 (not distressing at all) to 5 (extreme or very severe). Responses across the 12 items were then to be summed for two scores: severity (range = 0 – 36) and caregiver distress (range = 0 – 60).

Treatment burden

To assess whether there was any impact of the intervention on treatment burden, the recently developed Multimorbidity Treatment Burden Questionnaire (MTBQ) was to be administered to both patients and their carers at the medication review appointment and at two weeks' post-medication review (Duncan *et al.*, 2018). The MTBQ for patients (Appendix 66) contains ten items assessing different aspects of treatment burden (e.g. taking many medications, making recommended lifestyle changes). Participants were to be asked to indicate how much difficulty they had with their treatment by recording their response to each item on a five-point Likert scale, ranging from 0 (not difficult/does not apply) to four (extremely difficult). Total scores range from 0 to 50 and were to be categorised into 'no burden' (score 0), 'low burden' (score <10), 'medium burden' (score 10 to 22) and 'high burden' (score ≥22).

For carers, the MTBQ (Appendix 67) was to measure how much difficulty they have had looking after the patient (e.g. remembering how and when the patient needs to take their medication, arranging the patient's appointments with health professionals) and how this had impacted the carer's daily life (e.g. the financial impact of being a carer, adjusting their own lifestyle so that they can look after the PwD). There are 16 items and responses were to again be recorded on a five-point Likert scale, ranging from 0 (not difficult/does not apply) to four (extremely difficult). Total scores range from 0 to 50.

4.3.6 Ethical considerations and approval

This study was reviewed by the Office for Research Ethics Committees (ORECNI; Ref: 18/NI/0100) and received a favourable opinion in June 2018 (Appendix 68). However, the research team did experience difficulties in obtaining ethical approval initially. In our first submission to ORECNI in April 2018, we received an unfavourable opinion due to a number of reasons outlined by the Committee. In particular, the Committee asked us to revise the approach taken to screening and recruitment of patients to ensure that PwD provided initial consent to allow the community pharmacist to approach the patient's GP for confirmation of a diagnosis of mild-moderate dementia. Once a PwD was confirmed by their GP to be of a mild-moderate severity for inclusion in the study, the pharmacist would be required to make contact with the PwD and their carer again to inform them of the outcome of the GP screening and to give them more detailed information about the study. This resulted in the two-stage screening process that was outlined earlier in this Chapter.

The REC was also concerned about the potential for disruption to the patient/GP relationship if the patient's GP chose not to implement the medication changes recommended by the community pharmacist following the medication review and adherence check. The research team were clear in their response that PwD and their carers would be informed that the pharmacist could only make suggestions to the patient's GP about changes to the patient's medication regimen, and only the GP had the clinical and legal authority to implement those changes. This reflected usual practice and was similar to other community pharmacy-led initiatives such as the Managing Your Medicines and Medicine Use Review (MUR) services. Information clarifying this point was added to participant information sheets, consent forms and medication review information. We also intended to explore patients' and carers' views about this issue during the follow-up interview which would be conducted one or two weeks after the medication review appointment.

4.4 Results

Participant recruitment

Each of the first two community pharmacies that were contacted about the study agreed to take part in the feasibility study. One of these pharmacies was located in a rural village in NI, with close links to the local GP surgery which was situated close by. The second pharmacy was located in a town in the Greater Belfast metropolitan area. Again, this pharmacy had close links with a number of local GP surgeries in the vicinity. Both pharmacists had been interviewed as part of the qualitative work conducted during Phase 2, and had taken part in the task group work, and had shown great enthusiasm for the project.

However, both of these pharmacists experienced difficulties with patient screening and recruitment. In the case of the first pharmacist, as outlined earlier, this was due to her being moved to a different pharmacy approximately 12 miles away. Whilst in the previous pharmacy she had identified PwD and carers whom she could approach about the study, once in the new pharmacy she was unable to start the screening process due to a heavy workload in adjusting to her new role and knowing little about the new patient population. The second pharmacist was hindered in his ability to recruit patients due to his part-time working arrangements at that particular pharmacy (two full days per week). Whilst some initial screening activity took place, this pharmacist found it difficult to make an approach to patients and carers, and to progress the process further than this. Due to the difficulties experienced by both of these pharmacists, and despite a number of extensions to the timeframe provided for screening and recruitment, both felt unable to continue further and withdrew from the study.

Due to these events and the limited amount of time remaining before the study was due to end, we sought to recruit another pharmacy from the same retail chain as the first recruited pharmacy. This pharmacy was located in a large out-of-town shopping centre, which lies in a settlement area between two main towns in NI. Whilst the pharmacist had not taken part in any of the earlier Phase 2 work, she was keen to assist in delivering and testing the intervention. Due to the tight timeline for completion of the project, the pharmacist was given a deadline by which she had to complete screening and recruitment activity, to ensure that enough time remained for data collection and follow-up to take place. Whilst this pharmacist was able to undertake screening and identify two potentially eligible PwD, she was unable to approach either of these patients as they did not present at the pharmacy with their carer before the imposed deadline.

Community pharmacist feedback

The three recruited pharmacists each participated in an interview with a researcher to explore their experiences of taking part in the study and their suggestions for future improvement. The main issues discussed with these pharmacists are presented below.

Video and QRG use and usefulness

One of the pharmacists did not view the video or accompanying QRG and so therefore could not provide comment on these aspects of the intervention. The other two pharmacists had useful feedback to provide to the research team. The pharmacists felt that the video provided a brief

summary of the way in which they could approach a medication review and adherence check with a PwD and their carer, and this was preferred to having the information in written form:

“I thought it was a good way of demonstrating how it was meant to go. Reading words off a page doesn’t give you a visual of how things are meant to flow. It was a very good use of technology to aid that discussion more than anything. I think that it was a very good idea.” [CP_02]

“It [the video] definitely seemed to simplify things rather than, you know, a lot of reading. It was clear and visually it felt that it was achievable to do what was laid out. I thought that helped, you know, just understand the process the way it was laid out.” [CP_03]

The pharmacists talked about the confidence that the video had given them, especially in how to communicate appropriately with PwD or how to broach potentially difficult aspects of a medication review, e.g. suggesting that certain medications may not be needed by the patient:

“That’s probably another good thing about the video, I thought she [the pharmacist] did use quite simplified language, short sentences... there was nothing too complex in it so that was quite good in terms of how you would conduct a conversation.” [CP_03]

“It would’ve given you confidence in how you would’ve approached the situation or the conversation...that you would have been drawing out maybe the same points that another pharmacist had...just giving you confidence that what you were doing was along the right track.” [CP_03]

However, the scenario presented in the video may have been slightly unrealistic as the pharmacist did not face any disagreement from the PwD or carer when suggesting medication changes:

“...Say for example the quetiapine, where the lady said that she found that was very positive, that it really helped her, you know, there would be concerns. And especially maybe with multiple changes which may not happen and may not need to happen in practice, but it’s just how to deal with that perhaps.” [CP_03]

The pharmacist was unsure of how patient, carer or GP concerns may have been dealt with, had the study progressed:

“It’s just, you know, dealing with concerns of the carer or the patient with regard to those changes. And indeed, even the GP, you know, you’re making this suggestion and I suppose we don’t know what happens after that.” [CP_03]

The QRG was well received by the pharmacists, who felt that the accompanying information was easy to refer to and played to pharmacists’ strengths:

“In terms of having the quick reference guide alongside the video, I thought the two worked very well. Personally my mind works best with a list, so I appreciate a focused, step-by-step chain of events. Quick reference guides are great for that kind of thing. I think a lot of pharmacists are the same...they’ll have similar traits in how they work. Lists go a long way... ticking boxes... pharmacists love ticking boxes and checking something off a list, so things like that work well.” [CP_02]

The other pharmacist could envisage how useful the QRG would have been to complement the medication review, and to focus attention on areas of importance:

“I thought as I was reading it and going through I probably would have found that useful to have open when I was reviewing the medication had I recruited a patient, you know, just to ensure I was on the right track and looking at the right things.” [CP_03]

Online system for accessing video and QRG

Of the two pharmacists who viewed the video, both spoke positively about the Articulate® software which they used to access the video and the QRG online:

“It was intuitive software. I’m quite familiar with computers, so I found it easy to navigate and get around.” [CP_02]

The pharmacists discussed accessing the video and accompanying textual information using both computers and tablet devices, and no major access issues were reported. Both pharmacists had accessed the software to view the video and QRG on multiple occasions throughout the study.

Patient and carer screening and recruitment

One of the pharmacists was unable to start the screening process due to the move to another pharmacy, but the experience reinforced the importance of having good working relationships with local GPs:

“I suppose where I was previously it [the screening process] would have worked really well because I had a close working relationship with the GPs, so as soon as I would have sent them something I would have got it back within a few hours, whereas if I’d tried it in this location, I probably would have been chasing for weeks.” [CP_01]

This pharmacist also felt that knowing the patient population well, would have assisted with screening and recruitment:

“In my head I had the five patients I wanted in my previous store. They were the ones I had good relationships with already. I always felt it was how well you knew your customer base... it’s finding those right patients because you can make appointments with patients and things but unless you kind of know exactly who they are and whether they’ll come back, it’s a waste of energy that way.” [CP_01]

Of the pharmacists who made an attempt at patient and carer recruitment, the initial identification of PwD from the pharmacy PMR was something they were familiar with doing, and did not present any difficulties:

“We used our PMR system to identify patients who were on medications that would indicate a diagnosis. We ruled out people who had been taking them for a considerable amount of time who had undergone disease progression and were further along than what was suitable for the study. It narrows your pool a bit...” [CP_02]

“Initially we used the PMR system and put the medication [in] and, you know, just to make sure we were getting the patients who were eligible and then from that we would have highlighted on a PMR or if they were a weekly [medication compliance aid dispensed to patient once a week] put a note in with the prescription for the pharmacist to talk to them when they came in to pick it up.” [CP_03]

The first difficulty that these pharmacists experienced was making the approach to PwD and their carers when both presented at the pharmacy together, and selling the benefits of the research study to them:

“We aimed to make contact with the patient and carer. The difficulty was getting both [at the same time] and trying to explain to them that it mightn’t help them but would go a long way to helping others. Maybe that was the harder message to sell...” [CP_02]

“I suppose the challenges were the two patients that I was able to speak to, they seemed quite positive... that they were interested in it, but their carer wasn’t with them, not at that time, so both were patients in by themselves on these occasions. So the information I gave them was brief... and we left it that they would go and speak to their carer and come back. But that didn’t materialise.” [CP_03]

One of the pharmacists reported the reservations that patients and/or carers had about participating in the study. The complexity of the screening process appeared to be an issue and the time taken to complete this process:

“...Time and having to come back again to see someone else and then doing an interview and going from there. You have to contact the GP first. It

confused patients maybe. It maybe seemed slightly daunting or a bit too much for them.” [CP_02]

“We lost a few people who initially sounded positive. Nine times out of ten the carer was a family member and they weren’t always free because they were working. We did find a mix of that. Other people just weren’t interested. They didn’t fancy it. There were times we spoke to carers initially and there were a wee bit ‘Oh I don’t think he’d be up for that at all’. I don’t know how we get around it” [CP_02]

This was also echoed by another pharmacist who felt the need to act ‘in the moment’ in community pharmacy, which was difficult to do with the lengthy screening and recruitment process:

“...So if you send them away to come back again, you find you’ve lost momentum in it, whereas with the MURs [medicine use review – a service targeted to respiratory or diabetic patients taking multiple medications] it’s really good if they’re coming in to collect their medication, you just do it with them in the moment.” [CP_01]

“It does seem that it [the screening and recruitment process] would be quite drawn out, and if you were doing it with multiple [patients] it would probably be quite a task to do it all at once.” [CP_03]

Study documentation and communication with research team

All of the pharmacists had broadly positive feedback about the information they had received about the study, both prior to agreeing to participate and once they had been formally recruited into the study:

“It was really thorough, I knew what I was entering into.” [CP_01]

Two of the pharmacists commented on the volume of information contained within the study file. One of the pharmacists acknowledged that the study information and study file in particular was very detailed, yet understood the necessity for this:

“Having not been involved very much with research beforehand, it’s something that was brand new to me in terms of the volume of detailed material expected. Understandably you have to cross the ‘T’s and dot the ‘I’s for all kinds of reasons.” [CP_02]

Another pharmacist spoke about feeling overwhelmed by the study file:

“Well, it’s [the study file] quite big so it was a bit daunting when I saw it. And it does take quite a substantial amount of time to look over it.” [CP_03]

One of the pharmacists felt that she would have liked to have been better informed from the beginning about the study timescale:

“I suppose if I’m honest at this point, I wouldn’t have been aware of probably the timescale that might be involved, the various stages of consent, and then getting in touch with the prescriber...” [CP_03]

However, the general consensus of opinion was that there was little else the research team could have provided to the pharmacist participants, in terms of either written information or verbal communication, throughout the study:

“The support [from the research team] was fantastic.” [CP_01]

Suggestions for future intervention refinement and implementation

Having experienced challenges with screening and recruitment of patients, it was vital to obtain feedback from the participating pharmacists on how they felt the process could be improved in the future. One pharmacist felt that whilst community pharmacy was an ideal location to implement an intervention such as this, community pharmacists are limited by their lack of clinical information about patients:

“I would love to champion community pharmacy as a great intervention points. It definitely is, in communities, where you are going to catch most things that have been overlooked or missed completely. When it came to helping identify a patient somewhere along their pathway, we have limited clinical information.” [CP_02]

This pharmacist felt that, in the future, it would be important to initially create a link between a GP surgery and their local community pharmacy in order to deliver the intervention. The pharmacist also queried whether community pharmacies had the capacity to participate in research such as the current study:

“Potentially, if it was to go again, it would maybe identify a GP surgery and put them and their community pharmacy as a partnership. It could even be about identifying a GP with a specialist interest... that could be a way in. Maybe we’re lacking the tools at the minute to really function in research, well in this kind of research. Maybe we would be better as a partnership.” [CP_02]

Pharmacists were genuinely disheartened that they had not been able to complete the study and deliver the intervention fully:

“I’m just frustrated that I didn’t get to do it [the study].” [CP_01]

“I probably felt more that I was letting the research side down because I wasn’t able to really recruit or participate in the way I wanted.” [CP_02]

Through participating in the study, pharmacists had identified future learning opportunities and the study had emphasised the importance of considering medicines management issues for PwD:

“On the back of this, I’ve probably identified a learning need of my own. I probably will, over the next CPD [continuing professional development] cycle, identify some work I could do myself.” [CP_02]

“I suppose for me it highlighted the complexity of the dementia patient and probably made me think were we as pharmacists doing all that we could be doing? So I do see a benefit in having a service for those patients.” [CP_03]

4.5 Summary

This chapter describes the study that was planned to be undertaken in order to test the feasibility of the intervention developed to improve medicines management for PwD in primary care. Unfortunately, the research team experienced a number of challenges, both during ethical review and during the conduct of the study. This resulted in a limited amount of data being collected, and our analysis of this data is restricted to a narrative description of the participating community pharmacists’ views on the aspects of the feasibility study they managed to complete. The final discussion (Chapter 5) will explore these issues in greater detail, and will reflect upon our learnings from undertaking this feasibility study, and how we hope to progress this work in the future.

CHAPTER 5. Discussion

5.1 Introduction

This chapter summarises and discusses the findings from each phase of the project in order to directly address the aims and objectives of the research. The overall aim was to develop an intervention to improve medicines management for PwD in primary care in NI. The objectives related to: investigating prescribing trends and appropriateness of medicines prescribed to PwD, undertaking qualitative interviews with PwD, their carers, GPs and community pharmacists to identify key behaviours, barriers and facilitators associated with medicines management in order to develop a suitable intervention, and testing the feasibility of this intervention with PwD, carers and HCPs in primary care. These issues are discussed in subsequent sections in this chapter.

5.2 Observational pharmacoepidemiology

Based on a large dataset comprising nearly 7,000 PwD ($n=6,826$ patients), this study found that both polypharmacy (prescribing of ≥ 4 regular medications) and PIP were prevalent amongst the patient sample. Common instances of PIP were found to be prescribing of anticholinergic/antimuscarinic medications, followed by proton pump inhibitors at full therapeutic dosage for >8 weeks, acetylcholinesterase inhibitors with concurrent treatment with drugs that reduce heart rate, and benzodiazepines for ≥ 4 weeks. Both polypharmacy and female gender were associated with PIP, whereas age was not.

To the research team's knowledge, this was one of the first studies to apply the STOPP criteria to a large prescribing database in order to ascertain the prevalence of PIP amongst community-dwelling PwD. Previous studies had reported a lower prevalence of potentially inappropriate medication use (between 15-47%) among community dwelling PwD, as reported using either the Beers criteria or PRISCUS list, which is a tool developed for use in Germany (Fialová *et al.*, 2005; Lau *et al.*, 2010; Koyama *et al.*, 2013; Fiss *et al.*, 2013; Montastruc *et al.*, 2013). The prevalence of PIP in this study was nearly double that reported by Bradley and colleagues who investigated PIP in older people (aged ≥ 70 years) in NI using the STOPP criteria, but whose methodology did not focus specifically on PwD (Bradley *et al.*, 2012). In addition, we found that the prevalence of polypharmacy, as defined by the use of four or more repeat medications, was high amongst this patient population. Again, this was difficult to directly compare with previous studies which had used different numeric thresholds to define polypharmacy in their study populations. However, this finding is much greater than that reported by Lau *et al.* (2010) and Montastruc *et al.* (2013) who reported polypharmacy (≥ 5

medications) in 52% and 43% of community-dwelling PwD respectively. A more recently published study assessing longitudinal changes in potentially inappropriate medication exposure by dementia type following diagnosis reported that the total number of medications prescribed for PwD increased in the first year following diagnosis, by approximately 10% for those with Alzheimer's disease (Ramsey *et al.*, 2018). A high prevalence of polypharmacy is unsurprising in PwD, as often this patient population will suffer from a number of comorbidities due to their increasing age and frailty (Formiga *et al.*, 2009; Bunn *et al.*, 2014; Poblador-Plou *et al.*, 2014). Whilst patients in the current study population ranged in age from 34 to 100 years, they had a mean age of 79.6 years, and would therefore be expected to be receiving a number of different medications for comorbid conditions. There has been discussion within the literature about reducing reliance on numeric thresholds for polypharmacy and considering instead the appropriateness of polypharmacy, taking into account the fact that use of 'many drugs' may be necessary for those with multimorbidities (Duerden *et al.*, 2013; Hughes *et al.*, 2013). However, the association between the prescribing of multiple medications, dementia, and the risk of negative outcomes remains strong and should encourage clinicians to regularly review the number of medications that are prescribed for this patient population (Leelakanok and D'Cunha, 2018).

The study revealed a number of instances of PIP; some of these, such as the use of proton pump inhibitors at full therapeutic dosage for >8 weeks and benzodiazepines for ≥ 4 weeks, were unsurprising and were consistent with findings reported in other studies amongst older people (Bradley *et al.*, 2012; Bradley *et al.*, 2014) and PwD in care homes (Parsons *et al.*, 2012). The prescribing of anticholinergic/antimuscarinic medications in the study population, received by one quarter of patients (25.2%), was a concerning finding. The use of these drugs in PwD is not recommended due to their association with decline in both physical and cognitive function (Fox *et al.*, 2011; Tannenbaum *et al.*, 2012; Risacher *et al.*, 2016), and there is mounting evidence that anticholinergic drug use is associated with an increased risk of incident dementia (Gray *et al.*, 2015; Richardson *et al.*, 2018). Despite well-publicised risks, anticholinergic drug use remains widespread. The prevalence of anticholinergic drug use varies greatly, partly due to the range of tools used to assess anticholinergic burden, however use of these drugs has been reported between 20-69% of community-dwelling PwD (Koyama *et al.*, 2013; Montastruc *et al.*, 2013; Sura *et al.*, 2013; Mate *et al.*, 2015; Cross *et al.*, 2016; Hukins *et al.*, 2018; Turró-Garrida *et al.*, 2018). The availability of tools to assess anticholinergic burden to clinicians would provide invaluable during an in-depth medication review with dementia patients, and may help them to change patients to alternative drugs with lower anticholinergic burden. In some situations, non-pharmacological measures could be used as alternatives to prescribing anticholinergic

medications, for example, scheduling regular toilet breaks and making dietary modifications instead of using bladder antispasmodics (Specht, 2011).

The high prevalence of both polypharmacy and PIP could serve as an indicator that review of these patients is required to fully assess the appropriateness of the medication regimens used, particularly considering the strong relationship we observed between polypharmacy and PIP, which has been reported previously (Fialová *et al.*, 2005; Cahir *et al.*, 2010; Lau *et al.*, 2010; Bradley *et al.*, 2012; Parsons *et al.*, 2012; Fiss *et al.*, 2013; Montastruc *et al.*, 2013; Bradley *et al.*, 2014). The study also revealed that PIP among community-dwelling PwD was associated with female gender, but not age. Again, these relationships have been reported elsewhere (Cahir *et al.*, 2010; Bradley *et al.*, 2012; Bradley *et al.*, 2014) and would be of assistance to clinicians identifying patients at risk of PIP. These associations may be useful in generating hypotheses which could be explored in other datasets. In the context of the current project, having information on prescribing trends and key associations in this patient population, was helpful to the research team as we moved into the next phase of research and development of the intervention. For example, consideration of PIP, polypharmacy, and gender could be incorporated into clinicians' prescribing systems in order to alert them to such high-risk patients and potentially inappropriate medication combinations (Clyne *et al.*, 2015). Deprescribing is another way in which inappropriate medication use and polypharmacy may be managed (Scott *et al.*, 2015), and could also prove to be a useful intervention in this particular patient population. For example, 'drug holidays' (where medication is stopped for a trial period to assess effectiveness of treatment and/or remission of symptoms; Howland, 2009) could be advocated for anticholinergic medications, such as those for urinary incontinence. The practice of deprescribing has been a growing area in the literature over the past number of years, and it has been acknowledged that a wider evidence-base is needed to support such an approach (Garfinkel and Mangin, 2010; Scott *et al.*, 2013; Reeve *et al.*, 2014). Evidence-based guidelines are now starting to emerge in the literature to guide clinicians as to how to approach deprescribing in PwD (Bjerre *et al.*, 2018).

5.3 Qualitative interviews and intervention development

In Phase 2 we undertook a lengthy process of qualitative interviews, data analysis and intervention development in order to produce the final community pharmacy-based intervention that was presented in Chapter 3. This study formed part of a systematic and phased approach to intervention development that was modelled on the MRC framework (Medical Research Council, 2008). Intervention development has been described as the 'black box' or 'Cinderella' of complex intervention trial design, because important processes and decision-making in the early stages of

intervention development are seldom reported (Hoddinott, 2015). The study adds to the body of published work that has applied the MRC framework in the intervention development phase as initial exploratory work was conducted with PwD, their carers, GPs and community pharmacists as four groups of stakeholders that play key roles in medicines management for PwD in primary care. The 14-domain TDF (Cane *et al.*, 2012) was used as the underpinning theoretical model to gather comprehensive insights into the behaviours that needed to be targeted in order to improve medicines management. This provided the foundation for developing a theory-based intervention using specific BCTs to target key mediators (i.e. barriers and facilitators) of behaviour change.

One of the key strengths of the current study is that we endeavoured to consult key stakeholders who would be delivering or receiving the intervention during the development stages to extend the limited evidence-base around medicines management for PwD. In order to improve the recruitment of PwD to this Phase of the project, we took a number of approaches to sampling, i.e. through GP practices in primary care to sample PwD who may be living alone without a carer, and through memory clinics in secondary care to sample PwD/carer dyads. Whilst we successfully recruited the desired number of patient/carer dyads through secondary care, we did not manage to recruit our target of ten patients through primary care. This was unfortunate as a similar approach had been used successfully by a member of the research team in a previous study (Ilfie *et al.*, 2014). We then tried to use an alternative means of recruiting these patients, through the JDR database, however again this proved unsuccessful. These difficulties highlight the challenges of conducting research in this vulnerable patient population. Many of these challenges have been acknowledged previously within the literature (West *et al.*, 2017; Szabo *et al.*, 2018) and it is worth noting that these issues are still pertinent. The UK government, for example, has a strategy in place to promote dementia research through increased funding, research capacity, and the introduction of the JDR database, with an aim for 10% of PwD to participate in research (Department of Health, 2016). Recent publications have emphasised the importance of this also (National Institute for Health and Care Excellence, 2018; Pickett *et al.*, 2018). However, researchers and clinicians need to ensure that the barriers to inclusion of PwD in research are minimised as far as possible to ensure that these aims are met.

The PwD and carers interviewed during this study revealed that they did not experience any major problems or issues with medicines management at the current time, which was surprising as we would have anticipated that more would have arisen from these interviews. This is likely to be a function of the sample of patients recruited into the study. Whilst a formal cognitive assessment was not conducted, anecdotally, the recruited sample of patients was at mild-moderate stages of the disease,

had their medicines management needs well looked after by their local GP surgery and community pharmacy, and all had a carer (either a family member/spouse or formal care package) in place to assist them with their medicines. The research team are aware that the developed intervention would likely need to address different medicines management issues for those at moderate-severe stages of the disease, and refinement of the intervention for those at different stages of the disease trajectory may be a focus of future work. A key finding from the patient/carer interviews, which was considered by the research team to be integral to future intervention development, was that carer involvement is key, which is supported by the literature (While *et al.*, 2013; Poland *et al.*, 2014; Smith *et al.*, 2015; Aston *et al.*, 2017). However, due to the difficulties with recruitment outlined above, any problems faced by PwD living alone in the community and/or without carer assistance with medicines, are still largely unknown. This particular subset of dementia patients is at increased risk of becoming socially isolated, receiving inadequate medical supervision, and having unmet medical needs (Gilmour *et al.*, 2003; Miranda-Castillo *et al.*, 2010). Future work must focus on establishing the medicines management needs of these patients and how they can be supported.

The very broad concept of medicines management, in hindsight, created additional complexity during the intervention development process. The definition of medicines management we used throughout the project (Audit Commission, 2001) spans a number of different components, and therein a number of different (potentially target) 'behaviours' relevant to the process. This resulted in us having to include many different behaviours during data collection and analysis, and was reflected in the large number of theoretical domains identified as key domains (12 out of 14). An alternative strategy would have been to identify and define the 'problem' and 'target behaviour' more specifically at the start of the study (for example, to focus on adherence in PwD). However, at the outset of project planning, there was such a lack of literature in the area, that the research team felt it was necessary to explore the needs of patients, carers and HCPs as well as examining current practice, in order to understand the problem through a wider lens. We then spent time identifying the 'target behaviours' in relation to HCPs through the production of the narratives for each HCP group.

With the exception of the 'Intentions' and 'Optimism' domains, all of the theoretical domains were considered relevant to the target behaviours (i.e. prescribing and conducting medication review by GPs, and conducting medication review and monitoring adherence by community pharmacists). This illustrates the complex nature of the target behaviours, as well as the challenge faced by researchers in identifying key domains to target when developing interventions to change these behaviours. In selecting key domains, we noted that some of the barriers and facilitators reported by interview

participants overlapped (i.e. had an impact on) a number of domains. This meant that it may be more feasible to target domains as part of a future intervention. The importance of a broadly similar group of domains for both HCP groups highlights the commonalities in the perceived mediators of behaviour change within each group. For example, the importance of having a holistic knowledge of patients' home and social situation ('Knowledge') expressed by members of both professions in ensuring that medicines management is optimised for PwD facilitated HCPs when prescribing (GPs) or monitoring adherence (community pharmacists) where necessary. Despite identification of similar challenges within a number of domains (e.g. time and workload pressures under the 'Environmental context and resources' domain), perceptions of other domains as a barrier or facilitator differed between the groups. For example, each group's perceptions differed as to whose role it was to conduct medication review ('Social/professional role and identity'). Due to the selection of the same key domains, an overlap in the BCTs that would form the components of an intervention involving GPs and/or community pharmacists was expected. Having identified the challenges of these busy clinical environments in the primary care setting through the qualitative interviews (e.g. time and workload pressures), we prioritised BCTs that were unlikely to need repeated administration or delivery on a large number of occasions or over extended time periods to elicit the required changes in the target group's behaviour. This is why the BCT 'Health consequences' was chosen over other BCTs such as 'Feedback on behaviour' to target the 'Knowledge' domain.

The data analysis and intervention development process was conducted rigorously, but was time consuming, despite following similar analytical methodology which has been used by members of the research team in numerous preceding intervention development studies (Duncan *et al.*, 2012; Cadogan *et al.*, 2015; Patton *et al.*, 2018). At the time of data analysis, there was no formal guidance on how to operationalise the TDF, although a guide has since been published (Atkins *et al.*, 2017). However, there remain common challenges which have been previously reported (Cadogan *et al.*, 2015; Phillips *et al.*, 2015; Debono *et al.*, 2017; Patton *et al.*, 2018). In particular, developing a clear understanding of each domain and the associated theoretical constructs was problematic at times, even to those members of the research team who had previously used the 12-domain version of the TDF. We feel that the independent coding of the interview transcripts by two researchers, with a third involved in resolving disagreement where necessary, helped to deepen our understanding of the data in relation to the TDF domains. The researchers also encountered much overlap between the domains; again this has been reported previously (Cadogan *et al.*, 2015; Phillips *et al.*, 2015; Atkin *et al.*, 2017; Debono *et al.*, 2017; Patton *et al.*, 2018).

Having been through a lengthy analytical and intervention development process, the task groups gave the research team the opportunity to explore how proposed intervention components could be implemented in clinical practice (Mort and Finch, 2005; May *et al.*, 2011). The project was conducted during a time of great change within primary care in NI, with the creation of new practice-based pharmacist roles in GP surgeries. Whilst trying to re-contact community pharmacists about the task groups, we discovered that some of these pharmacists had moved into practice-based roles. Given that many of the GP participants referred to the potential for practice-based pharmacists to contribute to optimising medicine management for PwD, this will be an area for further research in the future. The PhD student affiliated to this project (MM) did undertake some exploratory work with a small number of practice-based pharmacists in a separate study, however it was difficult to engage with these pharmacists due to the new and evolving nature of the role.

Feedback gathered from the HCPs who participated in the task groups was invaluable, and we found that HCPs made many helpful and pragmatic suggestions regarding the draft interventions that were presented to them during the course of the task group sessions. For example, the action planning component that had been suggested by the research team was not regarded to be useful by GP participants, and the concept of a 'protocol' (which eventually became the QRG) was initially suggested by GP participants and enthusiastically supported by community pharmacist participants. In addition, the task groups also proved to be a useful way of re-engaging with HCPs who had previously participated in the qualitative work and this was helpful to us when it came to recruiting sites for the feasibility study in Phase 3.

5.4 Feasibility study

In Phase 3, we sought to test the community pharmacy-based intervention for feasibility (usability and acceptability) in two community pharmacies initially. Due to difficulties in recruiting PwD and carers in each of these pharmacies, a third community pharmacy was recruited, but no further advances in patient/carer recruitment were made. While many of the objectives of the feasibility study were not met (such as determining the acceptability of the medication review and adherence check process to PwD, carers or pharmacists, or the feasibility of the data collection procedures), we are cognisant of the value of conducting a feasibility study, and will be able to incorporate our learning from this experience as we plan future work.

Recruitment of the community pharmacies was relatively straightforward, and was helped by the fact that the research team had kept in contact with pharmacists who had participated in the interviews

in Phase 2 and had re-engaged with some of these pharmacists for the task groups. The pharmacists who participated in the feasibility study were enthusiastic about both the topic area and the research study.

Two out of the three pharmacists had viewed the online video and accompanying QRG. The feedback received from these pharmacists about these intervention components was positive, indicating that they may be considered acceptable for improving medicines management for PwD in primary care. One of the pharmacists did express reservations as to whether the patient and carer in the video may be as receptive in real life to the suggested medication changes. However, due to the feasibility study not being able to progress beyond patient screening, we were unable to determine the impact of the video and QRG on pharmacists' behaviour (i.e. conducting medication review and monitoring adherence).

We recognised from our earlier intervention work in Phase 2, that the community pharmacy work environment (i.e. time and workload pressures) was a major barrier to improving medicines management for PwD. We therefore sought to develop an intervention that would limit any additional workload for community pharmacists. The online video was kept as short as possible, and the online platform used to view the video and QRG could be accessed by participating pharmacists both in their workplace and at home. The medication review and adherence check that pharmacists were asked to conduct with PwD and carers, was no more arduous than other similar services provided in community pharmacy currently, such as the Medicine Use Review (MUR) service. The MUR is targeted to respiratory or diabetic patients who are taking multiple medicines (Health and Social Care Board, 2014); there is no similar service targeted to PwD currently. Therefore, the research team felt that the current intervention was, effectively, an extension of an existing service and should not pose any greater workload demands on community pharmacists.

The major challenge for community pharmacists was screening and recruiting PwD and their carers to the study. A two-stage screening process had been implemented, following difficulties obtaining ethical approval for the study, which involved pharmacists initially using the pharmacy PMR to search for dementia patients on four or more medicines, then approaching these patients and their carers to gauge initial interest in the study and to ask for consent to approach their GP to confirm a diagnosis of mild-moderate dementia. Feedback from the pharmacists indicated that this proved to be a difficult process to complete for a number of reasons. In some instances, patients and carers did not present at the pharmacy together, and where verbal information was provided to patients, it did not appear

to be passed on to the carer. In other situations, this initial screening and recruitment process was felt to be over-complicated, lengthy, and off-putting to potential participants. In contrast, when delivering the MUR service, community pharmacists are able to offer to conduct the MUR 'on the spot' (depending upon their availability at the time) due to this being undertaken in the context of a pharmacy service as opposed to a research study. Pharmacists therefore commented that this appeared more straightforward than the current intervention. However, the practical aspects of this must be considered, especially given the inherent difficulties in obtaining informed consent from PwD.

A feasibility study asks whether something can be done, should we proceed with it, and if so, how (Eldridge *et al.*, 2016). The research team do not feel that, given the challenges encountered during this study, the intervention has had sufficient opportunity to be tested for feasibility. Indeed, initial feedback from the participating pharmacists was broadly positive, and we feel that further refinement and feasibility testing is warranted. However, this will involve further consideration of recruitment of patients (and carers), and the role of the GP in the process. Clearly a collaborative approach between GPs and pharmacists is needed, due to pharmacists' lack of diagnostic information impeding their ability to fully screen and recruit PwD to the study. One way to overcome this would be to ask local GP practices to identify eligible patients according to the inclusion criteria; a list of patients approved by GPs could then be provided to the pharmacist who may then approach patients and carers when they would present to the pharmacy. However, this method may require a number of community pharmacies in a locality to be involved (as not all PwD would necessarily attend the same pharmacy), and would create additional complications for a feasibility study. It was evident from pharmacist feedback that good working relationships between GPs and community pharmacists would be key to the success of the intervention; this is emphasised within the literature (Niquille *et al.*, 2010; Kwint *et al.*, 2013) and will be borne in mind by the research team as we endeavour to refine the intervention for future feasibility testing.

5.5 Reflections on PPI

This project had a number of challenges and we had to be particularly mindful of the patient population with whom we were working (i.e. those with dementia) to ensure that project information was accessible to them. Therefore, PPI helped the research team to navigate through some of the difficulties. A PPI member of the PMG and research team, Dr. Hilary Buchanan, advised on the content of study documentation for Phases 2 and 3 before submission for ethical approval. This ensured that the language used was clear, unambiguous, and easy to understand. In addition, Dr. Buchanan's

insight as a retired GP also helped us as we planned how we would engage with, and recruit, GP surgeries in Phase 2 of the project.

The HCPs who participated in the task groups were especially helpful in advising on pragmatic aspects of intervention content and delivery. The discussions that members of the research team had with HCPs during the task groups very much shaped the decisions made on the final intervention.

5.6 Strengths and limitations of the research

The project has a number of strengths, which should be acknowledged:

1. At the time of conducting the observational pharmacoepidemiology in Phase 1, there had been very limited epidemiological research that had specifically explored prescribing for community-dwelling PwD. This is one of the largest epidemiological studies to use a prescription-based database to estimate PIP amongst community-dwelling PwD. The findings contribute to existing knowledge and understanding by identifying the prevalence of polypharmacy and PIP, and highlights associations between polypharmacy, PIP, age and gender. The results from this study were then used to inform and guide intervention development.
2. The research team adopted a thorough and systematic approach to the process of intervention development, using previously tested analytical methodology with which a number of researchers were familiar. In addition, the inclusion of two psychologists on the research team (LB and GM), both of whom had a knowledge of the TDF, helped to ensure correct operationalisation of the TDF and interpretation of the theoretical domains. All data were analysed independently by at least two members of the research team, which added to the validity and reliability of the coding process.
3. The interviews and the subsequent task groups provided valuable information from HCPs about the clinical context in which the draft interventions would be potentially implemented. This information was used to inform and refine the selection of intervention components, and also helped the research team select which intervention to take forward to feasibility testing in Phase 3.
4. Stakeholder involvement was comprehensive and generated comprehensive data to inform intervention development. Whilst we found recruitment of PwD to be challenging, it was important that this vulnerable patient group were involved in the intervention development process. Engagement with HCPs throughout the lifespan of the project helped the research team to recruit community pharmacy sites for the feasibility study.

5. Whilst we experienced specific challenges during Phase 3 of the project, which hindered our ability to confirm many aspects of feasibility, community pharmacists appeared to be supportive of the online video and QRG components of the intervention. The research team recognise the value of feasibility studies to determine if a study can be done and to assist in the development of larger randomised controlled trials (Eldridge *et al.*, 2016; Blatch-Jones *et al.*, 2018). In the current project, the feasibility work undertaken has highlighted that the proposed process of screening and recruiting PwD and carers will require refinement before further feasibility and pilot testing in the future.

However, there are a number of limitations that need to be taken into account when considering our findings:

1. The lack of clinical and diagnostic data in the EPD used in Phase 1, means there could be an underestimation of the prevalence of PwD. We had to identify patients who had received one of four drugs used in the management of dementias, using medications as a proxy for dementia diagnosis. Whilst this may have excluded patients with dementia of different aetiologies (not covered by the indications of the four drugs used as proxies) or those with severe/advanced disease in whom medication had been stopped, we had no alternative means of identifying the patient population for inclusion in the study.
2. In addition, the lack of clinical data within the EPD only allowed us to apply a subset of the STOPP criteria, and some diagnoses had to be determined using drug proxies, an analytical approach that has been used previously (Cahir *et al.*, 2010; Bradley *et al.*, 2012; Bradley *et al.*, 2014). Therefore, some instances of PIP identified in the study may not be clinically relevant, and clinicians must ensure that prescribing decisions are based upon their clinical and personal knowledge of the patient. A set of explicit prescribing criteria for dementia is under development in Australia (Page *et al.*, 2015; Page *et al.*, 2016) and may be useful to researchers carrying out similar epidemiological studies in the future.
3. The EPD was chosen for its relevance to the NI setting over other databases such as the Clinical Practice Research Datalink (CPRD), which is not representative of NI prescribing data (Herrett *et al.*, 2015). However, by using drug dispensing data like this, patient adherence to medication is assumed. Use of over-the-counter (OTC) medications purchased without a prescription is not accounted for, which may underestimate or overestimate PIP prevalence, and use of anticholinergic medications in particular due to the anticholinergic effect of many OTC sleeping aids and antihistamines.

4. Findings from the qualitative interviews undertaken with key stakeholders are not generalisable to the wider population of PwD, carers or HCPs. Recruitment of PwD living alone/without carer input and those with more advanced forms of the disease was limited. However, we did seek to sample participants across the province of NI, and the distribution of geographical locations enhances transferability of findings. As mentioned previously, participation was incentivised. The interview findings only reflect participants' perceptions of influences on their behaviour rather than the actual causes.
5. The findings from the HCP interviews highlight the complexities of medicines management and the importance of understanding and specifying the target behaviour(s) in order to understand what needs to change to achieve the desired behaviour. In hindsight, we may have benefited from specifying and seeking to identify the target behaviours earlier in the study so that we could be more specific about these during intervention development process.
6. Due to the tight timelines within the final phase of the project, we were unable to conduct a BCT coding exercise as a fidelity check. It would be prudent to ensure this is done before further feasibility testing in the future to investigate if the pre-specified BCTs embedded in the video are readily identifiable to an independent group of researchers, adding to the methodological rigour of the intervention development process.

5.7 Implications for practice

This project involved initial exploratory work to extend the evidence base for intervention development, followed by a feasibility study to assess various elements of research methodology as well as the developed intervention. Therefore, due to the nature of the work conducted during this project, implications for practice are somewhat limited. However, the following points are worthy of consideration:

- The need for appropriate and rational prescribing for PwD was highlighted by the findings from the pharmacoepidemiological study conducted in Phase 1. Regular and comprehensive medication review is warranted in PwD to ensure that prescribing and medicines-related issues are addressed in a timely fashion for these patients.
- The importance of carers was emphasised during the qualitative work undertaken with stakeholders. Healthcare professionals and researchers should consider the involvement of carers when developing future interventions for PwD.

5.8 Recommendations for future research

As a result of these findings, we consider that we have achieved many of the objectives which were originally established for this study. However, there are a number of key points that have been highlighted as worthy of future investigation, and in particular, further feasibility work will need to be conducted before a larger pilot trial may proceed.

1. The use of more detailed and comprehensive data sources, such as the Clinical Practice Research Datalink (CPRD) may provide a more reliable indicator of prescribing appropriateness in this patient population.
2. There needs to be further investigation into prescribing for community-dwelling PwD, and particularly anticholinergic drug use.
3. The effect of the changing landscape within primary care will need to be taken into account as researchers develop interventions to improve medicines management for PwD, and the contribution that other primary HCPs (such as general practice-based pharmacists) may make to optimising medicines use by PwD.
4. Recruitment of PwD and their carers in research remains a challenge, and we need to consider how best to enhance this in future work involving these stakeholder groups. Consideration of novel methods of recruitment such as the JDR may provide another option.
5. Further refinement of the current intervention will need to be undertaken so that feasibility testing can take place. The screening and recruitment process for PwD and carers should be reviewed, and a collaborative partnership between GPs and community pharmacists considered to streamline the process.

5.9 Pathway to impact

The overall purpose of this study was to develop an intervention to improve medicines management for PwD in primary care. Whilst such an intervention had been developed, following a systematic approach, it is too early to definitively outline the impact that this intervention will have in the future. The research team will now focus on further feasibility and pilot testing in order to work towards a larger randomised controlled trial to provide evidence to support the use of the developed intervention in clinical practice. In conducting the present project, we have also been able to generate important data relating to the appropriateness of prescribing for PwD in primary care, and this will contribute to wider prescribing knowledge in NI through appropriate dissemination. We also intend to use these findings to inform future exploratory work.

5.10 Final conclusions

Based on our findings we draw the following conclusions:

1. We have reported prescribing trends among community-dwelling PwD in NI. It appears evident from this data that there remain issues with appropriateness of prescribing for this patient population, particularly anticholinergic medications. This has been reinforced by guidance issued by NICE, which has recommended that interventions need to be developed to address the prescribing of these medicines.
2. We produced a large qualitative dataset from key stakeholders relevant to the development of the intervention (i.e. PwD, carers, primary HCPs). Whilst the data collected from PwD and carers did not reveal major issues with medicines management at the time of data collection, it was evident that carer involvement in future intervention development is critical. Interventions may need to be refined depending upon the disease trajectory.
3. Recruitment of PwD was challenging, particularly those living alone in the community who may have little or no carer assistance with their medicines.
4. The online video and QRG intervention components appeared to be acceptable to community pharmacists, although it was not possible to test other aspects of the intervention for feasibility (i.e. medication review and adherence check appointment, data collection procedures)
5. Screening of PwD and carers in community pharmacy in the feasibility study proved challenging, and pharmacists were restricted by their lack of access to diagnostic information. This process, and the role of the patient's GP, will need to be reconsidered before embarking on feasibility testing again in the future.

DISSEMINATION OF RESEARCH

Published abstracts (*denotes presenting author)

BARRY HE*, COOPER JA, RYAN C, PASSMORE AP, ROBINSON AL, MOLLOY GJ, DARCY CM, BUCHANAN H, HUGHES CM. (2015) how appropriate is prescribing for people with dementia in primary care? A cross-sectional analysis. *International Journal of Pharmacy Practice*; **23**: S10-11

Oral presentation. Royal Pharmaceutical Society Conference, Birmingham, UK. September 2015

McGRATTAN M*, BARRY H, RYAN C, COOPER J, PASSMORE AP, ROBINSON AL, MOLLOY G, DARCY C, BUCHANAN H, HUGHES C. (2017) Pharmacists' perceptions of the barriers and facilitators to successful medicines management for people with dementia in primary care. *International Journal of Pharmacy Practice*; **25**: S15-16

Oral presentation. Health Services Research and Pharmacy Practice Conference, Nottingham, UK. April 2017

BARRY HE*, McGRATTAN M, RYAN C, PASSMORE AP, ROBINSON AL, MOLLOY GJ, DARCY CM, BUCHANAN H, HUGHES CM. (2018) A qualitative study of healthcare professionals' perceptions of barriers and facilitators to successful medicines management for people with dementia in primary care. *International Journal of Pharmacy Practice*; **26**: S31-32

Oral presentation. Health Services Research and Pharmacy Practice Conference, Newcastle upon Tyne, UK. April 2018

BARRY HE*, BEDFORD L, McGRATTAN M, RYAN C, PASSMORE AP, ROBINSON AL, MOLLOY GJ, DARCY CM, BUCHANAN H, HUGHES CM. (2019) Development of a theory-based intervention to improve medicines management for people with dementia in primary care. *International Journal of Clinical Pharmacy*; **41**: 290

Oral presentation. European Society of Clinical Pharmacy International Symposium, Belfast, UK. October 2018

An abstract has been prepared based on the findings from the patient and carer interviews, and has been accepted for presentation at the Health Services Research & Pharmacy Practice Conference in April 2019.

Published journal articles

BARRY HE, COOPER JA, RYAN C, PASSMORE AP, ROBINSON AL, MOLLOY GJ, DARCY CM, BUCHANAN H, HUGHES CM. (2016) Potentially inappropriate prescribing among people with dementia in primary care: a retrospective cross-sectional study using the Enhanced Prescribing Database. *Journal of Alzheimer's Disease*; **52**: 1503-1513

McGRATTAN M, BARRY HE, RYAN C, COOPER JA, PASSMORE AP, ROBINSON AL, MOLLOY GJ, DARCY CM, BUCHANAN H, HUGHES CM. (2018) The development of a Core Outcome Set for medicines management interventions for people with dementia in primary care. *Age & Ageing*; doi:10.1093/ageing/afy172 (ePub before print 5 Nov 2018)

Two manuscripts are currently being prepared for submission to peer-reviewed journals, one presenting the data collected from HCPs and subsequent intervention development, and the other presenting the data collected from patients and carers. A manuscript will be prepared for submission to a peer-reviewed journal outlining the challenges faced during the feasibility study and areas for future research and intervention refinement.

Invited presentations

In addition to the above outputs, Dr. Heather Barry has been invited to give a number of presentations over the course of the project, at which she has presented study methodology and preliminary findings. These are outlined below:

1. *"The COMPARE study: development of a complex intervention to improve medicines management for people with dementia in primary care."*
Alzheimer's Research UK Northern Ireland Public Meeting. Mossley Mill, Newtownabbey. June 2017
2. *"Polypharmacy, medicines management and dementia."*
Nutricia Centre of Excellence/Alzheimer's Research UK Scientific Meeting. Riddel Hall, Belfast. June 2018
3. *"Developing a complex intervention to improve medicines management for people with dementia in primary care: challenges and lessons learned."*
Department of Family Medicine. McMaster University, Hamilton, Canada. July 2018
4. *"Matching pharmacy care to patients with dementia."*
European Society of Clinical Pharmacy International Symposium. Waterfront Hall, Belfast. October 2018

AUTHOR CONTRIBUTIONS

All data and intervention content is available from the corresponding author upon request.

PROFESSOR CARMEL M. HUGHES (Head of the School of Pharmacy, Queen's University Belfast) was the Chief Investigator, led the project design, oversaw the whole project, and is lead author of the report.

DR. HEATHER E. BARRY (formerly Research Fellow at Queen's University Belfast, now Lecturer in Pharmacy Practice, Queen's University Belfast) was involved in the conception and development of the project. She had day-to-day responsibility for project management for Phases 1 and 2, which included: conduct of the pharmacoepidemiology study; recruitment of and conducting of interviews with PwD, their carers, GPs and community pharmacists; analysis and interpretation of the results of the qualitative study; recruitment of and conducting of task group discussions with GPs and community pharmacists. She contributed to the writing of the report.

DR. LAURA E. BEDFORD (Research Fellow, Queen's University Belfast) had day-to-day responsibility for Phase 3 and contributed to the writing of the report.

MS. MÁIRÉAD MCGRATTAN (Postgraduate Research Student, Queen's University Belfast) assisted with data collection, analysis and interpretation of results in Phase 2, and conducted separate doctoral research complementary to the work undertaken as part of this project. She is a co-author of the report.

The following members of the Project Management Group oversaw management of the study, were involved in the planning and development of the study, provided advice and guidance on the development of the study protocols for each of the three phases and were involved in the analysis and interpretation of results. They are co-authors of the report.

PROFESSOR CRISTÍN RYAN (Professor in Pharmacy Practice, Trinity College Dublin)

PROFESSOR A. PETER PASSMORE (Professor of Ageing & Geriatric Medicine, Queen's University Belfast and Belfast Health & Social Care trust)

PROFESSOR A. LOUISE ROBINSON (Director, Newcastle University Institute for Ageing and Professor of Primary Care and Ageing)

DR. GERARD J. MOLLOY (Lecturer in Psychology)

MS. CARMEL M. DARCY (Consultant Pharmacist – Older People)

DR. HILARY BUCHANAN (Retired GP, former carer for a relative with dementia and previous research volunteer with the Alzheimer's Society)

ACKNOWLEDGEMENTS

This work was supported by the Health and Social Care Research and Development Division, Public Health Agency for Northern Ireland and Atlantic Philanthropies (COM/5020/14). We are very grateful for the support provided by Dr. Gail Johnston throughout the project.

The authors would like to sincerely thank all those who participated in the project: people with dementia; their carers; GPs and community pharmacists. This work would not have been possible without their contribution.

We wish to thank the staff at the HSC Business Services Organisation, Information and Registration Unit for supplying data from the Enhanced Prescribing Database. In particular we wish to recognise the technical support provided by Mr. Ricky McLaughlin during Phase 1 of the project.

We would also like to thank Drs. Janine Cooper, Helen Reid, Deborah Patton and Mr. John Barry for their feedback on the interview topic guides, and Mrs. Claire Leathem and colleagues in the Northern Ireland Clinical Research Network for their assistance with recruitment for Phase 2.

The authors are grateful for the expertise of Professor Tracy Finch in advising on the use task groups to inform intervention development.

Many thanks to Mr. Stephen Mullan from Video Production at Queen's University Belfast for shooting and editing the video that was used in the intervention. The authors would also like to acknowledge the video cast – Ms. Máiréad McGrattan, Mr. James McDowell and Mrs. Miriam Ferguson.

The researchers are extremely grateful to the staff in QUB Research Governance, particularly Dr. Stephen Liggett, Dr. Paula Tighe and Ms. Kathryn Taylor for their assistance and support with the various ethics and governance applications throughout the course of the project.

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APPENDICES

Appendix 1. List of drugs used as proxies for conditions listed in STOPP criteria

Condition	Assumption(s) made	Drugs used as proxies listed by British National Formulary (BNF) categories (Joint Formulary Committee, 2015) from which they were extracted
<i>Supraventricular tachyarrhythmias</i>	Presence of supraventricular tachyarrhythmias was assumed by dispensing of drug indicated for SVT	2.1.1 Cardiac glycosides 2.4 Beta-adrenoceptor blocking drugs 2.6.2 Calcium-channel blockers
<i>Gout</i>	Presence of gout was assumed by dispensing of drug indicated for gout	10.1.4 Gout and cytotoxic-induced hyperuricaemia
<i>Angina</i>	Criterion states 'concurrent nitrate therapy for angina'	2.6.1 Nitrates
<i>Dementia</i>	Presence of dementia was assumed by dispensing of drug indicated for dementia	4.11 Drugs for dementia
<i>Glaucoma</i>	Presence of glaucoma was assumed by dispensing of drug indicated for glaucoma	11.6 Treatment of glaucoma
<i>Cardiac conduction abnormalities</i>	Presence of cardiac conduction abnormalities was assumed by dispensing of anti-arrhythmic agent	2.3.2 Drugs for arrhythmias
<i>Prostatism or prior history of urinary retention or bladder outflow obstruction</i>	Presence of prostatism and prior history of urinary retention was assumed by dispensing of drugs indicated for BPH or for urinary retention	6.4.2 Male sex hormones and antagonists 7.4.1 Drugs for urinary retention
<i>Parkinsonism</i>	Presence of Parkinsonism was assumed by dispensing of dopaminergic and antimuscarinic drugs used in those with Parkinson's disease/Parkinsonism	4.9.1 Dopaminergic drugs used in Parkinsonism 4.9.2 Antimuscarinic drugs used in Parkinsonism

<i>Uncomplicated peptic ulcer disease or erosive peptic oesophagitis</i>	An assumption was made that if a PPI was dispensed, it was being used for these conditions	1.3.5 Proton Pump Inhibitors
<i>Moderate to severe COPD</i>	Presence of moderate-severe COPD was assumed by dispensing of short-acting beta ₂ agonist in combination with long-acting muscarinic antagonist, long-acting beta ₂ agonist plus inhaled corticosteroid	3.1.1 Adrenoceptor agonists 3.1.2 Antimuscarinic bronchodilators 3.1.3 Theophylline 3.1.4 Compound bronchodilator preparations 3.2 Corticosteroids
<i>Asthma</i>	History of asthma was assumed by dispensing of beta ₂ agonist, inhaled corticosteroid, leukotriene receptor antagonist, theophylline	3.1.1 Adrenoceptor agonists 3.1.3 Theophylline 3.2 Corticosteroids 3.3.2 Leukotriene receptor antagonists
<i>Acute or chronic respiratory failure</i>	Respiratory failure was assumed by dispensing of oxygen	3.6 Oxygen
<i>Severe hypertension</i>	Presence of severe hypertension was assumed by dispensing of ACE inhibitor (or angiotensin II receptor blocker) + calcium channel blocker + thiazide-like diuretic + alpha blocker	2.5.5.1 Angiotensin-converting enzyme inhibitors 2.5.5.2 Angiotensin-II receptor antagonists 2.5.4 Alpha-adrenoceptor blocking drugs 2.2.1 Thiazides and related diuretics 2.6.2 Calcium-channel blockers
<i>Severe heart failure</i>	Presence of severe heart failure was assumed by dispensing of ACE inhibitor (or angiotensin II receptor blocker) + beta-blocker + candesartan or spironolactone or eplerenone	2.5.5.1 Angiotensin-converting enzyme inhibitors 2.5.5.2 Angiotensin-II receptor antagonists

		2.4 Beta-adrenoceptor blocking drugs 2.2.4 Aldosterone antagonists
<i>Cardiovascular disease</i>	Cardiovascular disease was assumed by dispensing of any cardiovascular drug, e.g. diuretics; anti-arrhythmic drugs; beta-adrenoceptor blocking drugs; drugs for hypertension and heart failure; nitrates, calcium-channel blockers, and other antianginal drugs; antiplatelet drugs; lipid-regulating drugs	1.2 Positive inotropic drugs 2.2 Diuretics 2.3 Anti-arrhythmic drugs 2.4 Beta-adrenoceptor blocking drugs 2.5 Hypertension and heart failure 2.6 Nitrates, calcium-channel blockers and other antianginal drugs 2.7 Sympathomimetics 2.8 Anticoagulants and protamine 2.9 Antiplatelet drugs 2.10 Stable angina, acute coronary syndromes, and fibrinolysis 2.11 Antifibrinolytic drugs and haemostatics 2.12 Lipid-regulating drugs
<i>Type 2 diabetes mellitus</i>	Presence of type 2 diabetes was assumed by dispensing of biguanides, sulphonylureas or other antidiabetic drugs indicated for type 2 diabetes	6.1.2.1. Sulphonylureas 6.1.2.2 Biguanides 6.1.2.3 Other antidiabetic drugs
<i>Heart failure</i>	Presence of heart failure was assumed by dispensing of ACE inhibitor or angiotensin-II receptor antagonist in combination with a beta-blocker licensed	2.5.5.1 Angiotensin-converting enzyme inhibitors

for use in heart failure (bisoprolol,
carvedilol, nebivolol)

**2.5.5.2 Angiotensin-II
receptor antagonists**
**2.4 Beta-adrenoceptor
blocking drugs**

Appendix 2. Signed BSO data access agreement

Please ensure that the Data Destruction Notification (Appendix 1) is completed within the specified retention period and returned to the Personnel Data Guardian.

(H) Declaration: Requesting Organisation

Data Protection Undertaking on Behalf of the Organisation Wishing to Access the Data

My organisation requires access to the data specified and will conform to the Data Protection Act 1998 and the guidelines issued by the DHSSPS Executive in January 2009 in "The Code of Practice on Protecting the Confidentiality of Service User Information".

I confirm that the information requested, and any information extracted from it,

- Is relevant to and not excessive for the stated purpose
- Will be used only for the stated purpose
- Will be stored securely
- Will be held no longer than is necessary for the stated purpose
- Will be disposed of fully and in such a way that it is not possible to reconstitute it.
- That all measures will be taken to ensure personal identifiable data will not be disclosed to third parties.
- The Health and Social Care organisation will be informed of the data being deleted / destroyed.

I (*name:printed*) **Heather Barry** as the Authorised Officer of (*Organisation*) **Queen's University Belfast** declare that I have read and understand my obligations and adhere to the conditions contained in this Data Access Agreement.

Signed:


(Authorised Officer)

Date:

21/11/2014

Signed:


(Personal Data Guardian)

Date:

21/11/2014

Appendix 1

Data Destruction Notification and checklist

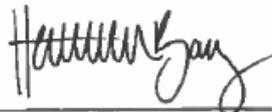
Authorised users of the person identifiable data have, under the terms and conditions of the Data Access Agreement, a requirement to destroy the data on or before the retention date stated in Section (H).

This form should be completed on destruction of the data and returned to the Personal Data Guardian.

This form should be completed on destruction of the data, and returned to:-

Information & Registration Unit
BSO
2 Franklin Street
Belfast
BT2 8DQ

Data Destruction Notification	
Name of Organisation	Queen's University Belfast
Name of Authorised Officer (please print)	Dr. Heather Barry
Position/Status	Research Fellow
Address	School of Pharmacy Queen's University Belfast 97 Lisburn Road Belfast BT9 7BL
Telephone Number	028 9097 2348
Mobile Number (Optional)	
Fax Number	028 9024 7794
Email Address	H.Barry@qub.ac.uk
Title of Agreement	A cross-sectional study of prescribing trends and appropriateness of prescribing for persons with dementia in primary care in Northern Ireland
Date Declaration Signed	21 st November 2014
Date Data Received	4 th December 2014
Date Data Destroyed	30 th November 2015

Signature	
Date	16 th February 2016

Appendix 3. Ethical approval received for Phase 1



Health Research Authority

NRES Committee London - City Road & Hampstead

Bristol Research Ethics Committee Centre
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 0117 342 1339

24 October 2014

Professor Carmel M. Hughes
Professor of Primary Care Pharmacy
Queen's University Belfast
School of Pharmacy
97 Lisburn Road
Belfast
BT9 7BL

Dear Professor Hughes

Study title: A cross-sectional study of prescribing trends and appropriateness of prescribing for persons with dementia in primary care in Northern Ireland

REC reference: 14/LO/1891

IRAS project ID: 163358

The Proportionate Review Sub-committee of the NRES Committee London - City Road & Hampstead reviewed the above application on 15 October 2014.

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 make a request to postpone publication, please contact the REC Assistant Miss Maeve Groot Bluemink, nrescommittee.london-cityroadandhampstead@nhs.net.

Ethical opinion

On behalf of the Committee, the sub-committee 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.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

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.

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

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").

Approved documents

The documents reviewed and approved were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Cover Letter REC]	1.0	09 October 2014
IRAS Checklist XML [Checklist_09102014]		09 October 2014
Letter from funder [Letter from HSC confirming funding approval]	N/A	14 August 2014
Letter from sponsor [QUB sponsor letter]	1.0	08 October 2014
Other [HEB CV]	N/A	19 September 2014
REC Application Form [REC_Form_09102014]		09 October 2014
Referee's report or other scientific critique report [Referee ID 20522]	N/A	
Referee's report or other scientific critique report [Referee ID 20350]	N/A	
Referee's report or other scientific critique report [Referee ID 20173]	N/A	
Research protocol or project proposal [Study Protocol]	1.0	29 September 2014
Summary CV for Chief Investigator (CI) [CMH CV]	N/A	22 September 2014

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Dr Mimi Bhattacharyya declared an interest in knowing a member of the research team. The Committee agreed that Dr Bhattacharyya could remain in the room and take part in the discussions.

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.

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/>

With the Committee's best wishes for the success of this project.

14/LO/1891

Please quote this number on all correspondence

Yours sincerely



pp

Dr David Slovick
Chair

Email: nrescommittee.london-cityroadandhampstead@nhs.net

Enclosures: List of names and professions of members who took part in the review

"After ethical review – guidance for researchers" [SL-AR2]

Copy to: Dr. Heather E. Barry, Queen's University Belfast

Appendix 4. Prevalence of potentially inappropriate prescribing in 2013 among 6,826 people with dementia in Northern Ireland by individual STOPP criterion

Criteria description (potential risk)	Number of patients	% of patients (95% CI)
Indication of medication		
Any drug prescribed beyond the recommended duration, where treatment duration is well defined		
Zopiclone and zolpidem (up to 4 weeks)	573	8.4 (7.8 – 9.1)
NSAIDs (up to 3 months)	124	1.8 (1.6 – 2.2)
Any duplicate drug class prescription (<i>optimisation of monotherapy within a single drug class should be observed prior to considering a new agent</i>)		
Opioid analgesics	346	5.1 (4.6 – 5.6)
Benzodiazepines	239	3.5 (3.1 – 4.0)
Stimulant laxatives	45	0.7 (0.5 – 0.9)
SSRIs	33	0.5 (0.3 – 0.7)
Statins	34	0.5 (0.4 – 0.7)
Cardiovascular system		
Beta-blocker in combination with verapamil or diltiazem (<i>risk of heart block</i>)	18	0.3 (0.2 – 0.4)
Amiodarone as first-line ¹ antiarrhythmic therapy in supraventricular tachyarrhythmias ² (<i>higher risk of side-effects than beta-blockers, digoxin, verapamil or diltiazem</i>)	7	0.1 (0.05 – 0.2)
Thiazide diuretic with a history of gout ² (<i>gout can be precipitated by thiazide diuretic</i>)	20	0.3 (0.2 – 0.5)
Phosphodiesterase type-5 inhibitors with concurrent nitrate therapy for angina ² (<i>risk of cardiovascular collapse</i>)	2	0.03 (0.01 – 0.1)
Antiplatelet/Anticoagulant drugs		
Long-term aspirin at doses greater than 150mg per day (<i>increased risk of bleeding, no evidence for increased efficacy</i>)	24	0.4 (0.2 – 0.5)
NSAID and vitamin K antagonist, direct thrombin inhibitor or factor Xa inhibitors in combination (<i>risk of major gastrointestinal bleeding</i>)	9	0.1 (0.07 – 0.3)

NSAID with concurrent antiplatelet agent(s) without PPI prophylaxis (<i>increased risk of peptic ulcer disease</i>)	117	1.7 (1.4 – 2.1)
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Central nervous system and psychotropic drugs

TCA with dementia, narrow-angle glaucoma, cardiac conduction abnormalities, prostatism, or prior history of urinary retention² (*risk of worsening these conditions*)

Dementia	335	4.9 (4.4 – 5.5)
Narrow-angle glaucoma	13	0.2 (0.1 – 0.3)
Cardiac conduction abnormalities	3	0.04 (0.01 – 0.1)
Prostatism or prior history of urinary retention	25	0.4 (0.3 – 0.5)
Initiation of TCAs as first-line antidepressant treatment (<i>higher risk of adverse drug reactions with TCAs than SSRIs or SNRIs</i>)	75	1.1 (0.09 – 1.4)
Benzodiazepines for ≥4 weeks (<i>no indication for longer treatment</i>)	777	11.4 (10.7 – 12.2)
Antipsychotics (other than quetiapine or clozapine) in those with Parkinsonism or Lewy Body Disease ² (<i>risk of severe extrapyramidal symptoms</i>)	51	0.8 (0.6 – 1.0)
Anticholinergics/antimuscarinics to treat extrapyramidal side-effects of neuroleptic medications (<i>risk of anticholinergic toxicity</i>)	29	0.4 (0.3 – 0.6)
Anticholinergics/antimuscarinics in patients with dementia ² (<i>risk of exacerbation of cognitive impairment</i>)	1718	25.2 (24.2 – 26.2)
Acetylcholinesterase inhibitors with concurrent treatment with drugs that reduce heart rate such as beta-blockers, digoxin, diltiazem, verapamil (<i>risk of cardiac conduction failure, syncope and injury</i>)	1276	18.7 (17.8 – 19.6)
Phenothiazines as first-line treatment, since safer and more efficacious alternatives exist (<i>phenothiazines are sedative, have significant antimuscarinic toxicity in older people, with the exception of prochlorperazine for nausea/vomiting/vertigo, chlorpromazine for relief of persistent hiccups and levopromazine as an antiemetic in palliative care</i>)	59	0.9 (0.7 – 1.1)

First generation antihistamines (<i>safer, less toxic antihistamines now widely available</i>)	635	9.3 (8.6 – 10.0)
Gastro-intestinal system		
Prochlorperazine or metoclopramide with Parkinsonism ² (<i>risk of exacerbating Parkinsonian symptoms</i>)	13	0.2 (0.1 – 0.3)
PPI for uncomplicated peptic ulcer disease or erosive peptic ulcer oesophagitis ² at full therapeutic dosage for >8 weeks (<i>dose reduction or earlier discontinuation indicated</i>)	1561	22.9 (21.9 – 23.9)
Oral elemental iron doses greater than 200mg daily (<i>no evidence of enhanced iron absorption above these doses</i>)	2	0.03 (0.01 – 0.1)
Respiratory system		
Theophylline as monotherapy for COPD ² (<i>safer, more effective alternatives; risk of adverse effects due to narrow therapeutic index</i>)	65	1.0 (0.8 – 1.2)
Systemic corticosteroids instead of inhaled corticosteroids for maintenance therapy in moderate-severe COPD ² (<i>unnecessary exposure to long-term side-effects of systemic corticosteroids and effective inhaled therapies are available</i>)	0	0.00
Antimuscarinic bronchodilators with a history of narrow-angle glaucoma or bladder outflow obstruction ² (<i>may exacerbate glaucoma or cause urinary retention</i>)		
Narrow-angle glaucoma	13	0.2 (0.1 – 0.3)
Bladder outflow obstruction	50	0.7 (0.6 – 1.0)
Non-selective beta-blocker with a history of asthma ² requiring treatment (<i>risk of increased bronchospasm</i>)	30	0.4 (0.3 – 0.6)
Benzodiazepines with acute or chronic respiratory failure ² (<i>risk of exacerbation of respiratory failure</i>)	6	0.09 (0.04 – 0.2)
Musculoskeletal system		
NSAID with severe hypertension or severe heart failure ² (<i>risk of exacerbation of hypertension or heart failure</i>)	0	0.00
COX-2 selective NSAIDs with concurrent cardiovascular disease ² (<i>increased risk of myocardial infarction and stroke</i>)	24	0.4 (0.2 – 0.5)
NSAID with concurrent corticosteroids without PPI prophylaxis (<i>increased risk of peptic ulcer disease</i>)	20	0.3 (0.2 – 0.5)

Urogenital system

Antimuscarinic drugs with dementia, or chronic cognitive impairment or narrow-angle glaucoma or chronic prostatism²
(*risk of increased confusion, acute exacerbation of glaucoma and urinary retention*)

Dementia or chronic cognitive impairment	631	9.2 (8.6 – 10.0)
Narrow-angle glaucoma	35	0.5 (0.4 – 0.7)
Chronic prostatism	122	1.8 (1.5 – 2.1)

Endocrine system

Sulphonylureas with a long duration of action with type 2 diabetes mellitus ² (<i>risk of prolonged hypoglycaemia</i>)	2	0.03 (0.01 – 1.1)
Thiazolidinediones in patients with heart failure ² (<i>risk of exacerbation of heart failure</i>)	0	0.00

Analgesic drugs

Use of oral or transdermal strong opioids as first-line therapy for mild pain (<i>WHO analgesic ladder not observed</i>)	49	0.7 (0.5 – 1.0)
Use of regular ³ (as distinct from PRN) opioids without concomitant laxative (<i>risk of severe constipation</i>)	715	10.5 (9.8 – 11.2)
Long-acting opioids without short-acting opioids for breakthrough pain (<i>risk of persistence of severe pain</i>)	610	8.9 (8.3 – 9.6)

Antimuscarinic/Anticholinergic drug burden

Concomitant use of two or more drugs with antimuscarinic/anticholinergic properties (<i>risk of increased antimuscarinic/anticholinergic activity</i>)	215	3.2 (2.8 – 3.6)
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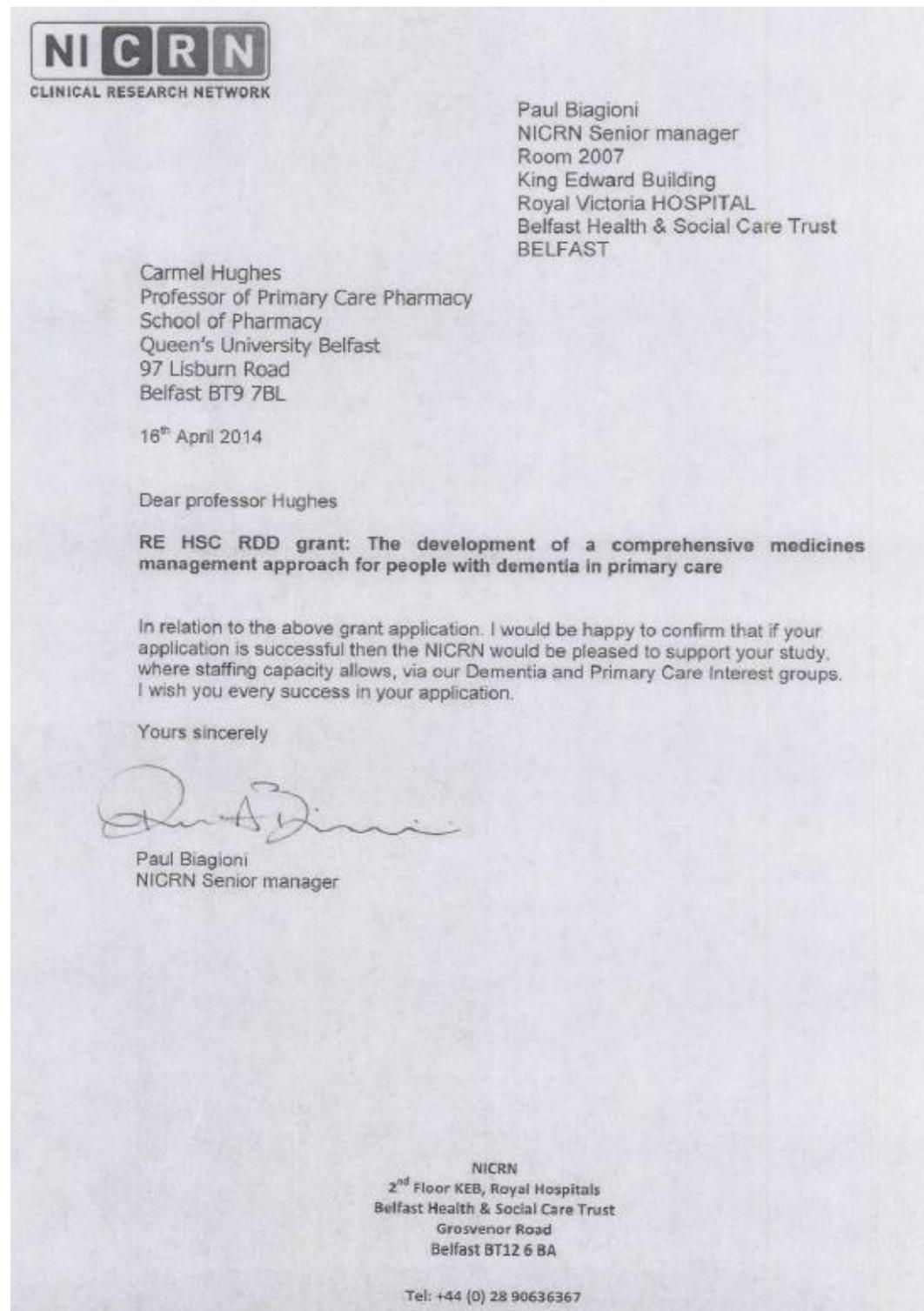
STOPP, Screening Tool of Older Persons Potentially Inappropriate Prescriptions; NSAID, non-steroidal anti-inflammatory drug; SSRI, selective serotonin reuptake inhibitor; TCA, tricyclic antidepressant; PPI, proton pump inhibitor; COPD, chronic obstructive pulmonary disease; COX-2, cyclooxygenase-2; WHO, world health organisation; PRN, when required

¹‘First-line’ therapy was determined by examining prescribing in the three months prior to starting the drug in question

²The use of drugs commonly indicated in certain disease conditions (such as gout, parkinsonism, glaucoma) were identified in the Enhanced prescribing Database (EPD) and used as proxies for diagnosis

³An opioid was defined as being used ‘regularly’ if a patient had received a prescription for an opioid for three consecutive months

Appendix 5. Northern Ireland Clinical Research Network (NICRN) letter of support



Appendix 6. Patient invitation letter (v3, 02.09.2015)



<Name and address of hospital>



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

Dear Sir or Madam,

I am writing to you, as researchers from Queen's University Belfast are conducting a study to find out more about how people with memory problems manage their medicines. You recently attended an appointment at the memory clinic at Belfast City Hospital. I am writing to a number of people who attend this clinic to enquire if they would be interested in volunteering to take part in this study.

I have enclosed a copy of a Participant Information Sheet which provides details about what taking part in this study would involve, and which hopefully should answer any questions you have about the study. It is important that you read this information before you decide whether or not to take part. The study would not require you to make any changes to your current prescribed medication or any other aspect of your care.

The study would involve taking part in an interview with a researcher from Queen's University Belfast. The interview would take place at your home and would last approximately one hour. The researcher would like to hear your views about your medicines, and how you feel your General Practitioner and Community Pharmacist help you with your medicines. If there is someone (e.g. a family member or friend) who helps you with your medicines they may also be asked to take part. People taking part in the study will receive £50. It is important that you are fully aware that participation in this study is entirely voluntary. You do not have to take part if you don't want to.

If you require further information before you decide what to do, please do not hesitate to contact the researcher **Dr. Heather Barry** by telephone: **028 9097 2348** or by email: H.Barry@qub.ac.uk.

Yours Sincerely,

<Signature>

<Name and job title of memory clinic consultant>

On behalf of the research team:

Professor Carmel Hughes, Dr. Heather Barry, Dr. Cristín Ryan, Dr. Janine Cooper, Professor Peter Passmore, Professor Louise Robinson, Dr. Gerry Molloy, Ms. Carmel Darcy, Dr. Hilary Buchanan

Appendix 7. Carer invitation letter (v3, 02.09.2015)



<Name and address of hospital>



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

Dear Sir or Madam,

I am writing to you, as researchers from Queen's University Belfast are conducting a study to find out more about how people with memory problems manage their medicines. You have been identified as someone who provides assistance to a person with memory problems with their medicines, and I am therefore writing to enquire if you would be interested in volunteering to take part in this study.

I have enclosed a copy of a Participant Information Sheet which provides details about what taking part in this study would involve, and which hopefully should answer any questions you have about the study. It is important that you read this information before you decide whether or not to take part. The study would not require the patient to make any changes to their current prescribed medication or any other aspect of their health care.

The study would involve taking part in an interview with a researcher from Queen's University Belfast. The interview would take place at the patient's home and would last approximately one hour. The researcher would like to hear your views about helping to manage medicines for a person with memory problems, and how you feel the patient's General Practitioner and Community Pharmacist help with their medicines. People taking part in the study will received £50. It is important that you are fully aware that participation in the study is entirely voluntary. You do not have to take part if you don't want to.

If you require further information before you decide what to do, please do not hesitate to contact the researcher **Dr. Heather Barry** by telephone: **028 9097 2348** or by email: H.Barry@qub.ac.uk.

Yours Sincerely,

<Signature>

<Name and job title of memory clinic consultant>

On behalf of the research team:

Professor Carmel Hughes, Dr. Heather Barry, Dr. Cristín Ryan, Dr. Janine Cooper, professor Peter Passmore, Professor Louise Robinson, Dr. Gerry Molloy, Ms. Carmel Darcy, Dr. Hilary Buchanan

Appendix 8. Patient information sheet (v3, 02.09.2015)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

PATIENT INFORMATION SHEET

Study title: Development of an intervention to improve medicines management for people with memory problems in primary care in Northern Ireland

You are being invited to take part in a research study. Before you decide whether you would like to take part, please take the time to read the following information. It is important that you understand why this research is being completed and what you will be asked to do if you agree to take part. If there is anything that is unclear, or if you would like more information, please contact the research team (see below for details). All communication will be treated confidentially.

What is the purpose of this study?

We know from other research studies that some people with memory problems often find it difficult to manage the medicines which have been prescribed for them by their General Practitioner (GP) and dispensed by the Community Pharmacist. Therefore, we want to put together a plan to try to help patients. In order to understand what patients think is important about managing their medicines, we want to hear about your experiences and views.

Why have I been chosen?

You recently attended an outpatient appointment at the memory clinic at <Name of hospital>. Patients attending this clinic who are living in their own homes and who are currently taking four or more medicines every day have been approached to take part in this study. If you have identified someone (e.g. a family member or friend) who helps you with your medicines, they may also be asked to take part in the study.

Do I have to take part?

It is up to you to decide whether or not to take part in this study. If you decide not to take part we will respect your decision and will make no further attempts to contact you. This will not affect the health care you receive in any way. If you do decide to take part, you will be asked to sign a consent form, and you will be given a copy of the consent form to keep. 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 to me if I take part?

A Research Nurse will contact you one week after you receive this information sheet to discuss if you might be interested in participating in the study and to answer any questions you may have. If you are interested in taking part, you will be asked to participate in an interview with a researcher. If someone helps you with your medicines they will also be asked to participate. You may choose to be interviewed together or separately. If you choose to be interviewed separately a PhD student, Mairead McGrattan, will accompany the researcher to assist with conducting the interviews. The interview will be conducted at a time and date to suit you, at your home. The interview will last approximately one hour (although this may vary between individuals) and will be audio-recorded (with your permission).

During the interview, you will be asked to describe your experiences of managing your medicines, how you feel your GP and Community Pharmacist help you with your medicines, and how it could be made easier for you to manage your medicines. After the interview, the audio-recording will be typed up, word for word. You will not be identified in any typed record of the interview. We will use this information to develop a plan to help people with memory problems manage their medicines. Your GP 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.

What are the possible disadvantages and risks of taking part?

There is little risk in taking part in this study. It is possible that the discussion may make you think about upsetting aspects of your medicines and conditions for which you take your medicines. If you find this distressing, you may withdraw at 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 will be sent a letter to tell them that you became upset during the interview 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, the researcher would like to visit you at home to conduct the interview.

What are the benefits of taking part?

Taking part will give you an opportunity to tell us about any difficulties you face in managing your medicines and how you feel medicines management may be improved for people with memory problems.

What will happen if I decide I 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 leave 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.

Who will have access to my information?

All information collected during the course of this study will be kept strictly confidential. Audio-recordings will be anonymous and your name will not appear in any publications. All data will be stored securely at the School of Pharmacy, Queen's University Belfast. At the end of the study the confidential records and files will be kept for 5 years and then destroyed. The confidential handling, storage and disposal of data are compliant with the Data Protection Act (1998). The research team will not have any access to your medical records. 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 Belfast may need to review information collected as part of the research.

If you mention something during the interview that suggests that you have been given the wrong treatment or that a healthcare 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. Otherwise your GP or Community Pharmacist will not be told about anything you talk about during the interview.

What will happen to the study results?

The findings from this study 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. Although quotes from the interviews may be included, no individual will be identified personally in any report or publication. You will be provided with a copy of the results at the end of the study.

Who is organising and funding the study?

The study is organised by the School of Pharmacy, Queen’s University Belfast. It is funded by the HSC Public Health Agency in Northern Ireland and The Atlantic Philanthropies.

Who has reviewed the study?

This study has been reviewed and given a favourable opinion by the NRES Committee – Cambridgeshire and Hertfordshire (15/EE/0103), and by Belfast Health and Social Care Trust Research Governance (15001CH-SP). The project has been peer reviewed by independent reviewers on behalf of the Public Health Agency.

What happens if there is a problem?

If you are unhappy about any aspect of the study, or the way you have been approached or treated during the course of this study, please contact the Chief Investigator, Professor Carmel Hughes. If you wish to complain formally, you can contact the Belfast Health and Social Care Trust Complaints Department (Tel: 028 9504 8000 or Email: complaints@belfasttrust.hscni.net). If you are unhappy with the response from the Trust, you can contact the Northern Ireland Ombudsman (Tel: 028 9023 3821 or Email: ombudsman@ni-ombudsman.org.uk).

Further information

If you would like more information, would like this leaflet in a different format, or have any queries about the study, please feel free to contact the research team:

Dr. Heather Barry

Research Fellow

School of Pharmacy

Queen’s University Belfast

97 Lisburn Road

Belfast, BT9 7BL

T: 028 9097 2348

E: H.Barry@qub.ac.uk

Professor Carmel Hughes

Chief Investigator

School of Pharmacy

Queen’s University Belfast

97 Lisburn Road

Belfast, BT9 7BL

T: 028 9097 2147

E: c.hughes@qub.ac.uk

Thank you for considering taking part in this study

Appendix 9. Carer information sheet



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

CARER INFORMATION SHEET

Study title: Development of an intervention to improve medicines management for people with memory problems in primary care in Northern Ireland

You are being invited to take part in a research study. Before you decide whether you would like to take part, please take the time to read the following information. It is important that you understand why this research is being completed and what you will be asked to do if you agree to take part. If there is anything that is unclear, or if you would like more information, please contact the research team (see below for details). All communication will be treated confidentially.

What is the purpose of this study?

We know from other research studies that some people with memory problems often find it difficult to manage the medicines which have been prescribed for them by their General Practitioner (GP) and dispensed by the Community Pharmacist. Therefore, we want to put together a plan to try to help patients and their carers. In order to understand what patients and their carers think is important about managing medicines, we want to hear about your experiences and views.

Why have I been chosen?

You have been identified as someone who provides assistance with medicines to a person with memory problems. The person to whom you provide help recently attended an outpatient appointment at the memory clinic at <Name of hospital>. Patients attending this clinic who are living in their own homes and who are currently taking four or more medicines every day have been approached to take part in this study.

Do I have to take part?

It is up to you to decide whether or not to take part in this study. If you decide not to take part we will respect your decision and will make no further attempts to contact you. If you do decide to take part, you will be asked to sign a consent form, and you will be given a copy of the consent form to keep. 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 the patient's normal care.

What will happen to me if I take part?

A Research Nurse will contact you one week after you receive this information sheet to discuss if you might be interested in participating in the study and to answer any questions you may have. If you are interested in taking part, you will be asked to participate in an interview with a researcher. The patient will also be asked to participate. You may choose to be interviewed together or separately. If you choose to be interviewed separately a PhD student, Mairead McGrattan, will accompany the researcher to assist with conducting the interviews. The interview will be conducted at a time and date to suit you, at the patient's home. The interview will last approximately one hour (although this may vary between individuals) and will be audio-recorded (with your permission).

During the interview, you will be asked to describe your experiences of providing assistance with medicines, how you feel the patient's GP and Community Pharmacist help the patient with their medicines, and how it could be made easier for the patient to manage their medicines. After the interview, the audio-recording will be typed up, word for word. You will not be identified in any typed record of the interview. We will use this information to develop a plan to help people with memory problems and their carers to manage medicines. You will receive £50 for taking part in the study.

What are the possible disadvantages and risks of taking part?

There is little risk in taking part in this study. It is possible that the discussion may make you think about upsetting aspects of the patient's medicines and conditions for which the patient take their medicines. If you find this distressing, you may withdraw at any time. To make it easier for you, the researcher would like to visit you at the patient's home to conduct the interview.

What are the benefits of taking part?

Taking part will give you an opportunity to tell us the difficulties you face in assisting the patient with their medicines and how you feel medicines management may be improved for people with memory problems.

What will happen if I decide I 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 leave the study may still be included in the study. The patient's normal medical care will not be affected if you decide you no longer wish to take part.

Who will have access to my information?

All information collected during the course of this study will be kept strictly confidential. Audio-recordings will be anonymous and your name will not appear in any publications. All data will be stored securely at the School of Pharmacy, Queen's University Belfast. At the end of the study the confidential records and files will be kept for 5 years and then destroyed. The confidential handling, storage and disposal of data are compliant with the Data Protection Act (1998). The research team will not have any access to the patient's medical records. 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 Belfast may need to review information collected as part of the research.

If you mention something during the interview that suggests that the patient has been given the wrong treatment or that a healthcare professional has not acted in a proper way, we may need to report this to the healthcare professional who cares for the patient, or to another authority. Otherwise the patient's GP or Community Pharmacist will not be told about anything you talk about during the interview.

What will happen to the study results?

The findings from this study 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. Although quotes from the interviews may be included, no individual will be identified personally in any report or publication. You will be provided with a copy of the results at the end of the study.

Who is organising and funding the study?

The study is organised by the School of Pharmacy, Queen's University Belfast. It is funded by the HSC Public Health Agency in Northern Ireland and The Atlantic Philanthropies.

Who has reviewed the study?

This study has been reviewed and given a favourable opinion by the NRES Committee – Cambridgeshire and Hertfordshire (15/EE/0103), and by Belfast Health and Social Care Trust Research Governance (15001CH-SP). The project has been peer reviewed by independent reviewers on behalf of the Public Health Agency.

What happens if there is a problem?

If you are unhappy about any aspect of the study, or the way you have been approached or treated during the course of this study, please contact the Chief Investigator, Professor Carmel Hughes. If you wish to complain formally, you can contact the Belfast Health and Social Care Trust Complaints Department (Tel: 028 9504 8000 or Email: complaints@belfasttrust.hscni.net). If you are unhappy with the response from the Trust, you can contact the Northern Ireland Ombudsman (Tel: 028 9023 3821 or Email: ombudsman@ni-ombudsman.org.uk).

Further information

If you would like more information, would like this leaflet in a different format, or have any queries about the study, please feel free to contact the research team:

Dr. Heather Barry

Research Fellow

School of Pharmacy

Queen's University Belfast

97 Lisburn Road

Belfast, BT9 7BL

T: 028 9097 2348

E: H.Barry@qub.ac.uk

Professor Carmel Hughes

Chief Investigator

School of Pharmacy

Queen's University Belfast

97 Lisburn Road

Belfast, BT9 7BL

T: 028 9097 2147

E: c.hughes@qub.ac.uk

Thank you for considering taking part in this study

Appendix 10. GP Practice invitation letter (v1, 27.02.2015)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

Dear <Name of Practice Manager or lead GP>,

Re: Development of an intervention to improve medicines management for people with dementia in primary care in Northern Ireland

We are writing to invite your GP practice to take part in the above named study. The aim of the study is to develop and refine an intervention focusing on medicines management in people with dementia in primary care. The research team wish to speak to people with dementia who are living alone in their own homes about their medicines and how they manage their medication. In order to do this, we would like to sample and recruit patients from your practice.

You have been approached to participate through a random search of GP practices across Northern Ireland. Should your practice decide to participate, patient recruitment will be conducted with the help of the Northern Ireland Clinical Research Network (Primary Care). Potentially eligible patients would be identified through an electronic search of your patient records, and an information pack would be posted to them to invite them to participate in the study. If a patient from the practice agrees to participate in the study, the research team would also like to interview the GP that the patient sees most frequently.

This study is run by the School of Pharmacy, Queen's University Belfast in collaboration with colleagues from: the School of Medicine, Dentistry and Biomedical Sciences, Queen's University Belfast; the Institute for Ageing and Health, Newcastle University; the School of Psychology, National University of Ireland Galway; Altnagelvin Hospital and the Alzheimer's Society. The study has received ethical approval from the NRES Committee East of England – Norfolk (15/EE/0103).

Please find enclosed a study information sheet, which provides more details about the study and which hopefully should answer any questions you may have. A Primary Care Research Nurse will be in contact with you over the next week to discuss if the practice would like to participate. In the meantime, if you require further information, please do not hesitate to contact the researcher **Dr. Heather Barry** by telephone: **028 9097 2348** or by email: **H.Barry@qub.ac.uk**.

Yours Sincerely,

<Signature>

Professor Carmel Hughes

Professor of Primary Care Pharmacy

<Signature>

Professor Peter Passmore

Professor of Ageing & Geriatric Medicine

<Signature>

Dr. Heather Barry

Research Fellow

On behalf of the research team:

Dr. Cristín Ryan, Dr. Janine Cooper, Professor Louise Robinson, Dr. Gerry Molloy, Ms. Carmel Darcy,
Dr. Hilary Buchanan

Appendix 11. GP Practice information sheet (v1, 27.02.2015)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

GP PRACTICE INFORMATION SHEET

Study title: Development of an intervention to improve medicines management for people with dementia in primary care in Northern Ireland

Your GP practice is being invited to take part in a research study. Before you decide whether you would like the GP practice to take part, please take the time to read the following information. It is important that you understand why this research is being completed and what the practice will be asked to do if you agree to participate. If there is anything that is unclear, or if you would like more information, please contact the research team (see below for details). All communication will be treated confidentially.

What is the purpose of this study?

People with dementia (PWD) are unique in terms of their medication needs compared with the general older population. Although they will also have co-morbid physical conditions and complex medication regimens, their impaired cognition and communication skills together with the presence of behavioural and psychological symptoms, generate additional challenges in medication adherence. Such challenges may influence doctors' prescribing behaviour and the quality of chronic illness management. There has been very limited research on medicines management in PWD, particularly those residing in primary care. We therefore aim to develop an intervention to improve medicines management for PWD in primary care. This intervention will incorporate the views of patients and their carers on medicines management, with those of the healthcare professionals involved in prescribing (GPs) and dispensing (Community Pharmacists) for these patients. These data will be used, together with literature on prescribing interventions, to develop the intervention.

Why has the practice been chosen?

The GP practice has been approached to participate in this study through a random search of GP Practices across Northern Ireland.

Does the practice have to take part?

It is up to you to decide whether or not to take part in this study. If you decide not to participate we will respect your decision and will make no further attempts to contact you. If you do decide to take part, you will be asked to sign a consent form, and you will be given a copy of the consent form to keep. You are free to withdraw from the study at any stage without giving a reason.

What will happen if the practice takes part?

If the practice participates in this study, the Northern Ireland Clinical Research Network (Primary Care) manager will make an appointment with the Practice Manager to arrange for a Research Nurse to either facilitate practice staff to conduct a computer search to identify potential patients or the Practice Manager will supply the Research Nurse with their own unique user name and passwords to do so. The search will be conducted using an existing disease register (in this case, the dementia register), READ coding and prescription information as appropriate to identify potentially suitable patients. Patients will be selected if they have a dementia diagnosis, are living at home on their own, and are taking four or more regularly prescribed medications. Once potentially eligible patients are identified from this search, a practice GP will be asked to confirm patient eligibility and their suitability to undertake an interview prior to them receiving study information from the practice. Study information will be mailed to eligible patients from the practice on practice-headed paper and with a letter, signed by the GP, inviting them to consider participation. Patients will be followed-up by telephone by the Research Nurse after one week to ascertain their interest in the study. If patients from your practice agree to participate in an interview, then the GP whom the patient sees most frequently and their Community Pharmacist may also be approached to see if they would like to contribute to the study.

What are the possible disadvantages and risks of taking part?

We do not foresee any risk to the practice in participating in this study.

What are the benefits of taking part?

Participation in this study may be beneficial for the practice's patients with dementia, as it will provide them with an opportunity to tell us about any difficulties they face in managing their medicines and how they feel medicines management may be improved for people with dementia.

What will happen if the practice decides it no longer wishes to take part?

The practice is free to withdraw from the study at any time. If you decide to do so, the data collected prior to the practice's withdrawal from the study may still be used.

Who will have access to study information?

All information collected during the course of this study will be kept strictly confidential. Data will be stored securely at the School of Pharmacy, Queen's University Belfast. At the end of the study the confidential records and files will be kept for 5 years and then destroyed. The confidential handling, storage and disposal of data are compliant with the Data Protection Act (1998). No patient identifiable data will be removed from the practice at any time. 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 Belfast may need to review information collected as part of the research.

What will happen to the study results?

The findings from this study will be used as part of a research project at Queen's University Belfast. Data may be published in academic journals and presented at conferences. Individual participants will be provided with a report of the results at the end of the study.

Who is organising and funding the study?

The study is organised by the School of Pharmacy, Queen's University Belfast. It is funded by the HSC Public Health Agency in Northern Ireland and The Atlantic Philanthropies.

Who has reviewed the study?

This study has been reviewed and given a favourable opinion by the NRES Committee East of England – Norfolk (15/EE/0103). The project has been peer reviewed by independent reviewers on behalf of the Public Health Agency.

What happens if there is a problem?

If the practice is unhappy about any aspect of the study, or the way it have been approached or treated during the course of this study, please contact the Chief Investigator, Professor Carmel Hughes.

Further information

If the practice would like more information, would like this leaflet in a different format, or have any queries about the study, please feel free to contact the research team:

Dr. Heather Barry

Research Fellow

School of Pharmacy

Queen's University Belfast

97 Lisburn Road

Belfast, BT9 7BL

T: 028 9097 2348

E: H.Barry@qub.ac.uk

Professor Carmel Hughes

Chief Investigator

School of Pharmacy

Queen's University Belfast

97 Lisburn Road

Belfast, BT9 7BL

T: 028 9097 2147

E: c.hughes@qub.ac.uk

Thank you for considering taking part in this study

Appendix 12. Research Governance – Care organisation approval

Care Organisation:	<Name of GP Practice>
Project Title:	Development of an intervention to improve medicines management for persons with dementia in primary care in Northern Ireland
Name of Lead GP	<Name of Lead GP>
Project Aims and Objectives:	<p>Study objectives:</p> <ol style="list-style-type: none"> 1. To identify the theoretical basis for the intervention by conducting qualitative semi-structured interviews with people with dementia and their carers, GPs and community pharmacists. 2. To develop a candidate (draft) intervention in which the behaviours of healthcare professionals (GPs and community pharmacists) will be targeted. 3. To test the feasibility of the intervention
Summary of Research	Persons with dementia (PWD) are unique in terms of their medication needs generating additional challenges in medication adherence. There has been limited research on prescribing, review, administration and adherence to medicines (all part of medicines management) in PWD, particularly for those residing in Primary Care. Calls have been made for research to focus on medicines management more broadly in PWD, to further understanding in this area and to aid the development of interventions to improve outcomes. The overall aim therefore of this study is to develop an intervention to improve medicines management for persons with dementia in primary care in Northern Ireland.
Impact of Research on Care Organisation:	<p>Patient Recruitment and Participation</p> <p>Potentially eligible patients will be identified through an electronic search of practice records for patients coded as having a diagnosis of dementia. The resulting list will be filtered by individual record using the study inclusion criteria checklist. The list of potentially eligible patients will be approved by the practice as suitable to receive the study invitation letter and information sheet by post (directly) from the practice. The role of the NICRN (PC) research nursing staff will be in facilitating participating practices to undertake the identification of potentially eligible patients and mail out the patient invitation letter and information sheet. They will also telephone patients as appropriate to check that they received the study mailing and ascertain their interest in participating in the study. The involvement for participating patients will be having a one to one interview with study researcher Dr Heather Barry and the study will aim to recruit one patient per practice. Written informed consent will be obtained by Dr Barry prior to commencing the interview which will be conducted at a suitable time and date at a venue chosen by the patient. Participants will be asked to describe their experiences of medicines</p>

	<p>management from their perspective. A copy of the patient's signed consent form will be given to the practice for their records and patients will receive a small monetary thank you for their time. The practice will receive £100 per patient enrolled in the study.</p> <p>GP Interviews Participating GP's will be interviewed by Study researcher Dr Heather Barry; the interview will be conducted at a suitable time and date at a venue chosen by the GP. It will be audio-recorded and should not last longer than an hour. During the interview, GP's will be asked to reflect on their prescribing behaviour for PWD and their approach to prescribing for these patients After the interview, the audio-recording will be transcribed by the researcher. On completion of the interview, GP's will be offered a certificate of participation which could be added to a continuing professional development portfolio. An honorarium of £50 will be provided as a token of appreciation for the time taken to participate in this study.</p> <p>Participating GPs will be asked to identify the local community pharmacies in which most of the practice's prescriptions are dispensed, in order to recruit community pharmacists to the study.</p>
Sponsor Organisation:	Queen's University Belfast
<p>This proforma is designed to describe the nature and scope of a research project and its likely impact on your care organisation as above. It seeks to provide assurance that the individual named below is aware of and consents to this research study taking place within the care organisation, in accordance with the protocol approved by the Research Ethics Committee and in accordance with the Research Governance Framework for Health and Social Care guidelines.</p> <p>As clinical governance lead of the above care organisation I am aware that the Medicines Management for Persons with Dementia in Primary Care Study will involve my organisation and agree to this taking place.</p>	
Name of General Practitioner:	
General Practitioner's Signature:	
Date:	

Appendix 13. Patient invitation letter (v1, 27.02.2015)

<To be printed on GP Practice headed paper>

<Date>

Dear <Patient name>

I am writing to you as researchers from Queen's University Belfast are undertaking a study to find out more about how people with memory problems manage their medicines. We are writing to a number of people from our practice to enquire if they would be interested in volunteering to take part in this study.

I have enclosed a copy of a Participant Information Sheet which provides details about what taking part in this study would involve. The study would not require you to make any changes to your current prescribed medication or any other aspect of your care.

The study would involve taking part in an interview with a researcher from Queen's University Belfast. The interview would take place at your home and would last approximately one hour. The researcher would like to hear your views about your medicines, and how you feel your General Practitioner and Community Pharmacist help you with your medicines. People taking part in the study will receive £50. It is important that you are fully aware that participation in this study is entirely voluntary. You do not have to take part if you don't want to.

If you require further information before you decide what to do, please do not hesitate to contact the researcher **Dr. Heather Barry** by telephone: **028 9097 2348** or by email: H.Barry@qub.ac.uk.

Yours Sincerely,

<Signature>

<Printed Name of GP>

<Printed Name of Practice>

Appendix 14. Patient information sheet (v1, 27.02.2015)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

PATIENT INFORMATION SHEET

Study title: Development of an intervention to improve medicines management for people with memory problems in primary care in Northern Ireland

You are being invited to take part in a research study. Before you decide whether you would like to take part, please take the time to read the following information. It is important that you understand why this research is being completed and what you will be asked to do if you agree to take part. If there is anything that is unclear, or if you would like more information, please contact the research team (see below for details). All communication will be treated confidentially.

What is the purpose of this study?

We know from other research studies that some people with memory problems often find it difficult to manage the medicines which have been prescribed for them by their General Practitioner (GP) and dispensed by the Community Pharmacist. Therefore, we want to put together a plan to try to help patients. In order to understand what patients think is important about managing their medicines, we want to hear about your experiences and views.

Why have I been chosen?

Patients registered with a general practice with memory problems who are living in their own homes and who are currently taking four or more medicines every day have been approached to take part in this study.

Do I have to take part?

It is up to you to decide whether or not to take part in this study. If you decide not to take part we will respect your decision and will make no further attempts to contact you. This will not affect the health care you receive in any way. If you do decide to take part, you will be asked to sign a consent form,

and you will be given a copy of the consent form to keep. 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 to me if I take part?

A Research Nurse will contact you one week after you receive this information sheet to discuss if you might be interested in participating in the study and to answer any questions you may have. If you are interested in taking part, you will be asked to participate in an interview with a researcher. The interview will be conducted at a time and date to suit you, either at your home or at the GP practice. The interview will last approximately one hour (although this may vary between individuals) and will be audio-recorded (with your permission).

During the interview, you will be asked to describe your experiences of managing your medicines, how you feel your GP and Community Pharmacist help you with your medicines, and how it could be made easier for you to manage your medicines. After the interview, the audio-recording will be typed up, word for word. You will not be identified in any typed record of the interview. We will use this information to develop a plan to help people with memory problems manage their medicines. Your GP 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.

What are the possible disadvantages and risks of taking part?

There is little risk in taking part in this study. It is possible that the discussion may make you think about upsetting aspects of your medicines and conditions for which you take your medicines. If you find this distressing, you may withdraw at 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 will be sent a letter to tell them that you became upset during the interview 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, the researcher would like to visit you at home to conduct the interview.

What are the benefits of taking part?

Taking part will give you an opportunity to tell us the difficulties you face in managing your medicines and how you feel medicines management may be improved for people with memory problems.

What will happen if I decide I 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 leave 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.

Who will have access to my information?

All information collected during the course of this study will be kept strictly confidential. Audio-recordings will be anonymous and your name will not appear in any publications. All data will be stored securely at the School of Pharmacy, Queen's University Belfast. At the end of the study the confidential records and files will be kept for 5 years and then destroyed. The confidential handling, storage and disposal of data are compliant with the Data Protection Act (1998). The research team will not have any access to your medical records. 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 Belfast may need to review information collected as part of the research.

If you mention something during the interview that suggests that you have been given the wrong treatment or that a healthcare 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. Otherwise your GP or Community Pharmacist will not be told about anything you talk about during the interview.

What will happen to the study results?

The findings from this study 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. Although quotes from the interviews may be included, no individual will be identified personally in any report or publication. You will be provided with a copy of the results at the end of the study.

Who is organising and funding the study?

The study is organised by the School of Pharmacy, Queen's University Belfast. It is funded by the HSC Public Health Agency in Northern Ireland and The Atlantic Philanthropies.

Who has reviewed the study?

This study has been reviewed and given a favourable opinion by the NRES Committee East of England – Norfolk (15/EE/0103). The project has been peer reviewed by independent reviewers on behalf of the Public Health Agency.

What happens if there is a problem?

If you are unhappy about any aspect of the study, or the way you have been approached or treated during the course of this study, please contact the Chief Investigator, Professor Carmel Hughes.

Further information

If you would like more information, would like this leaflet in a different format, or have any queries about the study, please feel free to contact the research team:

Dr. Heather Barry

Research Fellow

School of Pharmacy

Queen's University Belfast

97 Lisburn Road

Belfast, BT9 7BL

T: 028 9097 2348

E: H.Barry@qub.ac.uk

Professor Carmel Hughes

Chief Investigator

School of Pharmacy

Queen's University Belfast

97 Lisburn Road

Belfast, BT9 7BL

T: 028 9097 2147

E: c.hughes@qub.ac.uk

Thank you for considering taking part in this study

Appendix 15. GP invitation letter (v1, 27.02.2015)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

Date as postmark

Dear <Name of GP>,

Re: Development of an intervention to improve medicines management for people with dementia in primary care in Northern Ireland

We are writing to inform you that your patient <name> recently took part in the above study. A copy of their consent form is enclosed for your records.

We would also like to invite you take part in the study. The aim of the study is to develop and refine an intervention focusing on medicines management in people with dementia in primary care. As a component of this, we recognise that it is important to obtain the views of General Practitioners (GPs) involved in the prescribing of medicines for people with dementia. You have been approached to participate because you prescribe for people with dementia in your practice.

We have enclosed a copy of a Participant Information Sheet which provides details about what participating in this study would involve, and which hopefully should answer any questions you may have. The study will involve taking part in an interview with a researcher from Queen's University Belfast. The interview will take place at your place of work and would last approximately one hour. During this interview, you will be asked about your views of prescribing for people with dementia, your approach to prescribing for this patient population, and your perception of the barriers and facilitators to people with dementia appropriately managing their medicines in primary care. GP participants will be given £50 as a token of thanks for taking the time to be interviewed, and will receive a certificate of participation which can be added to your Continuing Professional Development portfolio.

This study is run by the School of Pharmacy, Queen’s University Belfast in collaboration with colleagues from: the School of Medicine, Dentistry and Biomedical Sciences, Queen’s University Belfast; the Institute for Ageing and Health, Newcastle University; the School of Psychology, National University of Ireland Galway; Altnagelvin Hospital and the Alzheimer’s Society. The study has received ethical approval from the NRES Committee East of England – Norfolk (15/EE/0103)

A Northern Ireland Clinical Research Network (Primary Care) Research Nurse will be in contact with you over the next week to discuss if you would like to participate. In the meantime, if you require further information, please do not hesitate to contact the researcher **Dr. Heather Barry** by telephone: **028 9097 2348** or by email: H.Barry@qub.ac.uk.

Yours Sincerely,

<Signature>

*Professor Carmel Hughes
Professor of Primary Care
Pharmacy*

<Signature>

*Professor Peter Passmore
Professor of Ageing & Geriatric
Medicine*

<Signature>

*Dr. Heather Barry
Research Fellow*

On behalf of the research team:

Dr. Cristín Ryan, Dr. Janine Cooper, Prof. Louise Robinson, Dr. Gerry Molloy, Ms. Carmel Darcy, Dr. Hilary Buchanan

Appendix 16. GP information sheet (v1, 27.02.2015)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

GP INFORMATION SHEET

Study title: Development of an intervention to improve medicines management for people with dementia in primary care in Northern Ireland

You are being invited to take part in a research study. Before you decide whether you would like to take part, please take the time to read the following information. It is important that you understand why this research is being completed and what you will be asked to do if you agree to participate. If there is anything that is unclear, or if you would like more information, please contact the research team (see below for details). All communication will be treated confidentially.

What is the purpose of this study?

People with dementia (PWD) are unique in terms of their medication needs compared with the general older population. Although they will also have co-morbid physical conditions and complex medication regimens, their impaired cognition and communication skills together with the presence of behavioural and psychological symptoms, generate additional challenges in medication adherence. Such challenges may influence doctors' prescribing behaviour and the quality of chronic illness management. There has been very limited research on medicines management in PWD, particularly those residing in primary care. We therefore aim to develop an intervention to improve medicines management for PWD in primary care. This intervention will incorporate the views of healthcare professionals involved in prescribing (GPs) and dispensing (Community Pharmacists) for these patients, together with patients' and their carers' views on medicines management. These data will be used, together with literature on prescribing interventions, to develop the intervention.

Why have I been chosen?

You have been approached to participate in this study because you are a GP who prescribes medicines for PWD.

Do I have to take part?

It is up to you to decide whether or not to take part in this study. If you decide not to participate we will respect your decision and will make no further attempts to contact you. If you do decide to take part, you will be asked to sign a consent form, and you will be given a copy of the consent form to keep. You are free to withdraw from the study at any stage without giving a reason.

What will happen to me if I take part?

A Northern Ireland Clinical Research Network (Primary Care) Research Nurse will contact you one week after you receive this information sheet to discuss if you might be interested in participating in the study and to answer any questions you may have. If you are interested in taking part, you will be asked to participate in an interview with a researcher. The interview will be conducted at a time and date to suit you, at your place of work. The interview will last approximately one hour (although this may vary between individuals) and will be audio-recorded (with your permission).

During the interview, you will be asked about your views of prescribing for PWD, your approach to prescribing for this patient population, and your perception of the barriers and facilitators to PWD appropriately managing their medicines in primary care. You will not be asked to provide any specific information about your patients. On completion of the interview, you will be offered a certificate of participation which could be added to your Continuing Professional Development (CPD) portfolio. You will also be offered an honorarium of £50 to compensate you for the time taken to participate in the study. After the interview, the audio-recording will be transcribed and analysed by the research team.

What are the possible disadvantages and risks of taking part?

There is a risk that participants may disclose poor practice during interviews. 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 which may involve informing the appropriate professional regulatory body.

What are the benefits of taking part?

Participation in this study may be beneficial for you, as it will ensure that any interventions developed from this work have involved those who firstly prescribe for PWD and those who will be implementing interventions in the future. This should, in the longer term, make any intervention effective and implementable. Furthermore, you will receive a certificate of participation, which could be used as part of your ongoing CPD.

What will happen if I decide I no longer wish to take part?

You are free to withdraw from the study at any time. If you decide to do so, the data collected prior to your withdrawal from the study may still be included in the final analysis.

Who will have access to my information?

All information collected during the course of this study will be kept strictly confidential. Interview transcripts will be anonymised and your name will not appear in any publications. All data will be stored securely at the School of Pharmacy, Queen's University Belfast. At the end of the study the confidential records and files will be kept for 5 years and then destroyed. The confidential handling, storage and disposal of data are compliant with the Data Protection Act (1998). 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 Belfast may need to review information collected as part of the research.

If you mention something during the interview that discloses poor practice, any cases will be reported to the Chief Investigator (Professor Carmel Hughes) who will take appropriate action on a case-by-case basis, which may involve referring it to the health professionals concerned and, if appropriate, to the appropriate regulatory authority (e.g. the General Medical Council).

What will happen to the study results?

The findings from this study will be used as part of a research project at Queen's University Belfast. Data may be published in academic journals and presented at conferences. Although quotes from the interviews may be included, no individual will be identified personally in any report or publication. You will be provided with a report of the results at the end of the study.

Who is organising and funding the study?

The study is organised by the School of Pharmacy, Queen's University Belfast. It is funded by the HSC Public Health Agency in Northern Ireland and The Atlantic Philanthropies.

Who has reviewed the study?

This study has been reviewed and given a favourable opinion by the NRES Committee East of England – Norfolk (15/EE/0103), and by Belfast Health and Social Care Trust Research Governance (15001CH-

SP). The project has been peer reviewed by independent reviewers on behalf of the Public Health Agency.

What happens if there is a problem?

If you are unhappy about any aspect of the study, or the way you have been approached or treated during the course of this study, please contact the Chief Investigator, Professor Carmel Hughes.

Further information

If you would like more information, would like this leaflet in a different format, or have any queries about the study, please feel free to contact the research team:

Dr. Heather Barry

Research Fellow

School of Pharmacy

Queen's University Belfast

97 Lisburn Road

Belfast, BT9 7BL

T: 028 9097 2348

E: H.Barry@qub.ac.uk

Professor Carmel Hughes

Chief Investigator

School of Pharmacy

Queen's University Belfast

97 Lisburn Road

Belfast, BT9 7BL

T: 028 9097 2147

E: c.hughes@qub.ac.uk

Thank you for considering taking part in this study

Appendix 17. Community pharmacist invitation letter (v1, 27.02.2015)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

Date as postmark

Dear <Name of Community Pharmacist>,

Re: Development of an intervention to improve medicines management for people with dementia in primary care in Northern Ireland

We are writing to invite you take part in the above named study. The aim of the study is to develop and refine an intervention focusing on medicines management in people with dementia in primary care. As a component of this, we recognise that it is important to obtain the views of healthcare professionals involved in the care of people with dementia. You have been approached to participate because you have been identified by a local General Practitioner (GP) as a Community Pharmacist who dispenses medicines for people with dementia. This GP has agreed to participate in the study.

We have enclosed a copy of a Participant Information Sheet which provides details about what participating in this study would involve, and which hopefully should answer any questions you may have. The study will involve taking part in an interview with a researcher from Queen's University Belfast. The interview will take place at your place of work and would last approximately one hour. During this interview, you will be asked about your views of prescribing and providing pharmaceutical care for people with dementia, your approach to dispensing of medicines for this patient population, and your perception of the barriers and facilitators to people with dementia appropriately managing their medicines in primary care. Community Pharmacist participants will be given £50 as a token of thanks for taking the time to be interviewed, and will receive a certificate of participation which can be added to your Continuing Professional Development portfolio.

This study is run by the School of Pharmacy, Queen's University Belfast in collaboration with colleagues from: the School of Medicine, Dentistry and Biomedical Sciences, Queen's University Belfast; the Institute for Ageing and Health, Newcastle University; the School of Psychology, National University

of Ireland Galway; Altnagelvin Hospital and the Alzheimer’s Society. The study has received ethical approval from the NRES Committee East of England – Norfolk (15/EE/0103).

The researcher will be in contact with you over the next week to discuss if you would like to participate. In the meantime, if you require further information, please do not hesitate to contact the researcher **Dr. Heather Barry** by telephone: **028 9097 2348** or by email: **H.Barry@qub.ac.uk**.

Yours Sincerely,

<Signature>

*Professor Carmel Hughes
Professor of Primary Care
Pharmacy*

<Signature>

*Professor Peter Passmore
Professor of Ageing & Geriatric
Medicine*

<Signature>

*Dr. Heather Barry
Research Fellow*

On behalf of the research team:

Dr. Cristín Ryan, Dr. Janine Cooper, Prof. Louise Robinson, Dr. Gerry Molloy, Ms. Carmel Darcy, Dr. Hilary Buchanan

Appendix 18. Community pharmacist information sheet (v1, 27.02.2015)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

COMMUNITY PHARMACIST INFORMATION SHEET

Study title: Development of an intervention to improve medicines management for people with dementia in primary care in Northern Ireland

You are being invited to take part in a research study. Before you decide whether you would like to take part, please take the time to read the following information. It is important that you understand why this research is being completed and what you will be asked to do if you agree to participate. If there is anything that is unclear, or if you would like more information, please contact the research team (see below for details). All communication will be treated confidentially.

What is the purpose of this study?

People with dementia (PWD) are unique in terms of their medication needs compared with the general older population. Although they will also have co-morbid physical conditions and complex medication regimens, their impaired cognition and communication skills together with the presence of behavioural and psychological symptoms, generate additional challenges in medication adherence. Such challenges may influence doctors' prescribing behaviour and the quality of chronic illness management. There has been very limited research on medicines management in PWD, particularly those residing in primary care. We therefore aim to develop an intervention to improve medicines management for PWD in primary care. This intervention will incorporate the views of healthcare professionals involved in prescribing (GPs) and dispensing (Community Pharmacists) for these patients, together with patients' and their carers' views on medicines management. These data will be used, together with literature on prescribing interventions, to develop the intervention.

Why have I been chosen?

You have been approached to participate in this study because you have been identified by a GP involved in the study as a Community Pharmacist who regularly dispenses medicines for PWD.

Do I have to take part?

It is up to you to decide whether or not to take part in this study. If you decide not to participate we will respect your decision and will make no further attempts to contact you. If you do decide to take part, you will be asked to sign a consent form, and you will be given a copy of the consent form to keep. You are free to withdraw from the study at any stage without giving a reason.

What will happen to me if I take part?

The researcher will contact you one week after you receive this information sheet to discuss if you might be interested in participating in the study and to answer any questions you may have. If you are interested in taking part, you will be asked to participate in an interview with the researcher. The interview will be conducted at a time and date to suit you, at your place of work. The interview will last approximately one hour (although this may vary between individuals) and will be audio-recorded (with your permission).

During the interview, you will be asked about your views of prescribing and providing pharmaceutical care for PWD, your approach to dispensing of medicines for this patient population, and your perception of the barriers and facilitators to PWD appropriately managing their medicines in primary care. On completion of the interview, you will be offered a certificate of participation which could be added to your Continuing Professional Development (CPD) portfolio. You will also be offered an honorarium of £50 to compensate you for the time taken to participate in the study. After the interview, the audio-recording will be transcribed and analysed by the research team.

What are the possible disadvantages and risks of taking part?

There is a risk that participants may disclose poor practice during interviews. 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 which may involve informing the appropriate professional regulatory body.

What are the benefits of taking part?

Participation in this study may be beneficial for you, as it will ensure that any interventions developed from this work have involved those who dispense and counsel PWD and their carers on dispensed medicines, and those who will be implementing interventions in the future. This should, in the longer term, make any intervention effective and implementable. Furthermore, you will receive a certificate of participation, which could be used as part of your ongoing CPD.

What will happen if I decide I no longer wish to take part?

You are free to withdraw from the study at any time. If you decide to do so, the data collected prior to your withdrawal from the study may still be included in the final analysis.

Who will have access to my information?

All information collected during the course of this study will be kept strictly confidential. Interview transcripts will be anonymised and your name will not appear in any publications. All data will be stored securely at the School of Pharmacy, Queen's University Belfast. At the end of the study the confidential records and files will be kept for 5 years and then destroyed. The confidential handling, storage and disposal of data are compliant with the Data Protection Act (1998). 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 Belfast may need to review information collected as part of the research.

If you mention something during the interview that discloses poor practice, any cases will be reported to the Chief Investigator (Professor Carmel Hughes) who will take appropriate action on a case-by-case basis, which may involve referring it to the health professionals concerned and, if appropriate, to the appropriate regulatory authority (e.g. the Pharmaceutical Society of Northern Ireland).

What will happen to the study results?

The findings from this study will be used as part of a research project at Queen's University Belfast. Data may be published in academic journals and presented at conferences. Although quotes from the interviews may be included, no individual will be identified personally in any report or publication. You will be provided with a report of the results at the end of the study.

Who is organising and funding the study?

The study is organised by the School of Pharmacy, Queen's University Belfast. It is funded by the HSC Public Health Agency in Northern Ireland and The Atlantic Philanthropies.

Who has reviewed the study?

This study has been reviewed and given a favourable opinion by the NRES Committee East of England – Norfolk (15/EE/0103), and by Belfast Health and Social Care Trust Research Governance (15001CH-SP). The project has been peer reviewed by independent reviewers on behalf of the Public Health Agency.

What happens if there is a problem?

If you are unhappy about any aspect of the study, or the way you have been approached or treated during the course of this study, please contact the Chief Investigator, Professor Carmel Hughes.

Further information

If you would like more information, would like this leaflet in a different format, or have any queries about the study, please feel free to contact the research team:

Dr. Heather Barry

Research Fellow

School of Pharmacy

Queen's University Belfast

97 Lisburn Road

Belfast, BT9 7BL

T: 028 9097 2348

E: H.Barry@qub.ac.uk

Professor Carmel Hughes

Chief Investigator

School of Pharmacy

Queen's University Belfast

97 Lisburn Road

Belfast, BT9 7BL

T: 028 9097 2147

E: c.hughes@qub.ac.uk

Thank you for considering taking part in this study

Appendix 19. Patient consent form (v1, 27.02.2015)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

Participant Study ID: _____

PATIENT CONSENT FORM

Study title: Development of an intervention to improve medicines management for people with memory problems in primary care in Northern Ireland

Please initial box

1. I confirm that I have read (or had read to me) and understood the information sheet dated <date> (<version number>) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and that this will not affect my legal rights or medical care.
3. I agree to this interview being audio-recorded.
4. I understand that quotes from the interview may be reproduced in reports and papers, but that confidentiality and anonymity will be maintained and it will not be possible to identify me from any publications.
5. I understand that what is discussed during the interview is confidential with the exception that if I disclose information that indicates poor practice by a healthcare professional, the researcher is legally obliged to pass on this information to the Chief Investigator who may refer it to the appropriate regulatory authority.
6. I agree to my GP being informed that I am taking part in this study and to my GP being informed if I become upset or distressed during the study.

7. I understand that my personal information (including consent forms) will be held securely in the School of Pharmacy, Queen's University Belfast and handled in accordance with the provisions of the Data Protection Act 1998.
8. I understand that data collected during the study may be looked at by authorised individuals from Queen's University Belfast and from regulatory authorities, for auditing purposes. I give permission for these individuals to have access to this information.
9. I agree to take part in the above study.

_____	_____	_____
Name of Participant (Please print)	Date	Signature
_____	_____	_____
Name of Researcher (Please print)	Date	Signature

When completed: one copy for participant and one copy for researcher

Appendix 20. Carer consent form (v1, 27.02.2015)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

Participant Study ID: _____

CARER CONSENT FORM

Study title: Development of an intervention to improve medicines management for people with memory problems in primary care in Northern Ireland

Please initial box

1. I confirm that I have read (or had read to me) and understood the information sheet dated <date> (<version number>) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and that this will not affect my legal rights.
3. I agree to this interview being audio-recorded.
4. I understand that quotes from the interview may be reproduced in reports and papers, but that confidentiality and anonymity will be maintained and it will not be possible to identify me from any publications.
5. I understand that what is discussed during the interview is confidential with the exception that if I disclose information that indicates poor practice by a healthcare professional, the researcher is legally obliged to pass on this information to the Chief Investigator who may refer it to the appropriate regulatory authority.

6. I understand that my personal information (including consent forms) will be held securely in the School of Pharmacy, Queen's University Belfast and handled in accordance with the provisions of the Data Protection Act 1998.

7. I understand that data collected during the study may be looked at by authorised individuals from Queen's University Belfast and from regulatory authorities, for auditing purposes. I give permission for these individuals to have access to this information.

8. I agree to take part in the above study.

Name of Participant Date Signature
(Please print)

Name of Researcher Date Signature
(Please print)

When completed: one copy for participant and one copy for researcher

Appendix 21. Healthcare professional consent form (v1, 27.02.2015)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

Participant Study ID: _____

HEALTHCARE PROFESSIONAL CONSENT FORM

Study title: Development of an intervention to improve medicines management for persons with dementia in primary care in Northern Ireland

Please initial box

1. I confirm that I have read and understood the information sheet dated <date> (<version number>) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and that this will not affect my legal rights.
3. I agree to this interview being audio-recorded.
4. I understand that quotes from the interview may be reproduced in reports and papers, but that confidentiality and anonymity will be maintained and it will not be possible to identify me from any publications.
5. I understand that what is discussed during the interview is confidential with the exception that if I disclose information that indicates poor professional practice, the researcher is legally obliged to pass on this information to the Chief Investigator who may refer it to the appropriate regulatory authority.
6. I understand that my personal information (including consent forms) will be held securely in the School of Pharmacy, Queen's University Belfast and handled in accordance with the provisions of the Data Protection Act 1998.

7. I understand that data collected during the study may be looked at by authorised individuals from Queen’s University Belfast and from regulatory authorities, for auditing purposes. I give permission for these individuals to have access to this information.

8. I agree to take part in the above study.

Name of Participant Date Signature
(Please print)

Name of Researcher Date Signature
(Please print)

When completed: one copy for participant and one copy for researcher

Appendix 22. Assessment of capacity checklist (v1, 27.02.2015)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

Participant Study ID: _____

ASSESSMENT OF PATIENT CAPACITY CHECKLIST

Study title: Development of an intervention to improve medicines management for people with memory problems in primary care in Northern Ireland

- | | Yes/No |
|--|--------|
| 1. Does the patient understand that they can consent to or refuse to participate in the study? | |
| 2. Does the patient understand what the research is about? | |
| 3. Does the patient understand and weigh-up the benefits and risks of agreeing or refusing to take part? | |
| 4. Has the patient communicated their decision to you in any way? | |

If the answer is YES to each of these items, then the patient is judged to have the capacity to consent to or refuse to take part in the study. If they wish to participate proceed with taking informed consent.

If the answer is NO to items 1-3 above, then the patient is judged NOT to have the capacity to consent to or to refuse to take part in the study.

Checklist completed by: _____

Date: _____

**Appendix 23. Healthcare professional certificate of participation (v1,
27.02.2015)**



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

Certificate of participation

For

Title of event: Interview to development of an intervention to improve
medicines management for persons with dementia in primary care in Northern
Ireland

Date of event: _____

Name of individual: _____

I hereby certify that the individual named above attended this event.

Signed: _____

Event organiser: Professor Carmel Hughes, Professor of Primary Care
Pharmacy, Queen's University Belfast

Date: _____

Appendix 24. Patient topic guide



PATIENT INTERVIEW TOPIC GUIDE

Development of an intervention to improve medicines management for people with memory problems in primary care in Northern Ireland

Introduction

"My name is <researcher name>, and I am a researcher from the School of Pharmacy, Queen's University Belfast. Thank you very much for making the time to speak with me today.

In this research project we are interested in finding out what medicines people with memory problems are taking, and how they manage those medicines. In the first part of the project we looked at the types of prescriptions received by patients in Northern Ireland during the year 2013. Now we are speaking to patients with memory problems and their carers (if this applies) to explore their views and experiences of their medicines in more detail. We are also speaking to GPs and community pharmacists as they are responsible for prescribing and dispensing medicines, and may have different views and experiences to patients and their carers. We plan to use all of the information we gather during this study to see if we can come up with a way to improve the use of medicines for people with memory problems which we will then test in the final part of the project.

Have you had a chance to read through the information sheet that was sent out to you? Are there any questions that you would like to ask me?"

Explaining what will happen in the interview and afterwards

"This is your opportunity to share your views about your medicines, how you manage them, and any difficulties you have in managing them. The interview should last approximately <estimated duration> minutes.

I will be recording the interview on a digital recorder, to ensure that we have an accurate and detailed record of what you say. The recording will be saved on a password-protected computer and only those immediately involved in the research study will listen to them. The recording will be typed up word-for-word and any names, locations, or anything else that could identify you or anyone you talk about will be removed so that the information is anonymous. After we have conducted interviews with all of the other participants we will analyse the information within the research team.

After the interview today I will write to your GP to let them know you have taken part in the study, and I will send them a copy of your consent form for their records. They will also be invited to participate in an interview about their views about their medicines, but this interview will have nothing to do with you and your name will not be mentioned.

You are free to stop the interview and/or recording at any point. If there are any questions that you would prefer not to answer, just let me know and we can move on to the next question.

Before we start I need to get written consent from you that you understand what the study involves; anything you say will be kept completely confidential; you will not be identified in any way; we can stop the interview at any time; and also that you are happy for the interview to be recorded. If you wouldn't mind, can you read through the consent form and initial each box to indicate that you understand and agree with each statement? There are two copies: you will keep one of them and I will keep the other for our records.

Have you any immediate questions about the study before we start the interview?"

[Turn the digital recorder on]

Demographic information

- Approximately, how many medicines do you take every day? [Ask to see a copy of patient's medication repeat list/medication if they are unable to provide this information.]
- In a typical month, approximately:
 - How many times would you be in contact with your GP (either face-to-face or over the telephone)?
 - How many times would you be in contact with your community pharmacist (either face-to-face or over the telephone)?

Behavioural elicitation

"Before we begin it would be useful if you can think about all the medications you are currently being prescribed and have been taking recently. Over the few questions I will be asking you to think about getting prescriptions from your doctor, getting medicines from your pharmacist, taking your medicines, and about any difficulties you may be having with your medicines."

Social/professional role and identity

- What do you think your responsibility is/responsibilities are in relation to your medicines?

- **Prompt:** Is there anything apart from these things that you should be responsible for?
- **Prompt:** Is there anything else about your medicines that you think others are responsible for?

Knowledge

- What do you know about your medicines?
 - **Prompt:** Knowledge of medicines
 - Do you know what each medicine is for?
 - Do you know how to take them?
 - Do you know about the possible side-effects of your medicines?
 - **Prompt:** Knowledge of the sources of support available to them and how to access these
 - For example, your GP, community pharmacist, hospital consultant, practice nurses

Skills

- Do you know how to get prescriptions from your doctor/ get medicines from your pharmacist/ take your medicines as advised?
 - **Prompt:** Are you able to get prescriptions from your doctor/ get medicines from your pharmacist/ take your medicines by yourself? If not, why not?
- What would be helpful to you to improve your ability to get/take your medicines in the future?

Beliefs about capabilities

- In what situations do you feel confident about getting/taking your medicines?
- In what situations do you **not** feel confident about getting/taking your medicines?
 - **Prompt:** What would help you to overcome these problems or difficulties?

Optimism

- How optimistic are you that you can overcome any problems with your medicines?
- What would make you feel less optimistic about overcoming any problems with your medicines?

Beliefs about consequences

- What do you think are the benefits of taking your medicines as prescribed?
 - **Prompts:** For yourself; carer; relatives; other patients; short- and long-term consequences
 - **Prompt:** Have you directly experienced any of these benefits?
- Can you think of any disadvantages to taking your medicines as prescribed?
- Are the benefits of taking all of your medicines worth the possible disadvantages?

Reinforcement

- What would encourage you to take your medicines?
 - **Prompts:** Is there anything that would encourage you to take your medicines??
- What would discourage you from taking your medicines?
 - **Prompts:** Side effects

Intentions

- Do you intend to get prescriptions from your doctor/ get medicines from your pharmacist/ take your medicines as prescribed?
- What would prevent you from getting prescriptions from your doctor/ get medicines from your pharmacist/ take your medicines as prescribed?

Goals

- To what extent is taking your medicines a priority for **you**?
- In what circumstances would **you** think it was less important to take your medicines?

Memory, attention and decision processes

- In this question I am interested to know how you remember to take your medicines. Do you have any reminders, prompts or routines?
 - **Prompt:** What is your usual routine? Is there something that/someone who helps you to remember to take your medicines?
- Are there any circumstances in which you might just forget or find it difficult to take your medicines?

Environmental context and resources

- What things would help you to take your medicines?
 - **Prompt:** Compliance aid; notes; other reminders
- What things might prevent you from taking your medicines?
 - **Prompt:** Home environment; being away from home

Social influences

- Who would influence your decisions to take your medicines?
 - **Prompts:** Carers or relatives; GP; community pharmacist; hospital consultant; other healthcare professionals
- Can you tell me more about how they influence/help you?

Emotion

- How does taking your medicines make you feel?
 - **Prompt:** For example, does it make you feel happy/sad/anxious? Is it a source of conflict between you and anyone else?
- (Depending upon how the patient responds) How does that influence your decision to take your medicines?

Behavioural regulation

- Do you have something in place that could help you check whether or not you have taken your medicines?
 - **Prompt:** For example, a diary, calendar, dosette box
- Can you tell me more about how this works for you?

Future planning

“The research team is interested in developing a plan to support and try to help patients with memory problems and their carers with medicines. It has been useful to hear about your experiences in more detail as this will help us to try and understand what patients and carers are struggling with when it comes to medicines, and therefore what aspects we should target as part of our approach to improve the use of medicines in the future.”

- If you were to think about the way in which your regular medicines are currently prescribed by the **GP**, can you tell me:
 - What works well with that process/system?
 - What could be done differently to 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:
 - What works well with that process/system?
 - 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, how would you feel about this?
 - What would you like to see happen as a result?

Closing the interview

“That brings us to the end of the interview.

Is there anything else about your medicines that we should have talked about, but didn’t?

Do you have any additional comments you would like to make?

Thank you very much for making the time to speak with me today.”

[Turn the digital recorder off]

Appendix 25. Carer topic guide



CARER INTERVIEW TOPIC GUIDE

Development of an intervention to improve medicines management for people with memory problems in primary care in Northern Ireland

Introduction

"My name is <researcher name>, and I am a researcher from the School of Pharmacy, Queen's University Belfast. Thank you very much for making the time to speak with me today.

In this research project we are interested to find out what medicines people with memory problems are taking, and how they manage those medicines. In the first part of the project we looked at the types of prescriptions received by patients in Northern Ireland during the year 2013. Now we are speaking to people with memory problems and their carers to explore their views and experiences with medicines in more detail. We are also speaking to GPs and community pharmacists as they are responsible for prescribing and dispensing medicines and may have different views and experiences to patients and their carers. We plan to use all of the information we gather during this study to see if we can come up with a way to improve the use of medicines for people with memory problems which we will then test in the final part of the project.

Have you had a chance to read through the information sheet that was sent out to you? Are there any questions that you would like to ask me?"

Explaining what will happen in the interview and afterwards

"This is your opportunity to share your views about the medicines that [patient name] is taking, how you help to manage them, and any difficulties you face in managing them. The interview should last approximately <estimated duration> minutes.

I will be recording the interview on a digital recorder, to ensure that we have an accurate and detailed record of what you say. The recording will be saved on a password-protected computer and only those immediately involved in the research study will listen to them. The recording will be typed up word-for-word and any names, locations, or anything else that could identify you or anyone you talk about will be removed so that the information is anonymous. After we have conducted interviews with all of the other participants we will analyse the information within the research team.

After the interview, I will write to [patient name]’s GP to let them know [patient name] has taken part in the study, and their GP will be invited to participate in an interview that will have nothing to do with you or the patient, and your name and the patient’s name will not be mentioned.

You are free to stop the interview and/or recording at any point. If there are any questions that you would prefer not to answer, just let me know and we can move on to the next question.

Before we start I need to get written consent from you that you understand what the study involves; anything you say will be kept completely confidential; you will not be identified in any way; we can stop the interview at any time; and also that you are happy for the interview to be recorded. If you wouldn’t mind, can you read through the consent form and initial each box to indicate that you understand and agree with each statement? There are two copies: you will keep one of them and I will keep the other for our records.

Have you any immediate questions about the study before we start the interview?”

[Turn the digital recorder on]

Demographic information

- Approximately, how many medicines does [patient name] take every day?
[Ask to see a copy of patient’s medication repeat list/medication if they are unable to provide this information]
- In a typical month, approximately:
 - How many times would you be in contact with the patient’s GP (either face-to-face or over the telephone)?
 - How many times would you be in contact with the patient’s community pharmacist (either face-to-face or over the telephone)?

Behavioural elicitation

“Before we begin it would be useful if you can think about all the medications [patient name] is currently being prescribed and has been taking recently. Over the next series of questions I will be asking you to think about getting prescriptions from the patient’s doctor, getting medicines for the patient from the pharmacist, the patient taking their medicines, and about any difficulties the patient may be having with their medicines.”

Social/professional role and identity

- What do you think your responsibility is/responsibilities are in relation to [patient name]'s medicines?
 - **Prompt:** Is there anything apart from these things that you should be responsible for?
 - **Prompt:** Is there anything else about [patient name]'s medicines that you think others are responsible for?

Knowledge

- What do you know about [patient name]'s medicines?
 - **Prompt:** Do you know what each medicine is for?
 - **Prompt:** Do you know how they should be taken?
 - **Prompt:** Do you know about the possible side-effects of each medicine?
 - **Prompt:** Knowledge of the sources of support available to them and how to access these
 - E.g. GP, community pharmacist, hospital consultant, practice nurses

Skills

- Do you know how to get [patient name]'s prescriptions from the doctor/[patient name]'s medicines from the pharmacist/ how [patient name] should take their medicines as advised?
 - **Prompt:** Are you able to get prescriptions from the patient's doctor/ get medicines from the patient's pharmacist/ support the patient to take their medicines as prescribed? If not, why not?
- What would be helpful to you to improve your ability to get [patient name]'s medicines/get [patient name] to take their medicines in the future?

Beliefs about capabilities

- In what situations do you feel confident about [patient name] getting/taking their medicines?
- In what situations do you **not** feel confident about [patient name] getting/taking their medicines?
 - **Prompt:** What would help you overcome these problems/difficulties?

Optimism

- How optimistic are you that you can overcome any problems with [patient name]'s medicines?
- What would make you feel less optimistic about overcoming any problems with [patient name]'s medicines?

Beliefs about consequences

- What do you think are the benefits of [patient name] taking their medicines as prescribed?

- **Prompt:** For the patient; carer; relatives; other patients; short- and long-term consequences
- Can you think of any disadvantages to [patient name] taking their medicines as prescribed?
- Are the benefits of [patient name] taking all of their medicines worth the possible disadvantages?

Reinforcement

- What would encourage you to get [patient name] to take their medicines?
 - **Prompt:** Is there anything that would encourage you to get [patient name] to take their medicines?
- What would discourage you from getting [patient name] to take their medicines?
 - **Prompt:** For example, medication side-effects

Intentions

- Do you intend to get [patient name] to take their medicines as prescribed?
- What would prevent you from getting [patient name] to take their medicines?
 - **Prompt:** Can you tell me why?

Goals

- To what extent is it a priority to **you** that [patient name] takes their medicines?
- In what circumstances would **you** think it was less important that [patient name] takes their medicines?

Memory, attention and decision processes

- In this question I am interested to know how you remember to get [patient name] to take their medicines. Do you have any reminders, prompts or routines?
 - **Prompt:** What is your usual routine? Is there something that/ someone who helps you to remember to get [patient name] to take their medicines?
- Are there any circumstances in which you might just forget or find it difficult to get [patient name] to take their medicines?

Environmental context and resources

- What things would help you to get [patient name] to take their medicines?
 - **Prompt:** Compliance aid; notes; other reminders
- What things might prevent you from getting [patient name] to take their medicines?
 - **Prompt:** Home environment; being away from home

Social influences

- Who would influence your decision to get [patient name] to take their medicines?
 - **Prompt:** Other relatives; patient's GP; community pharmacist; hospital consultant; other healthcare professional
- Can you tell me more about how they influence/help you?

Emotion

- How does [patient name] taking their medicines make you feel?
 - **Prompt:** For example, does it make you feel happy/sad/anxious? Is it a source of conflict between you and anyone else?
- (Depending upon how the carer responds) How does that influence your decision to get [patient name] to take their medicines?

Behavioural regulation

- Do you have something in place that could check whether or not [patient name] has taken their medicines?
 - **Prompt:** For example, a diary, calendar, dosette box
- Can you tell me more about how this works for you?

Future planning

"The research team is interested in developing a plan to support and try to improve the use of medicines for patients with memory problems and their carers. It has been useful to hear about your experiences in more detail as this will help us to try and understand what patients and their carers have difficulty with when it comes to medicines, and therefore what aspects we should target as part of our approach to improve the use of medicines in the future."

- If you were to think about the way in which [patient name]'s regular medicines are currently prescribed by their **GP**, can you tell me:
 - What works well with that process/system?
 - What could be done differently to make things better?
- And then if you were to think about the way in which [patient name]'s regular medicines are currently dispensed by the **community pharmacist**, can you tell me:
 - What works well with that process/system?
 - What could be done differently to make things better?

- If [patient name]'s GP or community pharmacist arranged to sit down with you and/or [patient name] and go through all the medicines that [patient name] is taking, how would you feel about this?
 - What would you like to see happen as a result?

Closing the interview

“That brings us to the end of the interview.

Is there anything else about the patient's medicines that we should have talked about, but didn't?

Do you have any additional comments you would like to make?

Thank you very much for making the time to speak with me today.”

[Turn the digital recorder off]

Appendix 26. GP topic guide



GP INTERVIEW TOPIC GUIDE

Development of an intervention to improve medicines management for people with dementia in primary care in Northern Ireland

Introduction

“My name is Heather Barry, and I am a researcher from the School of Pharmacy, Queen’s University Belfast. Thank you very much for making the time to speak with me today.

In this research project we are interested in finding out what medicines people with dementia are taking, and how they manage those medicines. In the first part of this project we analysed prescriptions received by patients in Northern Ireland during the year 2013, using prescribing data from the Business Services Organisation. We used a set of prescribing criteria to explore the appropriateness of prescribing for these patients. Now we are speaking to patients with dementia and their carers to explore their views and experiences of medicines management in more detail. We are also interviewing GPs and community pharmacists as they are responsible for prescribing and dispensing medicines for this patient population, and may have different views and experiences to patients and their carers. We plan to use all of the information we gather during this study to see if we can develop an intervention to improve medicines management for people with dementia, which will be tested for feasibility in the final part of the project.

Have you had a chance to read through the information sheet that was sent out to you? Are there any questions that you would like to ask me before we start?”

Explaining what will happen in the interview and afterwards

“The aim of this interview is to explore your views of medicines management in people with dementia, your approach to prescribing for this patient population, and your perceptions of the barriers and facilitators to successful medicines management for people with dementia in primary care. I’d like to focus specifically on people with dementia living within the community as opposed to those in nursing or residential care home settings. The interview should last approximately <estimated duration> minutes.

I will be recording the interview on a digital recorder, to ensure that we have an accurate and detailed record of what you say. The recording will be saved on a password-protected computer and only those immediately involved in the research study will listen to them. The recording will be typed up word-for-word and any names, locations, or anything else that could identify you will be removed so that the information is anonymous. After we have conducted interviews with all of the other participants we will analyse the information within the research team.

You are free to stop the interview and/or recording at any point. If there are any questions that you would prefer not to answer, just let me know and we can move on to the next question.

Before we start I need to get written consent from you that you understand what the study involves; anything you say will be kept completely confidential; you will not be identified in any way; we can stop the interview at any time; and also that you are happy for the interview to be recorded. If you wouldn't mind, can you read through the consent form and initial each box to indicate that you understand and agree with each statement? There are two copies: you will keep one of them and I will keep the other for our records.

Have you any immediate questions about the study before we start the interview?"

[Turn the digital recorder on]

Demographic information

- Can you tell me how long you have been practising as a GP?
- Have you completed any additional training (either formal or self-directed) in dementia?
- Approximately, what proportion of the patients in this practice have a diagnosis of dementia?
- On a typical working day in your practice, approximately:
 - How many dementia patients would you encounter (e.g. through face-to-face or over the telephone consultations)?
 - How many carers of dementia patients would you encounter?
- Approximately what proportion of your overall prescribing is for patients with dementia?
- What would be the average number of items regularly prescribed per dementia patient?

Definitions

"There is no widely-accepted definition of medicines management, although the term is often used. For the purpose of this project, we are adopting a definition of medicines management used by the Audit Commission (2001) which states that:

[Hand interview participant a card with definition printed on it]

'Medicines management encompasses the entire way that medicines are selected, procured, delivered, prescribed, administered, and reviewed to optimise the contribution that they make to producing informed and desired outcomes of patient care'

In short, the essential components of medicines management are prescribing, dispensing, administration, adherence, and medication review. The cornerstone of medicines management is ensuring that patients gain maximum benefit from their medicines, whilst also minimising the risk of harm."

Social/professional role and identity

- Thinking about medicines management for patients with dementia, what would you consider your contribution/responsibilities to be as a GP in ensuring that patients with dementia and their carers are able to manage medicines appropriately and effectively?*
- **Prompt:** Is there anything that you would consider to be beyond your contribution/ responsibility as a GP (in ensuring that patients with dementia and their carers can manage their medicines appropriately and effectively)?
- **Prompt:** Who do you think is responsible for these aspects beyond your contribution/responsibility?

***Note:** The participant's answer to this question will determine how subsequent questions are asked/worded (see below for sections shaded in grey)

Behavioural elicitation

"It would be helpful if you can think of a situation where you have prescribed medication and been responsible for the subsequent management of a patient with dementia. You may also have dealt with the patient's carer. For the rest of the questions I ask you, it might be useful to keep this example in mind. If you can't think of a specific situation, don't worry, just think about medicines management for patients with dementia in general terms using the definition I've given you."

Knowledge

- What knowledge do you think you need as a GP when <prescribing medicines for/ assessing adherence of/ conducting medication reviews in> patients with dementia?
 - **Prompt:** Clinical knowledge?
 - Specific knowledge sources/resources

- Is there anything specifically relating to prescribing/adherence/medication review in patients with dementia?
- **Prompt:** Knowledge of the patient's clinical picture
- **Prompt:** Knowledge of guidelines (specific to dementia)?
 - What guidelines?
 - What do such guidelines recommend?
- **Prompt:** Personal knowledge/experience of dementia?
 - What effect does this have on your clinical practice?

Skills

- What skills do you have as a GP to assist you when <prescribing medicines for/ assessing adherence of/ conducting medication reviews in> patients with dementia and dealing with any issues that may arise with <prescribing/ adherence/ medication review> in such patients?
 - **Prompt:** What skills do you have that would help you to engage with patients or their carers?
 - **Prompt:** What skills do you have that would help you to engage with other healthcare professionals?
- Is there any specific training which you feel would be helpful to you in order to improve <prescribing/ adherence/ medication review> for patients with dementia in the future?

Beliefs about capabilities

- In what situations do you feel confident about <prescribing medicines for/ assessing adherence of/ conducting medication reviews in> patients with dementia?
- In what situations do you **not** feel confident about <prescribing medicines for/ assessing adherence of/ conducting medication reviews in> patients with dementia?
 - **Prompt:** What would help you to overcome these problems or difficulties?

Optimism

- How optimistic are you that appropriate <prescribing/ adherence/ medication review> can be achieved for patients with dementia?
- What would make you feel less optimistic that appropriate <prescribing/ adherence/ medication review> can be achieved for patients with dementia?

Beliefs about consequences

- What do you think are the benefits of appropriate <prescribing/ adherence/ medication review> for patients with dementia?
 - **Prompt:** For patients; their carers; yourself; NHS; short and long-term consequences

- What do you think are the risks associated with inappropriate <prescribing/ adherence/ medication review> for patients with dementia?

Reinforcement

- What would encourage you to ensure <prescribing/ adherence/ medication review> is appropriate for patients with dementia?
 - **Prompt:** Are there any rewards or incentives for you or the practice, e.g. QOF, personal rewards, professional recognition?
- What would discourage you from improving <prescribing/ adherence/ medication review> for patients with dementia?

Intentions

- How do you plan (intend) to address issues with <prescribing/ adherence/ medication review> for patients with dementia?
- What would prevent you from addressing issues with <prescribing/ adherence/ medication review> for patients with dementia?

Goals

- To what extent is improving <prescribing/adherence/medication review/educating or counselling> for patients with dementia a priority for you?
 - If low/high priority, why?
- In what circumstances would you think it was less important to make any changes to <prescribing/ adherence/ medication review> for patients with dementia?

Memory, attention and decision processes

- How would you usually remember to address issues with <prescribing/ adherence/ medication review> for patients with dementia?
 - **Prompt:** For example, if there was an issue with patient adherence/ prescribing antipsychotic medications/ patient increasingly struggling with medicines but living alone?
- Are there any circumstances in which you might just forget or find it difficult to resolve these issues?
 - **Prompt:** How would you describe the complexity of decision-making in <prescribing/ adherence/ medication review> for patients with dementia?

Environmental context and resources

- What resources or support might help you to intervene when you encounter issues with <prescribing/ adherence/ medication review> in patients with dementia?
- What factors might prevent you from intervening when you encounter issues with <prescribing/ adherence/ medication review> in patients with dementia?
 - **Prompt:** Work environment and culture within practice; material resources available; critical incidents/events within the practice

Social influences

- Who would influence your decisions about dealing with issues with <prescribing/ adherence/ medication review> for patients with dementia?
 - **Prompt:** Patients; carers or relatives; community pharmacist; hospital consultant; colleagues within the practice/surgery; other healthcare professionals
 - **Prompt:** Can you tell me more about how this happens and what their influence is?

Emotion

- How does <prescribing/ supporting adherence/ performing medication review> for patients with dementia make you feel?
- How would your own work stress or emotional engagement with a patient and their carer influence your decisions to attempt to resolve issues with <prescribing/ adherence/ medication review> for patients with dementia?

Behavioural regulation

- Having decided the best course of action to resolve <prescribing/ adherence/ medication review> issues for a patient with dementia, are there any ways in which you can monitor whether or not it has been done?
 - **Prompt:** Following clinical guidelines or workplace protocols
- What strategies would you use to overcome these circumstances?

Intervention components

“The research team is interested in developing an intervention to support and improve medicines management for people with dementia and their carers. From reviewing the literature, we have found that interventions can be complex and often involve a number of different components. This makes it difficult to identify which components are the most important in terms of improving patient outcomes and achieving adequate medicines management.”

- What would you consider to be important components of an intervention to improve medicines management for people with dementia and their carers in primary care?
 - **Prompt:** Who should be involved in delivering these types of interventions in practice (e.g. carers, community pharmacists, GPs, practice nurses, voluntary sector)?
 - **Prompt:** What would each person/healthcare professional have to do?
 - **Prompt:** What are your thoughts on patient involvement in interventions – should patients be actively involved in the decisions about the medicines they are prescribed?
- What would be the facilitators to putting the type of intervention that you have described into practice?
- What would be the barriers to putting the type of intervention that you have described into practice?
- What would help the implementation of the intervention?
- What do you think should be measured as an outcome in an intervention study to support medicines management for people with dementia, i.e. how would you, personally, be persuaded that the intervention had improved medicines management? What are the important outcomes?

Closing the interview

“That brings us to the end of the interview.

Is there anything else about medicines management in people with dementia that you feel has not been covered?

Do you have any additional comments you would like to make as to the content of the interview or how it went?

Thank you very much for making the time to speak with me today.”

[Turn the digital recorder off]

Appendix 27. Community pharmacist topic guide



COMMUNITY PHARMACIST INTERVIEW TOPIC GUIDE

Development of an intervention to improve medicines management for people with dementia in primary care in Northern Ireland

Introduction

“My name is Heather Barry, and I am a researcher from the School of Pharmacy, Queen’s University Belfast. Thank you very much for making the time to speak with me today.

In this research project we are interested in finding out what medicines people with dementia are taking, and how they manage those medicines. In the first part of this project we analysed prescriptions received by patients in Northern Ireland during the year 2013, using prescribing data from the Business Services Organisation. We used a set of prescribing criteria to explore the appropriateness of prescribing for these patients. Now we are speaking to patients with dementia and their carers to explore their views and experiences of medicines management in more detail. We are also interviewing GPs and community pharmacists as they are responsible for prescribing and dispensing medicines for this patient population, and may have different views and experiences to patients and their carers. We plan to use all of the information we gather during this study to see if we can develop an intervention to improve medicines management for people with dementia, which will be tested for feasibility in the final part of the project.

Have you had a chance to read through the information sheet that was sent out to you? Are there any questions that you would like to ask me before we start?”

Explaining what will happen in the interview and afterwards

“The aim of this interview is to explore your views of medicines management in people with dementia, your approach to dispensing medication for this patient population, and your perceptions of the barriers and facilitators to successful medicines management for people with dementia in primary care. I’d like to focus specifically on people with dementia living within the community as opposed to those in nursing or residential care home settings. The interview should last approximately <estimated duration> minutes.

I will be recording the interview on a digital recorder, to ensure that we have an accurate and detailed record of what you say. The recording will be saved on a password-protected computer and only those immediately involved in the research study will listen to them. The recording will be typed up word-for-word and any names, locations, or anything else that could identify you will be removed so that the information is anonymous. After we have conducted interviews with all of the other participants we will analyse the information within the research team.

You are free to stop the interview and/or recording at any point. If there are any questions that you would prefer not to answer, just let me know and we can move on to the next question.

Before we start I need to get written consent from you that you understand what the study involves; anything you say will be kept completely confidential; you will not be identified in any way; we can stop the interview at any time; and also that you are happy for the interview to be recorded. If you wouldn't mind, can you read through the consent form and initial each box to indicate that you understand and agree with each statement? There are two copies: you will keep one of them and I will keep the other for our records.

Have you any immediate questions about the study before we start the interview?"

[Turn the digital recorder on]

Demographic information

- Can you tell me how long you have been practising as a community pharmacist?
- Do you hold any additional clinical qualifications, such as a certificate in non-medical prescribing?
- Have you completed any additional training (either formal or self-directed) in dementia?
- Approximately, what proportion of the patients who visit this pharmacy have dementia?
- On a typical working day in your pharmacy, approximately:
 - How many dementia patients would you encounter (e.g. face-to-face or over the telephone)?
 - How many carers of dementia patients would you encounter?
- Approximately what proportion of your overall dispensing activity is for people with dementia?
- What would be the average number of dispensed items per dementia patient?

Definitions

"There is no widely-accepted definition of medicines management, although the term is often used. For the purpose of the project, we are adopting a definition of medicines management used by the Audit Commission (2001) which states that:

[Hand interview participant a card with definition printed on it]

‘Medicines management encompasses the entire way that medicines are selected, procured, delivered, prescribed, administered, and reviewed to optimise the contribution that they make to producing informed and desired outcomes of patient care’

In short, the essential components of medicines management are prescribing, dispensing, administration, adherence, and medication review. The cornerstone of medicines management is ensuring that patients gain maximum benefit from their medicines, whilst also minimising the risk of harm”

Social/professional role and identity

- Thinking about medicines management for patients with dementia, what would you consider your contribution/responsibilities to be as a community pharmacist in ensuring that patients with dementia and their carers are able to manage medicines appropriately and effectively?*
- **Prompt:** Is there anything that you would consider to be beyond your contribution/responsibility as a community pharmacist (in ensuring that patients with dementia and their carers can manage their medicines appropriately and effectively)?
- **Prompt:** Who do you think is responsible for these aspects beyond your contribution/responsibility?

***Note:** The participant’s answer to this question will determine how subsequent questions are asked/worded (see below for sections shaded in grey)

Behavioural Elicitation

“It would be helpful if you can think of a situation where you have dispensed medication and been responsible for the subsequent pharmaceutical care of a patient with dementia. You may also have dealt with the patient’s carer. For the rest of the questions I ask you, it might be useful to keep this example in mind. If you can’t think of a specific situation, don’t worry, just think about medicines management for patients with dementia in general terms using the definition I’ve given you.”

Knowledge

- What knowledge do you think you need as a community pharmacist when <dispensing medicines for/ assessing adherence of/ conducting medication reviews in/ education or counselling> patients with dementia?
 - **Prompt:** Clinical knowledge
 - Specific knowledge sources/resources

- Is there anything specifically relating to dispensing/adherence/medication review in patients with dementia?
- **Prompt:** Knowledge of the patient's clinical picture
- **Prompt:** Knowledge of guidelines (specific to dementia)
 - What guidelines?
 - What do such guidelines recommend?
- **Prompt:** Personal knowledge/experience of dementia
 - What effect does this have on your clinical practice?

Skills

- What skills do you have as a community pharmacist to assist you when < dispensing medicines for/ assessing adherence of/ conducting medication reviews in/ education or counselling > patients with dementia and dealing with any issues that may arise with < dispensing/ adherence/ medication review/ education or counselling > in such patients?
 - **Prompt:** What skills do you have that would help you to engage with patients or their carers?
 - **Prompt:** What skills do you have that would help you to engage with other healthcare professionals?
- Is there any specific training which you feel would be helpful to you in order to improve < dispensing/ adherence/ medication review/ education or counselling > for patients with dementia in the future?

Beliefs about capabilities

- In what situations do you feel confident about < dispensing medicines for/ assessing adherence of/ conducting medication reviews in/ educating or counselling > patients with dementia?
- In what situations do you **not** feel confident about < dispensing medicines for/ assessing adherence of/ conducting medication reviews in/ educating or counselling > patients with dementia?
 - **Prompt:** What would help you to overcome these problems or difficulties?

Optimism

- How optimistic are you that appropriate < dispensing/ adherence/ medication review/ education or counselling > can be achieved for patients with dementia?
- What would make you feel less optimistic that appropriate < dispensing/ adherence/ medication review/ education or counselling > can be achieved for patients with dementia?

Beliefs about consequences

- What do you think are the benefits of appropriate <dispensing/ adherence/ medication review/ education or counselling> for patients with dementia?
 - **Prompt:** For patients; their carers; yourself; NHS; short- and long-term consequences
- What are the risks associated with inappropriate <dispensing/ adherence/ medication review/ education or counselling> for patients with dementia?

Reinforcement

- What would encourage you to ensure <dispensing/ adherence/ medication review/ education or counselling> is appropriate for patients with dementia?
 - **Prompt:** Are there any rewards or incentives for you or the pharmacy, e.g. services income, personal rewards, professional recognition?
- What would discourage you from ensuring <dispensing/ adherence/ medication review/ education or counselling> is appropriate for patients with dementia?

Intentions

- How do you plan (intend) to address issues with <dispensing/adherence/medication review/ educating or counselling> for patients with dementia?
- What would prevent you from addressing issues with <dispensing/adherence/medication review/ educating or counselling> for patients with dementia?

Goals

- To what extent is improving <dispensing/adherence/medication review/educating or counselling> for patients with dementia a priority for you?
 - If low/high priority, why?
- In what circumstances would you think it was less important to make any changes to <dispensing/ adherence/ medication review/ education or counselling> for patients with dementia?

Memory, attention and decision processes

- How would you usually remember to address issues with <dispensing/ adherence/ medication review/ education or counselling> for patients with dementia?
 - **Prompt:** For example, if there was an issue with dispensing antipsychotic medications/ patient adherence/ patient increasingly struggling with medicines but living alone?
- Are there any circumstances in which you might just forget or find it difficult to resolve these issues?

- **Prompt:** How would you describe the complexity of decision-making in <dispensing/ adherence/ medication review/ education or counselling> for patients with dementia?

Environmental context and resources

- What resources or support might help you to intervene when you encounter issues with <dispensing/ adherence/ medication review/ education or counselling> in patients with dementia?
- What factors might prevent you from intervening when you encounter issues with <dispensing/ adherence/ medication review/ education or counselling> in patients with dementia?
 - **Prompt:** Work environment and culture within the pharmacy; material resources available; critical incidents/events within the pharmacy

Social influences

- Who would influence your decisions about dealing with issues with <dispensing/ adherence/ medication review/ education or counselling> for patients with dementia?
 - **Prompt:** Patients; carers or relatives; GP; hospital consultant; pharmacy colleagues; other healthcare professionals
 - **Prompt:** Can you tell me more about how this happens and what their influence is?

Emotion

- How does <dispensing medication/ supporting adherence/ conducting medication review/ educating or counselling> for patients with dementia make you feel?
- How would your own work stress or emotional engagement with a patient and their carer influence your decisions to attempt to resolve issues with <dispensing/ adherence/ medication review/ education or counselling> for patients with dementia?

Behavioural regulation

- Having decided the best course of action to resolve <dispensing/ adherence/ medication review/ education or counselling> issues for a patient with dementia, are there any ways in which you can monitor whether or not it has been done?
 - **Prompt:** Following clinical guidelines or workplace protocols
- What strategies would you use to overcome these circumstances?

Intervention components

“The research team is interested in developing an intervention to support and improve medicines management for people with dementia and their carers. From reviewing the literature, we have found

that, generally, interventions can be complex and often involve a number of different components. This makes it difficult to identify which components are the most important in terms of improving patient outcomes and achieving adequate medicines management.”

- What would you consider to be important components of an intervention to improve medicines management for people with dementia and their carers in primary care?
 - **Prompt:** Who should be involved in delivering these types of interventions in practice (carers, community pharmacists, GPs, practice nurses, voluntary sector)?
 - **Prompt:** What would each person/healthcare professional have to do?
 - **Prompt:** What are your thoughts on patient involvement in interventions – should patients be actively involved in the decisions about the medicines they are prescribed?
- What would be the facilitators to putting the type of intervention that you have described into practice?
- What would be the barriers to putting the type of intervention that you have described into practice?
- What would help the implementation of the intervention?
- What do you think should be measured as an outcome in an intervention study to support medicines management for people with dementia, i.e. how would you, personally, be persuaded that the intervention had improved medicines management? What are the important outcomes?

Closing the interview

“That brings us to the end of the interview.

Is there anything else about medicines management in people with dementia that you feel has not been covered?

Do you have any additional comments you would like to make as to the content of the interview or how it went?

Thank you very much for making the time to speak with me today.”

[Turn the digital recorder off]

Appendix 28. Beliefs about Medicines Questionnaire (BMQ)

Participant Study ID: _____

BMQ-Specific: Your views about medicines prescribed for you

- I would like to ask you about your personal views about medicines prescribed for you.
- These are statements other people have made about their medicines.
- Please indicate the extent to which you agree or disagree with them by ticking the appropriate box.
- There are no right or wrong answers. I am interested in your personal views.

1. My health, at present, depends on my medicines.

Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
<input type="checkbox"/>				

2. Having to take medicines worries me.

Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
<input type="checkbox"/>				

3. My life would be impossible without my medicines.

Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
<input type="checkbox"/>				

4. Without my medicines I would be very ill.

Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
<input type="checkbox"/>				

5. I sometimes worry about long-term effects of my medicines.

Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
<input type="checkbox"/>				

6. My medicines are a mystery to me.

Strongly agree

Agree

Uncertain

Disagree

Strongly disagree

7. My health in the future will depend on my medicines.

Strongly agree

Agree

Uncertain

Disagree

Strongly disagree

8. My medicines disrupt my life.

Strongly agree

Agree

Uncertain

Disagree

Strongly disagree

9. I sometimes worry about becoming too dependent on my medicines.

Strongly agree

Agree

Uncertain

Disagree

Strongly disagree

10. My medicines protect me from becoming worse.

Strongly agree

Agree

Uncertain

Disagree

Strongly disagree

BMQ-General: Your views about medicines in general

- I would like to ask you about your personal views about medicines in general
- These are statements other people have made about medicines in general.
- Please indicate the extent to which you agree or disagree with them by ticking the appropriate box.
- There are no right or wrong answers. We are interested in your personal views.

1. Doctors use too many medicines

Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
<input type="checkbox"/>				

2. People who take medicines should stop their treatment for a while every now and again.

Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
<input type="checkbox"/>				

3. Most medicines are addictive.

Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
<input type="checkbox"/>				

4. Natural remedies are safer than medicines.

Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
<input type="checkbox"/>				

5. Medicines do more harm than good.

Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
<input type="checkbox"/>				

6. All medicines are poisons.

Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
<input type="checkbox"/>				

7. Doctors place too much trust on medicines.

Strongly agree

Agree

Uncertain

Disagree

Strongly disagree

8. If doctors had more time with patients they would prescribe fewer medicines.

Strongly agree

Agree

Uncertain

Disagree

Strongly disagree

Appendix 29. TDF domain definitions and theoretical constructs (Cane *et al.*, 2012; Michie *et al.*, 2014)

Domain	Definition¹	Theoretical constructs represented within each domain
Knowledge	<i>An awareness of the existence of something</i>	Knowledge (including knowledge of condition/scientific rationale); procedural knowledge; knowledge of task environment
Skills	<i>An ability or proficiency acquired through practice</i>	Skills; skills development; competence; ability; interpersonal skills; practice; skill assessment
Memory, attention and decision processes	<i>The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives</i>	Memory; attention; attention control; decision-making; cognitive overload/tiredness
Behavioural regulation	<i>Anything aimed at managing or changing objectively observed or measured actions</i>	Self-monitoring; breaking habit; action planning
Social/professional role and identity	<i>A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting</i>	Professional identity; professional role; social identity; identity; professional boundaries; professional confidence; group identity; leadership; organisational commitment
Beliefs about capabilities	<i>Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use</i>	Self-confidence; perceived competence; self-efficacy; perceived behavioural control; beliefs; self-esteem; empowerment; professional confidence
Optimism	<i>The confidence that things will happen for the best or that desired goals will be attained</i>	Optimism; pessimism; unrealistic optimism; identity
Beliefs about consequences	<i>Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation</i>	Beliefs; outcome expectancies; characteristics of outcome expectancies; anticipated regret; consequents
Intentions	<i>A conscious decision to perform a behaviour or a resolve to act in a certain way</i>	Stability of intentions; stages of change model; Transtheoretical model and stages of change

Goals	<i>Mental representations of outcomes or end states that an individual wants to achieve</i>	Goals (distal/proximal); goal priority; goal/target setting; goals (autonomous/controlled); action planning; implementation intention
Reinforcement	<i>Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus</i>	Rewards (proximal/distal, valued/not valued, probable/improbable); incentives; punishment; consequents; reinforcement; contingencies; sanctions
Emotion	<i>A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event</i>	Fear; anxiety; affect; stress; depression; positive/negative affect; burn-out
Environmental context and resources	<i>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</i>	Environmental stressors; resources/material resources; organisational culture/climate; salient events/critical incidents; person x environment interaction; barriers and facilitators
Social influences	<i>Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours</i>	Social pressure; social norms; group conformity; social comparisons; group norms; social support; power; intergroup conflict; alienation; group identity; modelling

¹All definitions are based on definitions from the American Psychological Associations' Dictionary of Psychology

Appendix 30. Task group presentation



**Development of an
intervention to improve
medicines management
for people with dementia
in primary care**

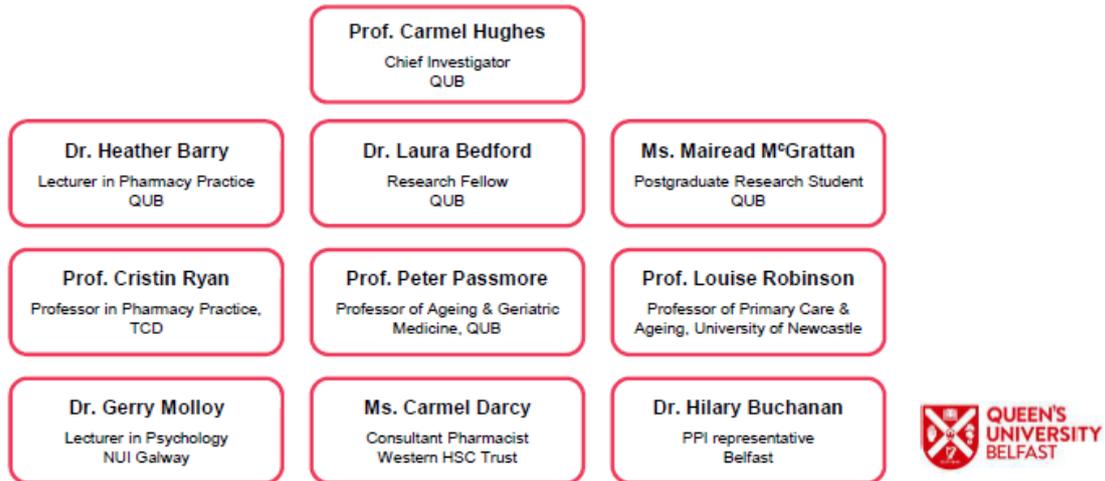
Dr. Heather Barry, Dr. Laura Bedford, Ms. Mairead M^cGrattan
5th December 2017

Agenda

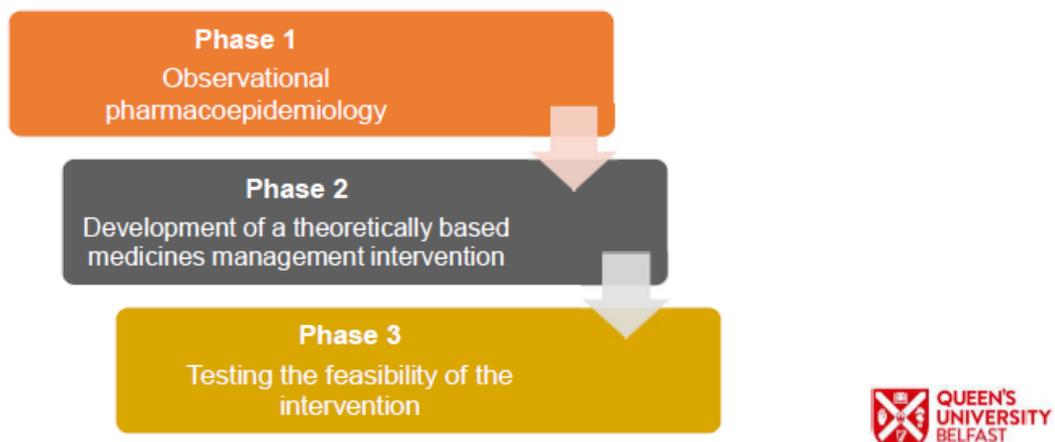
- Overview of project
- Summary of findings from Phase 1
- Aim and Method for Phase 2
- **Task 1: classifying interview statements**
- Analysis and intervention development
- **Task 2: feedback on target behaviours**
- Presentation of a candidate (draft) intervention
- **Task 3: appraisal of proposed intervention**



Project team



Overview of project



Phase 1: Aim and Method

Aim: To investigate potentially inappropriate prescribing (PIP) among patients with dementia (PWD) in Northern Ireland.

Method:

- A retrospective cross-sectional study was conducted, using data from the Enhanced Prescribing Database
- Patients were eligible if a dementia drug was dispensed to them during 2013
- Overall prevalence of potentially PIP and most common instances of PIP were calculated.



Phase 1: Results

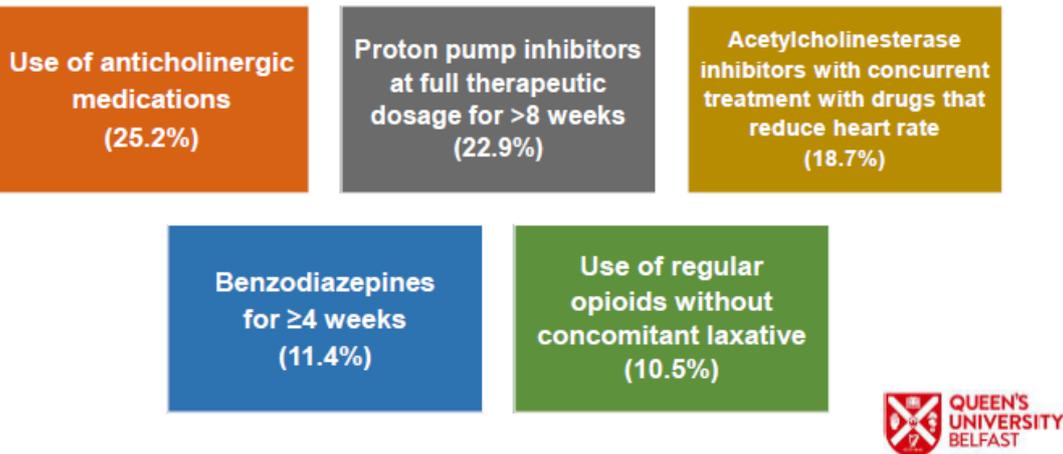
Study population:
6,826 patients

Polypharmacy
(≥4 repeat
medicines):
81.5%

PIP prevalence:
64.4%



Phase 1: Most common instances of PIP



Phase 2: Aim and Method

Aim: To identify the behaviours that facilitate, or act as a barrier to, medicines management in people with dementia (PWD)

Method: 1-1 semi-structured interviews conducted with PWD and their carers, GPs and community pharmacists ($n=63$).

Participants were asked to describe their experiences of medicines management, their perceptions of barriers and facilitators to achieving appropriate medicines management, and their views on potential intervention components and outcome measures.



Task 1: classifying interview statements

Categorise the ten sample statements from community pharmacist interviews:

- True
- False
- Interesting



Phase 2: Analysis and intervention development

Aim: To identify behaviours that facilitate, or act as a barrier to, appropriate medicines management

Method: Data from the qualitative study, together with the findings from the epidemiological work conducted in Phase 1, were brought together to identify target behaviours.



Task 2: feedback on target behaviours

- Two target behaviours, specific to community pharmacists, were identified:
 1. Monitoring adherence
 2. Conducting medication reviews
- Any comments or suggestions for change?



Phase 2: proposed intervention

Two-part intervention

1. Online video

Demonstration of how community pharmacists can **monitor adherence** both at the Pharmacy and at the patients home [will need pharmacists suggestions for video content]. Video will include feedback from the pharmacist, PWD, and their carer which emphasises the positive outcomes of monitoring adherence. The video will also include a demonstration of how a structured **medication review** for a PWD can be conducted (e.g. using the STOPP criteria or Anticholinergic Cognitive Burden Scale). This video will be accompanied by a checklist.



2. Protocol

Following the videos, Pharmacists will be able to access a protocol for monitoring adherence and conducting medication reviews.

3. Mentoring system or online discussion forum

In order to provide the opportunity for discussion with other community pharmacists, a 1-1 mentoring scheme or online discussion forum could be incorporated as part of the intervention.



Task 3

Use of the APEASE criteria to appraise the proposed intervention (Atkins, 2016):

Criteria	Question
Affordability	Can it be delivered to budget?
Practicability	Can it be delivered as designed?
Effectiveness and cost-effectiveness	Does it work (ratio of effect to cost)?
Acceptability	Is it appropriate?
Side-effects/safety	Does it have any unwanted side-effects or unintended consequences?
Equity	Will it reduce or increase the disparities in health/wellbeing/standard of living?



Appendix 31. Target behaviour summaries for discussion during GP task group

1. Prescribing	
What	<ul style="list-style-type: none">• GPs must ensure that they are prescribing appropriately for people with dementia.• Special consideration to be given to potentially inappropriate medications/combinations identified in the phase 1 work
When	At any time when prescribing a new or repeat medication for a dementia patient, which could be: <ul style="list-style-type: none">• During a face-to-face consultation• Following a telephone call• When signing off repeat prescriptions
Where	In the GP surgery
How often	Any time GPs are prescribing
With whom	Alone or in conjunction with the patient and/or the patient's carer (depending upon situation)
2. Conducting medication reviews	
What	Conduct regular and comprehensive medication review* for dementia patients, following a structured and systematic process * Medication review will also include an assessment of appropriateness of prescribing and adherence
When	During medication review appointment
Where	In the GP surgery or at the patient's home
How often	<ul style="list-style-type: none">• Initial review following diagnosis• Annual review thereafter?
With whom	Alone or with the patient and/or their carer

Appendix 32. Target behaviour summaries for discussion during community pharmacist task group

1. Monitoring adherence

What	Pharmacists must ensure they are regularly checking patient adherence to medication (PMR check, asking questions of patients and/or carers, checking previous compliance aid, making home visit) when they are dispensing medication for people with dementia.
When	Routinely during dispensing process
Where	In the pharmacy and/or in the patient's home (in order to make an accurate assessment of adherence)
How often	Monthly* *home visits not required monthly but could be arranged (e.g., twice a year)
With whom	Alone and with input from the patient and/or their carer

2. Conducting medication reviews

What	Conduct regular and comprehensive medication review* for dementia patients, following a structured and systematic process * Medication review will also include an assessment of appropriateness of prescribing and adherence
When	During medication review appointment
Where	In the Pharmacy or at the patient's home
How often	<ul style="list-style-type: none">• Initial review following diagnosis• Annual review thereafter?
With whom	Alone or with the patient and/or their carer

Appendix 33. APEASE criteria task

Task 3. APEASE criteria	
<p>Affordability (Can it be delivered to budget?)</p>	<p>Yes <input type="checkbox"/></p> <p>No <input type="checkbox"/></p> <p>Comments:</p>
<p>Practicability (Can it be delivered as designed?)</p>	<p>Yes <input type="checkbox"/></p> <p>No <input type="checkbox"/></p> <p>Comments:</p>
<p>Effectiveness and cost-effectiveness (Does it work (ratio of effect to cost)?)</p>	<p>Yes <input type="checkbox"/></p> <p>No <input type="checkbox"/></p> <p>Comments:</p>

<p>Acceptability (Is it appropriate?)</p>	<p>Yes <input type="checkbox"/></p> <p>No <input type="checkbox"/></p> <p>Comments:</p>
<p>Side-effects/safety (Does it have any unwanted side-effects or unintended consequences?)</p>	<p>Yes <input type="checkbox"/></p> <p>No <input type="checkbox"/></p> <p>Comments:</p>
<p>Equity (Will it reduce or increase the disparities in health/wellbeing/</p>	<p>Yes <input type="checkbox"/></p> <p>No <input type="checkbox"/></p> <p>Comments:</p>

standard of living?)	
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Appendix 34. Ethical approval received for Phase 2



Health Research Authority

NRES Committee East of England - Norfolk

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0115 883 9525

23 March 2015

Professor Carmel M. Hughes
Professor of Primary Care Pharmacy
Queen's University Belfast
School of Pharmacy
97 Lisburn Road
Belfast
BT9 7BL

Dear Professor Hughes

Study Title:	Development of an intervention to improve medicines management for persons with dementia in primary care in Northern Ireland
REC reference:	15/EE/0103
IRAS project ID:	174296

The Research Ethics Committee reviewed the above application at the meeting held on 16 March 2015.

Provisional opinion

The Committee is unable to give an ethical opinion on the basis of the information and documentation received so far. Before confirming its opinion, the Committee requests that you provide the further information set out below.

Authority to consider your response and to confirm the Committee's final opinion has been delegated to the Chair.

Further information or clarification required

1. Please recruit only those carers who attend the Memory Clinic.
2. Please include in the Participant Information Sheet details of the involvement of the PhD student in the study.

If you would find it helpful to discuss any of the matters raised above or seek further clarification from a member of the Committee, you are welcome to contact the REC Manager, Tracy Leavesley on NRESCommittee.Eastofengland-Norfolk@nhs.net

When submitting a response to the Committee, the requested information should be electronically submitted from IRAS. A step-by-step guide on submitting your response to the REC provisional opinion is available on the HRA website using the following link: <http://www.hra.nhs.uk/nhs-research-ethics-committee-rec-submitting-response-provisional-opinion/>

Please submit revised documentation where appropriate underlining or otherwise highlighting the changes which have been made and giving revised version numbers and dates. You do not have to make any changes to the REC application form unless you have been specifically requested to do so by the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 22 April 2015.

Summary of the discussion at the meeting

- **Social or scientific value; scientific design and conduct of the study**

The Committee discussed you had opted to exclude participants who lack capacity to consent, although the study is working with patients who have dementia and agreed this was appropriately managed throughout the application.

- **Recruitment arrangements and access to health information, and fair participant selection**

The Committee discussed the process for recruiting carers into the study and agreed it would be inappropriate for you to telephone the carers without any kind of forewarning. The Committee agreed a better way forward with the recruitment of this group would be to only invite those carers who accompany the patient to the Memory Clinic to take part in the study.

- **Informed consent process and the adequacy and completeness of participant information**

The Committee noted you intend to involve a PhD student in the study but that this is not mentioned in the Participant Information Sheet. It was agreed that this would need to be included within the Information Sheet as the study will form part of their PhD qualification.

Documents reviewed

The documents reviewed at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Cover letter to REC]		03 March 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor letter]		02 March 2015
GP/consultant information sheets or letters [GP practice invitation letter]	1	27 February 2015

GP/consultant information sheets or letters [GP practice information sheet]	1	27 February 2015
IRAS Checklist XML [Checklist_03032015]		03 March 2015
IRAS Checklist XML [Checklist_03032015]		03 March 2015
Letter from funder [Letter from HSC PHA confirming award]		14 August 2014
Letter from sponsor [Sponsor letter]		02 March 2015
Letters of invitation to participant [Patient invitation letter (for those sampled through memory clinics)]	1	27 February 2015
Letters of invitation to participant [Patient invitation letter (for those sampled through GP practices)]	1	27 February 2015
Letters of invitation to participant [Carer invitation letter]	1	27 February 2015
Letters of invitation to participant [GP invitation letter]	1	27 February 2015
Letters of invitation to participant [Community Pharmacist invitation letter]	1	27 February 2015
Other [Dr. Heather Barry CV]		23 February 2015
Participant consent form [Patient consent form]	1	27 February 2015
Participant consent form [Carer consent form]	1	27 February 2015
Participant consent form [Healthcare professional consent form]	1	27 February 2015
Participant information sheet (PIS) [Patient information sheet (for those sampled through memory clinics)]	1	27 February 2015
Participant information sheet (PIS) [Patient information sheet (for those sampled through GP practices)]	1	27 February 2015
Participant information sheet (PIS) [Carer information sheet]	1	27 February 2015
Participant information sheet (PIS) [GP information sheet]	1	27 February 2015
Participant information sheet (PIS) [Community Pharmacist information sheet]	1	27 February 2015
REC Application Form [REC_Form_03032015]		03 March 2015
Referee's report or other scientific critique report [Referee ID 20173]		
Referee's report or other scientific critique report [Referee ID 20350]		
Referee's report or other scientific critique report [Referee ID 20522]		
Research protocol or project proposal [Phase 2 protocol]	1	27 February 2015
Summary CV for Chief Investigator (CI) [Prof. Carmel Hughes CV]		23 February 2015

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet

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.

15/EE/0103

Please quote this number on all correspondence

Yours sincerely

A handwritten signature in black ink, appearing to be 'M. Sheldon', with a long, sweeping underline that extends to the right.

Dr Michael Sheldon (Chair)

Email: NRESCommittee.EastofEngland-Norfolk@nhs.net

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments.

Copy to: Dr. Heather E. Barry

Ms. Alison Murphy, Belfast Health & Social Care Trust

Appendix 35. Summary findings from patient interviews (n=18)

Domain	Facilitator	Barrier	Comments
Knowledge	Unclear: Most patients had no/limited knowledge about their medicines, but many did not wish to know or said they had great trust in their GP/prescriber	Memory deficits (limitation to retaining knowledge)	Difficult to identify specific facilitators/barriers to target under this domain as patients did not make explicit links between their knowledge (or lack of) and medicine-taking behaviour Not a feasible target domain for intervention if patients are unable to retain or not interesting in acquiring further information about their medicines
Skills	None	Unable to manage own prescription ordering	<u>Least discussed domain</u> (only mentioned by one participant) Skills do not appear to present any issues or problems to patients
Memory, attention and decision processes	Having a routine in place at home Family/carers to help administer medication (linked to Social Influences) Weekly compliance aid (linked to ECR) Medication checklist (tick when taken)	Memory deficits Being away from home/on holiday	<u>Most discussed domain</u> Many patients talked about medicine-taking being part of a routine, linked to mealtimes/bedtime. Often patients/carers popped tablets out from compliance aid, into egg cup, from which tablets were then taken
Behavioural regulation	Checking relevant blister in compliance aid/medication checklist (linked to ECR) Family/carer involvement to check up on patient (linked to Social Influences)	None identified	Strong overlap with other theoretical domains
Social/professional role and identity	Role in medicines management: Taking their medicines Assistance from family/carers	None identified	Nearly all patients identified that their responsibility was to take their medicines

Beliefs about capabilities	Having family/carer input and assistance (linked to Social Influences)	Changes made to medicines	<p>Patients displayed confidence and competence with regard to their medicine-taking, and denied having any issues</p> <p>It would be prudent for healthcare professionals to ensure that changes to medicines are kept to a minimum in this patient group</p>
Optimism	Unclear: there were mixed responses to this question, although the majority of patients who did discuss it expressed optimism in overcoming any problems with their medicines. Patients did not make explicit links between their optimism and medicine-taking behaviour	Unclear	<p><u>Domain seldom discussed</u></p> <p>Difficult to identify specific facilitators/barriers to target under this domain</p>
Beliefs about consequences	Unclear: Patient identified positive consequences of taking their medicines (health benefits), however it is difficult to establish the influence of these beliefs on their behaviour	Side-effects (mentioned by one patient)	Difficult to identify specific facilitators/barriers to target under this domain as patients did not make explicit links between their beliefs and medicine taking
Intentions	Unclear: On the whole patients displayed positive intentions to take their medicines. It is difficult to establish the influence of these intentions on their behaviour	None	Difficult to identify specific facilitators/barriers to target under this domain
Goals	Unclear: Most patients stated that medicine-taking was a high priority for them, however they did not make any link between their goals/priority and medicine-taking behaviour		Difficult to identify specific facilitators/barriers to target under this domain
Reinforcement	<p>Positive health outcomes (e.g. symptom control)</p> <p>Family members and healthcare professionals (linked to Social Influences)</p>	None identified	Difficult to identify specific facilitators/barriers to target under this domain
Emotion	None identified	Being dependent upon others (frustration)	Difficult to identify specific facilitators/barriers to target under this domain. The barriers mentioned in the previous column were only identified by a small number of patients.

		Negative outcomes/side-effects (fear/worry)	Would an intervention that would promote independence of patients be feasible?
Environmental context and resources	Carers/Family members to help administer medication (linked to Social Influences) Weekly compliance aid Pharmacy delivery service	None identified	The majority of patients had their medication dispensed in a weekly compliance aid and family members/formal carers assisted with administration of medication from this pack
Social influences	Family/carers GP Community pharmacist Other healthcare professionals (e.g. nurses/hospital consultants)	None identified	Patients placed great trust in healthcare professionals and their knowledge and judgement

Appendix 36. Summary findings from carer interviews (n=15)

Domain	Facilitator	Barrier	Comments
Knowledge	<p>Knowledge about indications of certain medications</p> <p>Knowledge of potential side effects</p> <p>Knowledge of sources of information available- patient information leaflets, internet</p>	<p>Limitations to knowledge – unsure of indications of all medicines patient is taking</p> <p>Trust in prescriber</p>	<p>Knowledge varied between carers. Most carers indicated that they would welcome more information from GP or pharmacist.</p> <p>Carer education could be a potential component of an intervention</p>
Skills	Carers comfortable with the process of ordering prescriptions	None identified	<p><u>Least discussed domain</u></p> <p>Skills do not appear to present any problems or issues to carers</p>
Memory, attention and decision processes	<p>Having a daily routine in place – for example, associating medicine-taking with meals</p> <p>Weekly compliance aid (linked to ECR domain)</p> <p>Medication checklist (tick when taken)</p>	Night time medicine more often missed than morning medicines	<p>Carers play a large role in prompting patients to take medicines and will be an integral component of future intervention</p> <p>Routine extremely important</p>
Behavioural regulation	<p>Checking the relevant blister in the compliance aid/ medication checklist</p> <p>Use of technology, for example mobile phones – to remind patient of what day it is (so patient is then aware if they have taken their tablets for that day or not)</p>	None identified	Patient confusion regarding the day of the week (and therefore unsure whether they had taken their medicines for that day) was mentioned by a few carers – only one carer discussed overcoming this issue through patient using the mobile phone to check the day
Social/professional role and identity	<p>Carers responsible for a range of medicines management activities:</p> <ul style="list-style-type: none"> Ordering prescriptions 	None identified	Carers' roles varied depending on extent of community pharmacy input, and severity of patient's condition

	<ul style="list-style-type: none"> Collecting medicines from pharmacy Dispensing medicines into own compliance aid/ eggcup (where patient not on a pharmacy prepared compliance aid) Checking adherence 		<p>Almost all carers considered part of their role to be making sure the patient takes their medication</p> <p>Carer involvement is <u>key</u> in a future intervention</p>
Beliefs about capabilities	Self-efficacy – often conditional, e.g. confident provided the compliance aid is in place	<p>Lack of confidence in patient’s abilities if left alone</p> <p>Perceived lack of confidence when patient’s condition worsens</p>	<p>Carers did not highlight lack of confidence in their own abilities, only from the patient’s point of view</p> <p>Intervention may need to be altered as cognitive impairment declines and new issues become relevant</p>
Optimism	Unclear: participants who discussed this domain generally expressed optimism in their own ability to overcome any problems relating to medicines management. Optimism was often conditional – as long as the patient stays well	Unclear: participants who discussed this domain often expressed pessimism in terms of the patients own ability to overcome any problems relating to medicines management	Difficult to identify specific facilitators/barriers to target under this domain
Beliefs about consequences	<p>Positive health outcomes</p> <p>Benefits outweigh risks</p>	<p>Side effects</p> <p>Awareness and concern over future progression of disease (linked to Emotion and Beliefs about Capabilities)</p>	<p><u>Frequently discussed domain</u></p> <p>Carers often discussed being unsure about the effectiveness of the memory tablet as they do not know how much worse the patient would be without it</p> <p>Carer education – potential component of an intervention</p>
Intentions	<p>Carers displayed positive intentions to getting patient to take their medicines</p> <p>Carers also displayed positive intentions to speaking to GP/ pharmacist if any issues were to arise (related to social influences domain)</p>	None identified	<p>Difficult to identify specific facilitators/barriers to target under this domain</p> <p>This domain does not appear to be problematic for carers</p>

Goals	Majority of carers indicated that patients taking their medicines is a high priority. Goal: To keep patient well for as long as possible	If patient was unwell (and physically unable to take tablets) medicine-taking would become less of a priority	Difficult to identify specific facilitators/barriers to target under this domain
Reinforcement	Positive health outcomes (e.g. control of pain, slowing progression of disease) Rewarding patient for taking medicines (e.g. chocolate)	Side-effects of medicines would discourage carer from wanting to give the medicine to patient	Most carers reported that patients do not need encouraged to take their medicines
Emotion	Positive emotions associated with patient taking medicines – reassured in knowing medicines are keeping patient well	Concern/worry about future problems, such as the patient refusing medicines or becoming physically unable to take medicines (related to beliefs about consequences)	Difficult to identify specific facilitators/barriers to target under this domain Does an intervention need to be targeted at a future point in the disease trajectory when these worries and concerns become pertinent for carers? Alternative is to tailor interventions to issues at different stages of disease progression, but this may not be feasible and we do not have data on what these issues are
Environmental context and resources	Compliance aid Pharmacy services – ordering prescriptions, collecting prescriptions from GP surgery, delivering medicines to patient’s home Accessibility of pharmacists	Difficulties in speaking to GP/ getting appointments/ limited time to discuss issues in a ten-minute appointment slot Confusion resulting from different brands of the same tablet – problematic for PWD	Compliance aid in place for most patients (either made up by community pharmacy or by carer) and deemed the most effective aid to medicine-taking activities by the majority of carers Changes to medicines and brands of medicines should be kept to a minimum in this patient population
Social influences	Family members/ patient themselves GP Community pharmacists	Lack of continuity of GPs – seeing different doctor each appointment can be difficult	<u>Most discussed domain</u> The majority of carers reported good relationships with the community pharmacist and GP. Carers

	Other healthcare professionals (nurses, hospital consultants)		also placed great trust in healthcare professional's knowledge and judgement. Future intervention should try to ensure continuity of care by healthcare professionals.
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Appendix 37. Determinants (i.e. barriers and facilitators) of general practitioners' (GPs') medicines management behaviour identified within each TDF domain and illustrative quotes

Theoretical domain	Behaviour specified	Determinants	Quotes
Knowledge	Prescribing	<ul style="list-style-type: none"> Clinical knowledge (facilitator) 	<i>"Certainly knowledge of what potential medications could make them worse. The likes of the anticholinergics especially, or else sedatives or analgesics. Obviously you need to have a reasonable knowledge of pharmacology"</i> [GP_13]
		<ul style="list-style-type: none"> Knowledge of patient's home situation (facilitator) 	<i>"Whenever you prescribe for an individual you're looking at the whole situation"</i> [GP_01]
		<ul style="list-style-type: none"> Lack of knowledge about drugs for dementia due to initiation in secondary care (barrier) 	<i>"And then if they're going on a combination of drugs as well, I'm never quite sure of what combination of dementia drugs can be used together"</i> [GP_06]
Skills	Medication Review	<ul style="list-style-type: none"> Competence in performing medication review (facilitator) 	<i>"It's our ability to perform medication reviews in the practice and, I mean, it's very easy"</i> [GP_14]
		<ul style="list-style-type: none"> Communication skills (facilitator) 	<i>"So that's where communication comes in. So much when things aren't working it's down to communication. I mean, I just bang on all the time about communication, with the patient, the family, and all the people involved"</i> [GP_02]
		<ul style="list-style-type: none"> Lack of training aimed at improving GPs' ability to manage PwD (barrier) 	<i>"And if somebody has ideas how we manage with these patients, that's...yeah...certainly welcome any training"</i> [GP_13]
Memory, attention and decision processes	Medication Review	<ul style="list-style-type: none"> Prompts from computer systems, community pharmacists, patients' family members, notes/memos (facilitator) 	<i>"Via QOF [Quality Outcomes Framework] I will get reminders when patients with dementia are due their dementia review, we have some sort of system"</i> [GP_07] <i>"We are very dependent on the community to notice things and for either relatives or neighbours to raise issues and pass the word"</i> [GP_09]
		<ul style="list-style-type: none"> Time and heavy workload associated with forgetting to address issues (barrier) 	<i>"You sometimes don't have the luxury of half an hour later remembering 'Did I make that phone call, did I check up on somebody?' But if you had the time you would have"</i> [GP_01]

			<p><i>"I could easily forget, yes in the middle of a busy day. Something might be raised. I try to write it down on my to-do list and sort it out" [GP_10]</i></p>
		<ul style="list-style-type: none"> • Issues often addressed opportunistically or at 'crisis point' (barrier) 	<p><i>"You tend to find that a patient comes to your attention opportunistically when you are reviewing them because of illness or whatever" [GP_12]</i></p> <p><i>"That is a big issue...that it's opportunistic rather than focused" [GP_14]</i></p>
Behavioural regulation	Prescribing, Medication Review	<ul style="list-style-type: none"> • Practice computer system prompts highlighting when prescriptions are being ordered by patients (facilitator) 	<p><i>"If the repeat prescribing is set up we should be able to tell from our system what's being prescribed, and when it's being prescribed, and is it being prescribed at the right intervals?" [GP_03]</i></p> <p><i>"It would flag on our system if they're ordering too early or over-ordering" [GP_05]</i></p>
		<ul style="list-style-type: none"> • Checking with carers and pharmacists (facilitator) 	<p><i>"If you've done something and want to follow up on it, you can speak to a carer or somebody that you can rely on for them to phone you back or something, you need to put some sort of safety net there" [GP_15]</i></p>
		<ul style="list-style-type: none"> • Lack of structured protocols present barrier to follow-up (barrier) 	<p><i>"There's no checking system in place and that's quite a good valid point" [GP_06]</i></p>
Social/professional role and identity	General	<ul style="list-style-type: none"> • Professional identity – all part of the job (facilitator) 	<p><i>"I think most general practitioners are good at heart and they just try to do the best they can. So I've no problem about it and it's part of good practice" [GP_01]</i></p>
		<ul style="list-style-type: none"> • Professional boundaries between primary and secondary care (barrier) 	<p><i>"And the other thing I think is that there's a bit of a cut-off between GPs and consultants, certainly in this Trust, I don't feel that there's a very natural [relationship]. I think we could work at improving that" [GP_07]</i></p>
Beliefs about capabilities	Prescribing	<ul style="list-style-type: none"> • Professional confidence in areas of prescribing and ongoing monitoring of dementia drugs (facilitator) 	<p><i>"Well I suppose patients who have been things for years, it's fairly easy to keep monitoring that side of things" [GP_03]</i></p> <p><i>"When they have an established diagnosis [of dementia] ultimately I think we are pretty comfortable in managing them and adjusting their medications up or down" [GP_04]</i></p>
		<ul style="list-style-type: none"> • Dealing with patients who have carer support (facilitator) 	<p><i>"I think I'm more comfortable when there is someone at home with them who you know is taking responsibility for their medication" [GP_05]</i></p>

			<i>"It's the ones living alone who have not got any carer. They would pose a big problem certainly" [GP_11]</i>
		<ul style="list-style-type: none"> • Limitations of professional confidence, e.g. initiation of dementia drugs, management of pain and BPSD, high risk drugs (barrier) 	<p><i>"And the other area I think we find very difficult is managing the psychological and behavioural issues" [GP_07]</i></p> <p><i>"I think because the specialist dementia drugs are secondary care initiated, I am a little bit...I wouldn't say unhappy about it, but I'm just...a bit more hesitant because how do I measure whether they're working or not?" [GP_10]</i></p>
Optimism	General	<ul style="list-style-type: none"> • Pessimism regarding patients managed at home compared to, e.g. nursing home residents (barrier) 	<i>"It's straight forward enough if they're in a nursing home, and they're being administered their medication but if they are still on their own at home and they're not deemed to be bad enough to go into a home, that's the tricky area. Because who does take responsibility for that then?" [GP_11]</i>
Beliefs about consequences	Prescribing	<ul style="list-style-type: none"> • Benefits acknowledged, e.g. prevention of falls, hospitalisations (facilitator) 	<i>"Well less adverse reactions, less adverse events, you would hope that you would keep them well, keep them on their feet, and keep them out of hospital because they're obviously high risk for all of those things. Yeah, it's just good sense" [GP_03]</i>
		<ul style="list-style-type: none"> • Concerns about polypharmacy (barrier)/ deprescribing as a facilitator 	<p><i>"And they can do with reducing the medication rather than adding another one to counteract some other effect and creating more polypharmacy" [GP_09]</i></p> <p><i>"I think that perhaps in the elderly population in general, too many medications are prescribed. And often I feel that patients might even benefit from coming off a lot of tablets than being on a lot of things, maybe that would be something in the future that happens more" [GP_15]</i></p>
		<ul style="list-style-type: none"> • Belief that adherence will be poor in PwD (barrier) 	<p><i>"The risk is with a dementia patient is assuming that they will take their medications for something else, that they want to take all their antibiotic in one day or not finish the course. That kind of thing" [GP_10]</i></p> <p><i>"So then there's obviously compliance...I think you just have to assume it's not going to be very good. They're always at risk, aren't they?" [GP_11]</i></p>

Intentions	General	<ul style="list-style-type: none"> • Workload and time (barrier) 	<p><i>"The week just disappears and your best intention 'I'll call and see Mr X'...unless you literally stick it in the book and it's there for everybody to see, the next thing there are a few other calls and you defer it for another day..." [GP_02]</i></p>
Goals	Prescribing Medication Review	<ul style="list-style-type: none"> • Belief that PwD are no more of a priority than other patient groups (barrier) 	<p><i>"My concern would be that those are not the only patients that are looked at because I think we have a much bigger problem going on in our practice. It is not just dementia and it's those other folk out there...we have well over a hundred on weekly dispensing. So there're a lot of people out there struggling with their medications" [GP_08]</i></p>
Reinforcement	Prescribing, Medication Review	<ul style="list-style-type: none"> • Lack of funding (barrier) 	<p><i>"The financial side will always... GPs will always jump for that. I hold my hands up. But if there isn't an incentive to do the thing right it can turn into a bit of a tick-box thing and you just tick, tick, tick but you don't actually do the thing, do you know what I mean?" [GP_02]</i></p>
Emotion	Prescribing	<ul style="list-style-type: none"> • Concern about vulnerability of patient group (barrier) 	<p><i>"I probably worry more about them because they're not always...if they don't have competency...it's to do with the autonomy you know? It's like treating children sometimes because you've got to take the responsibility for somebody else" [GP_03]</i></p> <p><i>"You do worry more with patients with dementia. You know, just, is it safe? It's simple as that, is a medication safe, whatever they're on. And I think that would probably be in your mind more with patients with dementia" [GP_15]</i></p>
		<ul style="list-style-type: none"> • Greater anxiety when dealing with patients alone/without family support (barrier) 	<p><i>"The ones I suppose you worry about is the elderly patient who has very early dementia and there is nobody else to supervise them" [GP_09]</i></p>
Environmental context and resources	Prescribing, Medication Review	<ul style="list-style-type: none"> • Community pharmacists as a resource/bringing issues to attention of GP (facilitator) 	<p><i>"Or the pharmacist would be a good source of information as well because quite often they will know the patient" [GP_05]</i></p>
		<ul style="list-style-type: none"> • Future role for practice-based pharmacists (facilitator) 	<p><i>"There is certainly a role which needs to be developed for an actual pharmacist or prescribing pharmacist in surgeries to review all patients, but particularly the patients who are on repeat prescribing of numerous drugs, say five, say ten or more items" [GP_01]</i></p>

			<p><i>"...And potentially a pharmacist in practice as well. We don't have that luxury at the moment in terms of this area but there's no doubt that's a big aspect" [GP_14]</i></p>
		<ul style="list-style-type: none"> Limited time/workload to complete thorough medication review (barrier) 	<p><i>"I think to actually properly do reviews on these types of patients, rather than go through a quick box ticking, it takes time. The time issue is the major factor. I just don't have time to give that body of patients, who demand most of my time because of their multiple pathologies, I just don't have the time" [GP_01]</i></p> <p><i>"I think time is the thing... protected time. What I've seen is, general practice has changed from a job whereby twenty years ago we were seeing minor self-limited illnesses that took five minutes to sort out. Primary care has now changed whereby the patients that we are seeing tend to be complex, they tend to be elderly, to try and sort these patients in ten minutes is now becoming impossible" [GP_12]</i></p>
Social influences	Prescribing	<ul style="list-style-type: none"> Community pharmacists (facilitator) 	<p><i>"Often they'll tell the pharmacist 'Have you not got... I prefer the wee white one' and sometimes the pharmacist will phone us and say 'Oh look I think the reason they're not taking that is because they don't like that particular tablet, if you change it to this it might be easier done'" [GP_03]</i></p> <p><i>"Well, I suppose the chemist, you know, it's not the first time I've prescribed something and the chemist says, 'Are you sure you want to prescribe this?' The chemist can be very useful, you know, and says, like there's a potential interaction here" [GP_13]</i></p>
		<ul style="list-style-type: none"> Patients' carers/family members (facilitator) 	<p><i>"Carers would often feed back to us if there's confusion about medication, or they're not taking it correctly they would let us know in which case then we could try and address it. I think family wishes are a big thing. If the patient is not capable of managing or making the decisions then I think the family decide, because it's obviously them who are going to be have to be dealing with it" [GP_05]</i></p>
		<ul style="list-style-type: none"> GP colleagues and psychogeriatricians (facilitator) 	<p><i>"Once the psychiatrists start using stuff then we'll jump on the bandwagon fairly quickly" [GP_02]</i></p> <p><i>"Yeah, there's different people in here [GP colleagues] sort of have different niches if you like. So, for example, if you've any queries about any anticoagulation you ask</i></p>

			[name of colleague]. <i>So yeah, you just bounce it off each other as well and sort of say "What do you think or would you just stop that...?"</i> [GP_03]
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Appendix 38. Determinants (i.e. barriers and facilitators) of community pharmacists' medicines management behaviour identified within each TDF domain and illustrative quotes

Theoretical domain	Behaviour specified	Determinants	Quotes
Knowledge	Monitoring adherence	<ul style="list-style-type: none"> Knowledge of patient's home situation (facilitator) 	<p><i>"It's a small community pharmacy and I know all my patients with dementia. And I probably know their home situation...I would know if they are on their own, if they do have carers, how good they are at remembering to take their medication"</i> [CP_08]</p>
		<ul style="list-style-type: none"> Lack of knowledge of care system and support available to PwD and carers (barrier) 	<p><i>"...The care system, that's not something I always know about and sometimes if we knew that, how it works, maybe we might be able to implement...help with the medicines management aspect of it"</i> [CP_14]</p>
		<ul style="list-style-type: none"> Breaks in continuity of pharmacist care (barrier) 	<p><i>"I think you really need to know the patient. There's no point in one pharmacist dealing with the patient one week and one pharmacist dealing with them the next week"</i> [CP_11]</p>
		<ul style="list-style-type: none"> Reliability of information provided by patient or carer (barrier) 	<p><i>"People quite often are just going to tell you what you want to hear"</i> [CP13]</p> <p><i>"Trying to piece the whole thing together rather than just taking their word for it at the counter"</i> [CP_15]</p>
Skills	Medication Review, Monitoring adherence	<ul style="list-style-type: none"> Communication skills (facilitator) 	<p><i>"Communication is key...I think it's very important to have that ear to listen to what the person is saying rather than what you think they're saying. I think that personally I've developed over the years, I wouldn't have it when I just started, but over the years I've learnt just to listen to this person, let them get to the end of what they're telling you because the secret might be in the last few words"</i> [CP_05]</p>
		<ul style="list-style-type: none"> Relationship-building (facilitator) 	<p><i>"What I have found useful is building those relationships with carers network and other support networks for them"</i> [CP_02]</p> <p><i>"...Because they are regular patients a lot of those people you would have that rapport with them so you maybe know that there is something wrong"</i> [CP_06]</p>

		<ul style="list-style-type: none"> Lack of training in dealing/negotiating with PwD (barrier) 	<p><i>"When the pharmacy is busy and there're a lot of people watching that interaction taking place and you're trying to remain calm, you're trying to diffuse the situation without offending the patient who is probably more agitated then normal anyway. I don't think we receive enough training on that" [CP_12]</i></p>
Memory, attention and decision processes	Monitoring adherence	<ul style="list-style-type: none"> Strategies used by pharmacists to monitor adherence, e.g. patient no-show, pharmacy PMR, notes/alerts on computer system (facilitator) 	<p><i>"You can kind of keep an eye on adherence...they sign for it [compliance aid] every week and when no-one appears there starts to be a wee problem and then you start to think where are they and you check in with the GPs, and the patient's representative and stuff" [CP_03]</i></p> <p><i>"If there's any issues that arise through the PMR, there is an area for notes so I will write any notes, so let's say sometimes people bring their weekly box back and we will see that they have not taken a day's tablets or something like that. I will type into the notes" [CP_09]</i></p> <p><i>"People who have compliance issues almost flag themselves up if they use the same pharmacy. Because we can tell by their records, you're too early for that" [CP_12]</i></p>
		<ul style="list-style-type: none"> Patient lack of formal dementia diagnosis (barrier) 	<p><i>"I suppose once you hear initially of a diagnosis of dementia then you do start to think about compliance and that sort of thing and like maybe lining up medication and that for the patient and suggesting like a [weekly compliance aid] pack and just to ensure that they are taking all of their medicines not just their dementia medication. And I suppose until you do get that diagnosis you don't really think too much about their compliance" [CP_08]</i></p>
Behavioural regulation	Monitoring adherence	<ul style="list-style-type: none"> Weekly compliance aids (facilitator) 	<p><i>"When we'd be delivering it out [compliance aid] I would always try to either take it with me or have them maybe show me that it's empty" [CP_07]</i></p>
		<ul style="list-style-type: none"> Following up directly with patients/carers (facilitator) 	<p><i>"Because most of them tend to be weekly dispensed you have a lot of contact with them or their family members and you can check how things are going" [CP_07]</i></p> <p><i>"I suppose something with the carers just to ensure how compliant the patient is with the medicines, maybe just to check up with them...But I suppose it's the</i></p>

			<i>carer that kind of ensures that they take the medication so that kind of helps the patient” [CP_08]</i>
		<ul style="list-style-type: none"> Pharmacy computer system/checking PMR (facilitator) 	<p><i>“But again even looking through, if you are looking at a PMR to ensure they are ordering stuff monthly or every couple of months” [CP_06]</i></p> <p><i>“I would be looking at our patient medication records to see if they’re compliant” [CP_10]</i></p>
Social/professional role and identity	General	<ul style="list-style-type: none"> Professional identity – all part of the job (facilitator) 	<p><i>“I usually go the extra mile and get too maybe involved in the thing. You want to fix it. I think, as pharmacists, we tend to be like that” [CP_06]</i></p> <p><i>“I suppose that’s part of the job just to try and get the best outcome for the patient” [CP_08]</i></p>
		<ul style="list-style-type: none"> Accessibility of community pharmacists (facilitator) 	<i>“I suppose we are health care professionals and that probably puts us in a unique bracket in a way because we may deal with these patients more than any other health care professional. They might not see their GP as often” [CP_02]</i>
		<ul style="list-style-type: none"> Good working relationships with GPs (facilitator) 	<p><i>“Making sure that at the start of treatment that there is a good relationship between the prescriber and the pharmacist. That we know if the patient has been reviewed, we know what’s happening with their treatment, and that we are able to take a wee bit of responsibility for it” [CP_02]</i></p> <p><i>“Here I’d say we’ve got a good working relationship that we can check in with each other...so we’ve got a good understanding of what patients are out there and need a bit of extra support and help but I’d say we link in quite well” [CP_03]</i></p>
		<ul style="list-style-type: none"> Professional boundaries with GP (barrier) 	<i>“But with medicines management I kind of feel maybe GPs feel that that’s their job and that we’re encroaching on their territory slightly. I find that especially when we are in close proximity to a surgery we don’t want to feel like when we do the MURs [Medicines Use Reviews] like I would have to explain to them it’s replication not duplication” [CP_07]</i>
Beliefs about capabilities	Monitoring adherence	<ul style="list-style-type: none"> Lack of confidence in dealing with patients alone (barrier) 	<i>“I suppose if the patient was on their own and you were worried about them taking an antibiotic or getting maybe something new for like diabetes or something that I thought maybe they were going to have issues with, that would be a problem” [CP_08]</i>

		<ul style="list-style-type: none"> Lack of confidence in dealing with perceived complicated cases (barrier) 	<p><i>"I am confident in the routine ones, if you know what I mean...once it gets more complicated where they are really still struggling and no matter how clear you make it to them they are just incapable of grasping it. I find that quite difficult then, I think that starts getting out of my control. That is where I get a wee bit... I am out of my comfort zone" [CP_09]</i></p>
		<ul style="list-style-type: none"> Limitations to professional confidence - belief that control is lost once patient leaves pharmacy (barrier) 	<p><i>"We can be sure that we have given them the right medications with the right instructions and the right information, but after that it is beyond our control" [CP_05]</i></p>
		<ul style="list-style-type: none"> Limitations to professional confidence – conducting medication review (barrier) 	<p><i>"I would feel apprehensive about sitting down and having a medication review with someone like that because it's just so difficult..." [CP_07]</i></p>
Optimism		<ul style="list-style-type: none"> Multifaceted approach needed (barrier) 	<p><i>"There are so many things that can have an impact on that [appropriate medicines management]...we're kind of only one part in that really...it involves a lot of other parts coming together for that to happen" [CP_14]</i></p>
Beliefs about consequences	Medication Review, Monitoring adherence	<ul style="list-style-type: none"> Benefits acknowledged, e.g. improved patient outcomes, QOL (facilitator) 	<p><i>"Gives them that extended quality of life, where the disease doesn't impact so much on their lives day-to-day" [CP_01]</i></p> <p><i>"I suppose improved patient outcomes is the ultimate...that's what our job is to improve a patient's lifestyle and health overall. Prolong their life and prolong a good quality of life, which is more important. And probably keep them in their own home if possible" [CP_07]</i></p>
		<ul style="list-style-type: none"> Belief that adherence will be poor in PwD, with particular concern about overdose (barrier) 	<p><i>"...That they're going to take too much of their medication or they're not going to take enough of their medication...probably risks as well that they'll become confused and take their other medications as well so leading to hospitalisation..." [CP_03]</i></p> <p><i>"It's just being aware of those patients with dementia and how at risk they are and how important it is for them to actually take their medicines and that their not taking too much or taking everything" [CP_08]</i></p>

			<i>"Because you don't know if they're going to not use, or if they're going to overuse...My concern of it would also be the overdosing on medicines as well"</i> [CP_13]
Intentions	Not identified	<ul style="list-style-type: none"> • Positive intentions expressed to help dementia patients 	<i>"So I would hope I'm saying with confidence that if there's an issue, an intervention required, it always happens. It may not always happen just instantly; it may be that we'll say to the patient that I can't get through the doctor. I have to phone back after two, can we take your number and give you a ring then. So every intervention that is required should be carried out"</i> [CP_05]
Goals	Monitoring adherence	<ul style="list-style-type: none"> • Belief that dementia patients no more of a priority than other patient groups 	<i>"It's not just dementia patients just anybody in general"</i> [CP_03] <i>"I would consider them as patients that definitely need their medication sorted out as easy and as straight forward as possible, and the information always passed onto the carer. But I mean they're as much of a priority as anyone else"</i> [CP_08]
		<ul style="list-style-type: none"> • Dementia patients not a priority due to small proportion (barrier) 	<i>"Sometimes you just sort of shove it to the side and you focus more on the diabetes or the big ones, so to speak...I think what I said earlier, the fact that it's only about 5% of my patients. I think I am guilty of myself sometimes not prioritising as much as I should"</i> [CP_09] <i>"There's nothing above and beyond for a dementia patient...They don't form a big proportion of our patients so it's not my biggest priority. The dementia thing did cross my mind before but what isn't a primary issue probably here because it's such a small proportion of patients. But it's definitely still an issue. Something that could be done better"</i> [CP_12]
Reinforcement	Monitoring adherence	<ul style="list-style-type: none"> • Personal rewards in helping PwD (facilitator) 	<i>"The reward for me personally, yeah...I enjoy doing it because it's a personal thing, there's a difference there"</i> [CP_04]
		<ul style="list-style-type: none"> • Financial cost of making up weekly compliance aids (barrier) 	<i>"There's no money in those as such, like weekly dispensing isn't money for the pharmacy anymore. It's done at a cost to us. It's just to ensure patient compliance"</i> [CP_01]

			<i>"And now there's no actual fee or incentive given to the pharmacy to do that because I think possibly people were pushing a lot of them through some of those schemes years ago" [CP_02]</i>
Emotion	Monitoring adherence	<ul style="list-style-type: none"> Understanding of condition aids empathy (facilitator) 	<p><i>"So I think empathy with where they are and you try to understand...but in a way you can't...so you're trying to build that kind of understanding, but trying to learn off them as well of where they've been and where they're going" [CP_03]</i></p> <p><i>"And I feel empathy is important. I think it's a quality I have. It's an important quality that's probably overlooked a lot in pharmacy" [CP_07]</i></p>
		<ul style="list-style-type: none"> Greater concern when dealing with patients alone (barrier) 	<i>"There are times when I am nervous. If it is the patient themselves, sometimes you just don't know that what you're saying is going in. Sometimes you don't know if you've done a good job and they just look at you and they nod as if they fully understand and then they walk out the door and they haven't got a clue what you've just said" [CP_09]</i>
		<ul style="list-style-type: none"> Pressure from carers to dispense medication in weekly compliance aid (barrier) 	<i>"I'm getting very frustrated... I don't need this, you know. More fights on the phone...I start losing my temper and then I lose the plot" [CP_04]</i>
Environmental context and resources	Medication Review, Monitoring adherence	<ul style="list-style-type: none"> Pharmacy prescription ordering and delivery services (facilitator) 	<i>"I know pharmacies don't get paid for deliveries and you know but every pharmacy probably does deliveries, which is I think is drastically undervalued service by the NHS" [CP_07]</i>
		<ul style="list-style-type: none"> No access to patient's full medical record (barrier) 	<i>"A full medical history helps and it's not always possible in a community pharmacy when people are coming between pharmacies because, as of yet, we don't have national care records" [CP_01]</i>
		<ul style="list-style-type: none"> Time/work environment pressures (barriers) 	<p><i>"Unfortunately when it comes to those compliance aids I know that pharmacies do get quite busy with them and can only take on so many patients" [CP_02]</i></p> <p><i>"The only way I've found that you get a true picture is going to their home to see what the setup is and as a community pharmacist you feel very tied unless you do have that flexibility of double cover to actually get a true picture of what the situation is and people's homes" [CP_03]</i></p>

			<p><i>"In recent years we haven't done very many formal medicines management or medicines use reviews. Time being the main issue. We have great desire to do them, great intention to do them, but we just haven't found ourselves with an awful lot of time to do them" [CP_05]</i></p>
Social influences	Medication Review, Monitoring adherence	<ul style="list-style-type: none"> • Patient's family members/carers (facilitator) 	<p><i>"I suppose people who will have an influence on that will be people who have given us more information. So the family, the carer, the patient themselves, the GP. If there's a psychiatric nurse. All the people from whom you get your information because that information will inform the decision" [CP_05]</i></p> <p><i>"The main person that you would rely on the most to give you an opinion on how things were in situ would be the designated carer, whether that be the home help, or the son, or the husband, or the daughter, or the wife. Because outside of ourselves they'd obviously have the most contact with them" [CP_07]</i></p> <p><i>"And family members, they know the patient better than anyone, so they can advise you what is going to suit a particular patient better" [CP_09]</i></p>
		<ul style="list-style-type: none"> • Pharmacist's own family (facilitator) 	<p><i>"I guess I was just thinking about my own family. And that if someone received that diagnosis, you would want at least someone in the vicinity to be aware, even if it's just a neighbour to say look just in case you see anything, or you haven't seen them in a few days, it's just so that someone is aware really more than anything" [CP_01]</i></p> <p><i>"And the reason why I learn through experience is because my dad had dementia" [CP_04]</i></p> <p><i>"My granny had dementia so I suppose me working with other patients, it's maybe a little bit easier for me...because I have dealt with that in my own family" [CP_11]</i></p>
		<ul style="list-style-type: none"> • Pharmacy colleagues (facilitator) 	<p><i>"We've the support of each other. You know with the support in the pharmacy, in the branch, of each other, of our knowledge between ourselves" [CP_02]</i></p>

			<i>"I have probably adapted the way I treat them based on the more mature pharmacists watching them do it, see how they treated them, the interaction, and more or less copy them" [CP_12]</i>
		<ul style="list-style-type: none"> • Other healthcare professionals, particularly patient's GP (facilitator) 	<p><i>"I suppose if we noticed an adherence problem we would go back to the GP and we'd communicate between each other" [CP_03]</i></p> <p><i>"Your GPs, you work closely with them every day you'd know a lot of them, and there definitely wouldn't be any problem just ringing one up...or a certain GP if you knew that they prescribed it and having a quick chat with them...that definitely wouldn't be an issue" [CP_14]</i></p>
		<ul style="list-style-type: none"> • Social workers and formal carers (barriers) 	<i>"I suppose sometimes social workers can influence your decision. They can sometimes prompt the fact that the person might need a compliance aid. Care workers can do that as well. We can't be told do that, it has to be a decision that you come to yourself" [CP_02]</i>

Appendix 39. Healthcare professional (HCP) narratives based on target behaviours

TARGET BEHAVIOUR	PRESCRIBING
<i>Who needs to perform the behaviour?</i>	General Practitioners
<i>What do they need to do differently to achieve the desired change?</i>	Ensure they are prescribing <u>appropriately</u> for people with dementia. Special consideration must be given to potentially inappropriate medications/combinations identified during Phase 1 work
<i>When do they need to do it?</i>	At any time when prescribing a new or repeat medication for a dementia patient, which could be: <ul style="list-style-type: none"> - during a face-to-face consultation - following a telephone call - when signing off repeat prescriptions
<i>Where do they need to do it?</i>	In the GP surgery
<i>How often do they need to do it?</i>	Any time they are prescribing
<i>With whom do they need to do it?</i>	Alone or in conjunction with the patient and/or patient's carer (depending upon situation)

TARGET BEHAVIOUR	CONDUCTING MEDICATION REVIEW
<i>Who needs to perform the behaviour?</i>	General practitioners Community pharmacists
<i>What do they need to do differently to achieve the desired change?</i>	Conduct regular and comprehensive medication review* for dementia patients, following a structured and systematic process *Medication review will also include an assessment of appropriateness of prescribing and adherence
<i>When do they need to do it?</i>	During medication review appointment
<i>Where do they need to do it?</i>	In the GP surgery, pharmacy, or at the patient's home
<i>How often do they need to do it?</i>	Initial review following diagnosis Annual review thereafter?
<i>With whom do they need to do it?</i>	Alone* or with the patient and/or their carer *There may be some elements of medication review that could take place prior to GP/pharmacist discussion with patient and carer

TARGET BEHAVIOUR	MONITORING ADHERENCE
<i>Who needs to perform the behaviour?</i>	Community pharmacists
<i>What do they need to do differently to achieve the desired change?</i>	Ensure that they are regularly checking patient adherence to medication (PMR check, asking questions of patient and/or carers, checking previous compliance aid, making home visit) when they are dispensing medication for people with dementia
<i>When do they need to do it?</i>	Routinely during dispensing process
<i>Where do they need to do it?</i>	In the pharmacy and/or in the patient's home (in order to make an accurate assessment of adherence)
<i>How often do they need to do it?</i>	Monthly* *Home visit not required monthly, but could be arranged e.g. twice a year
<i>With whom do they need to do it?</i>	Alone, and with input from the patient and/or their carer

Appendix 40. Mapping of behaviour change techniques (BCTs) to key domains for inclusion in an intervention to improve medicines management for PwD in primary care

Theoretical domain	BCTs identified from Cane <i>et al.</i> (2015)	BCTs identified from Michie <i>et al.</i> (2008)	Selected BCTs as proposed intervention components (including reasons to justify exclusion of other BCTs)
<i>Knowledge</i>	<ol style="list-style-type: none"> 1. Health consequences 2. Biofeedback 3. Antecedents 4. Feedback on behaviour 	<ol style="list-style-type: none"> 5. Information regarding behaviour, outcome 	<p>Health consequences (BCT 1): HCPs will be provided with information detailing and emphasising the health benefits of performing the behaviour. There will need to be a focus on what will happen if the behaviour is performed and not performed.</p> <p><u>Reasons for not selecting other BCTs:</u></p> <p>BCT 2: not applicable as feedback about the body using an external monitoring device is unlikely to have an impact on the target behaviours.</p> <p>BCT 3: intervention would likely need to be tailored to individual HCPs to account for variation in emotions, cognitions, social and environmental situations that would predict performance of the behaviour.</p> <p>BCTs 4, 5: likely to require repeated administration and/or extended time periods to effect required changes in target behaviours.</p>
<i>Skills</i>	<ol style="list-style-type: none"> 1. Graded tasks 2. Behavioural rehearsal/practice 	<ol style="list-style-type: none"> 6. Goal/target specified: behaviour or outcome 7. Monitoring 	<p>Modelling/demonstration of behaviour by others (BCT 13): HCPs would be provided with a demonstration of how to</p>

	<ul style="list-style-type: none"> 3. Habit reversal 4. Body changes 5. Habit formation 	<ul style="list-style-type: none"> 8. Self-monitoring 9. Rewards; incentives (inc. self-evaluation) 10. Graded task starting with easy task 11. Increasing skills: problem-solving, decision-making, goal-setting 12. Rehearsal of relevant skills 13. Modelling/demonstration of behaviour by others 14. Homework 15. Perform behaviour in different settings 	<p>perform the behaviour during a typical encounter/consultation with a PwD and their carer.</p> <p><u>Reasons for not selecting other BCTs:</u> BCTs 1, 2, 3, 5, 7, 8, 10, 12, 14: likely to require repeated administration and/or extended time periods to effect required changes in target behaviours.</p> <p>BCT 4: Not applicable as a direct change in HCPs; body structure/functioning is unlikely to have an impact on the target behaviours.</p> <p>BCT 6: not possible to establish an acceptable goal/target in terms of the number of PwD that HCPs would perform target behaviours on because ideally the target behaviours should be performed on all PwD.</p> <p>BCT 9: not within scope of project to offer rewards/incentives.</p> <p>BCT 11: intervention would likely need to be tailored to individual HCPs to account for baseline variation in skill levels.</p> <p>BCT 15: not applicable as the intervention will target HCPs in their normal place of work.</p>
<i>Memory, attention and decision processes</i>	No BCTs linked to this domain	<ul style="list-style-type: none"> 1. Self-monitoring 2. Planning, implementation 3. Prompts, triggers, cues 	<p>Self-monitoring (BCT 1): HCPs would be asked to record whether they have performed the target behaviour(s) and review this at designated intervals to ensure that medication issues are actioned.</p>

Planning, implementation (BCT 2; equivalent to 'Action planning'): HCPs would be encouraged to plan in detail their performance of the target behaviour(s) in advance of performing them.

Reasons for not selecting other BCTs:

BCT 3: not within scope of project to introduce environmental or social stimuli with the purpose of prompting or cueing the target behaviours.

Behavioural regulation

1. Self-monitoring of behaviour
2. Goal/target specified: behaviour or outcome
3. Contract
4. Planning, implementation
5. Prompts, triggers, cues
6. Use of imagery

Self-monitoring of behaviour (BCT 1): see under 'Memory, attention and decision processes' domain.

Planning, implementation (BCT 4): see under 'Memory, attention and decision processes' domain.

Reasons for not selecting other BCTs:

BCT 2: not possible to establish an acceptable goal/target in terms of the number of PwD that HCPs would perform the target behaviours on, because ideally the target behaviours should be performed on all PwD.

BCT 3: not within the scope of the project to impose additional contractual obligations on HCPs.

BCT 5: see under 'Memory, attention and decision processes' domain.

				BCT 6: used in the context of implementing other BCTs through the use of planned images (visual, motor, sensory); not applicable in the context of this research project.
<i>Social/professional role and identity</i>	No BCTs linked to this domain	1.	Social processes of encouragement, pressure, support	Social processes of encouragement, pressure, support (BCT 1): HCPs would be encouraged to seek support/mentorship from other colleagues and/or primary healthcare professionals which would encourage and support them in engaging with PwD and their carers to improve medicines management. For example, community pharmacists would be encouraged to seek support from the local general practice-based pharmacist.
<i>Beliefs about capabilities</i>	1. Verbal persuasion to boost self-efficacy 2. Focus on past successes	3. 4. 5. 6. 7. 8. 9. 10. 11.	Self-monitoring Graded task, starting with easy task Increasing skills: problem-solving, decision-making, goal-setting Coping skills Rehearsal of relevant skills Social processes of encouragement, pressure, support Feedback Self-talk Motivational interviewing	Self-monitoring (BCT 3): see under 'Memory, attention and decision processes' domain. Social processes of encouragement, pressure, support (BCT 8): see under 'Social/professional role and identity' domain. <u>Reasons for not selecting other BCTs:</u> BCTs 1, 10: intervention would likely need to be tailored to individual HCPs to account for baseline variation in self-efficacy levels. BCT 2: not suitable due to potential variation in experience amongst HCPs (i.e. if HCPs do not have previous experience of performing the target behaviours then this BCT will not apply to them).

BCTs 4, 9: likely to require repeated administration and/or extended time periods to effect required changes in target behaviours.

BCTs 5, 6, 7: intervention would likely need to be tailored to individual HCPs to account for baseline variation in skills levels.

BCT 11: not within scope of project to offer motivational interviewing to individual HCPs.

Beliefs about consequences

- | | |
|---|--|
| 1. Emotional consequences | 11. Self-monitoring |
| 2. Salience of consequences | 12. Persuasive communication |
| 3. Covert sensitization | 13. Information regarding behaviour, outcome |
| 4. Anticipated regret | 14. Feedback |
| 5. Social and environmental consequences | |
| 6. Comparative imagining of future outcomes | |
| 7. Vicarious reinforcement | |
| 8. Threat | |
| 9. Pros and cons | |
| 10. Covert conditioning | |

Salience of consequences (BCT 2) and Social and environmental consequences (BCT 5): HCPs will be provided with information from HCPs, PwD and carers emphasising the social and environmental benefits of performing the behaviours. There will need to be a memorable focus on what will happen if the behaviour is performed and not performed.

Self-monitoring (BCT 11): see under 'Memory, attention and decision processes' domain.

Reasons for not selecting other BCTs:

BCT 1: emotional consequences of performing the target behaviours have not been established.

BCTs 3, 4: not applicable as intervention is focused on wanted behaviours as opposed to unwanted behaviours.

BCT 6: intervention would likely need to be tailored to individual HCPs as the imagining and comparing of future

outcomes of changed versus unchanged behaviour is likely to vary between individuals.

BCTs 7, 10, 14: likely to require repeated administration and/or extended time periods to effect required changes in target behaviours.

BCT 8: not within scope of project to implement future punishment or removal of reward as a consequence of HCPs performing an unwanted behaviour.

BCT 9: intervention would likely need to be tailored to individual HCPs because if advised to identify and compare pros and cons of performing the target behaviours, assessments are likely to vary between individuals.

BCT 12: difficult to have a credible source present evidence-based arguments in favour of or against the target behaviours as few interventions to date have examined clinically relevant outcomes.

BCT 13: intervention would likely need to be tailored to individual HCPs to account for baseline variation in skills levels when advising on how to perform the target behaviours.

<i>Goals</i>	1. Goal setting (outcome)	6. Goal/target specified:	Action planning (BCT 5): see under 'Memory, attention and decision processes' domain; equivalent to planning, implementation BCT.
	2. Goal setting (behaviour)	behaviour or outcome	
	3. Review of outcome goal(s)	7. Contract	

	<ol style="list-style-type: none"> 4. Review behaviour goals 5. Action planning (including implementation intentions) 	<ol style="list-style-type: none"> 8. Rewards, incentives (inc. self-evaluation) 9. Graded task, starting with easy task 10. Increasing skills: problem-solving, decision-making, goal-setting 11. Social processes of encouragement, pressure, support 12. Persuasive communication 13. Information regarding behaviour, outcome 14. Motivational interviewing 	<p>Social processes of encouragement, pressure, support (BCT 11): see under ‘Social/professional role and identity’ domain.</p> <p><u>Reasons for not selecting other BCTs:</u></p> <p>BCTs 1, 2, 6: not possible to establish an acceptable goal/target in terms of the target behaviours to be achieved or number of PwD that HCPs would perform target behaviours on because ideally the target behaviours should be performed on all PwD.</p> <p>BCTs 3, 4: not possible to review behaviour or outcome goals if acceptable goals not set/established (as per BCTs 1, 2 above).</p> <p>BCT 7: See under ‘Behavioural regulation’ domain.</p> <p>BCTs 8, 9, 10: See under ‘Skills’ domain.</p> <p>BCTs 12, 13: See under ‘Beliefs about consequences’ domain</p> <p>BCT 14: See under ‘Beliefs about capabilities’ domain</p>
<i>Reinforcement</i>	<ol style="list-style-type: none"> 1. Threat 2. Self-reward 3. Differential reinforcement 4. Incentive 5. Thinning 6. Negative reinforcement 	Domain not included in matrix	<p><u>Reasons for not selecting BCTs:</u></p> <p>BCT 1: see under ‘Beliefs about consequences’ domain.</p> <p>BCT 2: difficult to have a HCP reward self with material or other valued object(s) if effort and/or progress has been made in performing the target behaviours.</p>

	<ul style="list-style-type: none"> 7. Shaping 8. Counter conditioning 9. Discrimination training 10. Material reward 11. Social reward 12. Non-specific reward 13. Response cost 14. Anticipation of future rewards or removal of punishment 		<p>BCTs 3, 5, 6, 7, 8, 9, 13: not within scope of project to implement future punishment, removal of reward or reinforcement for performing or not performing target behaviours.</p> <p>BCTs 4, 10, 11, 12, 14: see under 'Skills' domain (equivalent to 'Rewards, incentives BCT).</p>
<i>Emotion</i>	<ul style="list-style-type: none"> 1. Reduce negative emotions 2. Emotional consequences 3. Self-assessment of affective consequences 4. Social support (emotional) 	<ul style="list-style-type: none"> 5. Stress management 6. Coping skills 	<p>BCT 4: encapsulated by 'Social processes of encouragement, pressure, support' BCT under 'Social/professional role and identity' domain.</p> <p><u>Reasons for not selecting BCTs:</u> BCTs 1, 3, 5, 6: intervention would likely need to be tailored to individual HCPs to account for variation in levels of emotions, stress and coping skills associated with performance of target behaviour.</p> <p>BCT 2: see under 'Beliefs about consequences' domain.</p>
<i>Environmental context and resources</i>	<ul style="list-style-type: none"> 1. Restructuring the physical environment 2. Discriminative (learned) cue 3. Prompts/cues 4. Restructuring the social environment 	<ul style="list-style-type: none"> 6. Environmental changes (e.g. objects to facilitate behaviour) 	<p><u>Reasons for not selecting BCTs:</u> BCTs 1, 6: not within the scope of the project to restructure HCPs' physical work environment.</p> <p>BCT 2: not within the scope of project to offer reward (e.g. monetary fee) for performing target behaviours.</p>

	5. Avoidance/changing exposure to cues for the behaviour		<p>BCT 3: see under ‘Memory, attention and decision processes’ domain.</p> <p>BCT 4: not within the scope of project to restructure HCPs’ social environment.</p> <p>BCT 5: not applicable as intervention is seeking to promote performance of target behaviours as opposed to avoiding/reducing exposure to cues for the target behaviours.</p>
<i>Social influences</i>	<ol style="list-style-type: none"> 1. Social comparison 2. Social support or encouragement (general) 3. Information about others’ approval 4. Social support (emotional) 5. Social support (practical) 6. Vicarious reinforcement 7. Restructuring the social environment 8. Modelling or demonstrating the behaviour 9. Identification of self as role model 	<ol style="list-style-type: none"> 11. Social process of encouragement, pressure, support 12. Modelling/demonstration of behaviour by others 	<p>Social support or encouragement (BCT 2)/ Social process of encouragement, pressure, support (BCT 11): see under ‘Social/professional role and identity’ domain.</p> <p>Modelling or demonstrating the behaviour/ Modelling/demonstration of behaviour by others (BCT 12): see under ‘Skills’ domain.</p> <p><u>Reasons for not selecting BCTs:</u></p> <p>BCT 1: difficult to draw meaningful comparisons between HCPs’ performance of target behaviours.</p> <p>BCT 3: difficult to establish PwD’s views on HCPs performing the target behaviours due to clinical heterogeneity amongst PwD in terms of comorbidities and medications used.</p> <p>BCTs 4, 5: encapsulated by BCT 2.</p>

10. Social reward

BCT 6: see under 'Beliefs about consequences' domain.

BCT 7: see under 'Environmental context and resources' domain.

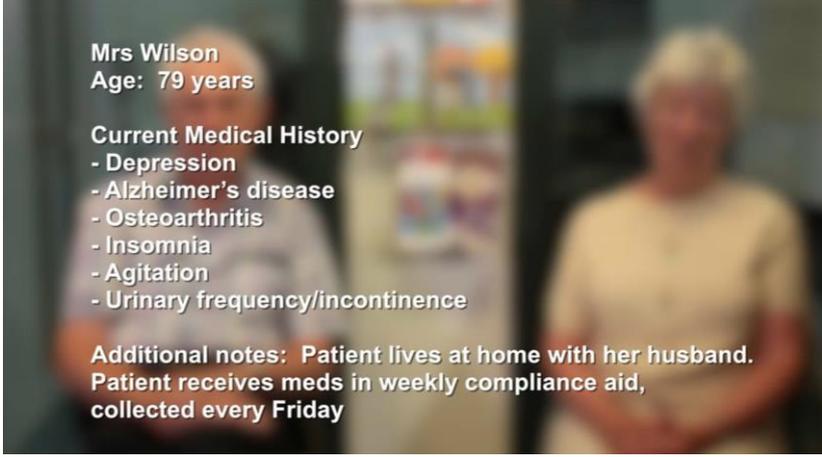
BCT 9: likely to require repeated administration and/or extended time periods to effect required changes in HCPs' behaviours.

BCT 10: see under 'Skills' domain (equivalent to 'Rewards, incentives BCT').

Appendix 41. Video stills

Medicines management for people
with dementia in primary care





Mrs Wilson
Age: 79 years

Current Medical History

- Depression
- Alzheimer's disease
- Osteoarthritis
- Insomnia
- Agitation
- Urinary frequency/incontinence

Additional notes: Patient lives at home with her husband. Patient receives meds in weekly compliance aid, collected every Friday



3. Quetiapine:
25mg tablets, Half tablet at 5pm

Antipsychotic medication use in people with dementia can increase cognitive decline as well as risk of cerebrovascular events and death.



Appendix 42. Community pharmacist invitation letter (v1, 20.03.2018)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

Dear <Name of Pharmacist>,

Study title: A feasibility study of an intervention to improve medicines management for people with dementia in primary care in Northern Ireland

We are writing to invite you to take part in the above named study. You previously participated in this project by taking part in a one-to-one interview with a researcher, and a task group, during which your views and experiences of managing medicines for people with dementia were explored. With all of the information that we have collected, we have developed an intervention to assist community pharmacists in overcoming some of the identified challenges encountered in achieving optimal medicines management for people with dementia. The intervention will be delivered through a short video (of approximately ten minutes' duration) demonstrating the conduct of a medication review and adherence checking between a community pharmacist, a patient with dementia, and their carer. A quick reference guide will also be provided. The intervention has been developed by a multidisciplinary research team from Queen's University Belfast, Trinity College Dublin, Belfast Health and Social Care Trust, Newcastle University, National University of Ireland Galway, and the Western Health and Social Care Trust.

We plan to run a feasibility study with community pharmacists to test how this intervention works in practice. Please find enclosed a study information sheet, which describes what taking part involves, and a consent form. If you have any queries, please do not hesitate to contact the Research Fellow (Dr. Laura Bedford), or any other member of the research team as detailed below. We will contact you by phone over the next week to discuss whether or not you would like to take part in this study.

Yours sincerely,

<Signature>

Prof. Carmel Hughes

Head of School of Pharmacy

<Signature>

Dr. Heather Barry

Lecturer in Pharmacy Practice

<Signature>

Dr. Laura Bedford

Research Fellow

On behalf of the research team:

Ms. Máiréad McGrattan, Prof. Cristín Ryan, Prof. Peter Passmore, Prof. Louise Robinson, Dr. Gerry Molloy, Ms. Carmel Darcy, Dr. Hilary Buchanan.

Contact details for more information:

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Head of School

School of Pharmacy

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Belfast, BT9 7BL

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Email: c.hughes@qub.ac.uk

Dr. Heather Barry

Lecturer in Pharmacy Practice

School of Pharmacy

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Telephone: 028 9097 2139

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Dr. Laura Bedford

Research Fellow

School of Pharmacy

Queen's University Belfast

97 Lisburn Road

Belfast, BT9 7BL

Telephone: 028 9097 2348

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Appendix 43. Community pharmacist information sheet (v1, 20.03.2018)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

COMMUNITY PHARMACIST INFORMATION SHEET

Study title: A feasibility study of an intervention to improve medicines management for people with dementia in primary care in Northern Ireland

You are being invited to take part in a research study. Before you decide whether you would like to take part, please take the time to read this information. It is important that you understand why this research is taking place and what you will be asked to do if you agree to participate. If there is anything that is unclear, or if you would like more information, please contact the research team (see below for details). All communication will be treated confidentially.

What is the purpose of the study?

People with dementia (PWD) are unique in terms of their medication needs compared with the general older population. Their impaired cognition and communication skills, together with the presence of behavioural and psychological symptoms, generate additional challenges in medication adherence. There has been limited research on medicines management in PWD, particularly for those residing in primary care, which constitutes the vast majority of PWD. This study forms part of an ongoing research project in which we have conducted interviews with GPs, community pharmacists, PWD and their carers. With the information we have collected, along with the literature on prescribing interventions, we have developed an intervention to assist community pharmacists in overcoming some of the identified challenges that were encountered in achieving adequate medicines management for people with dementia.

Why have I been chosen?

You have been asked to take part because you were previously identified as a community pharmacist who regularly dispenses medicines for PWD and you participated in this research study by taking part in a one-to-one interview with a researcher and a task group.

Do I have to take part?

It is up to you to decide whether or not to take part in this study. If you decide not to participate we will respect your decision and will make no further attempts to contact you. If you do decide to take part, you will be asked to sign a consent form, and you will be given a copy of the consent form to keep. The original form will be kept securely at the School of Pharmacy, Queen's University Belfast. You are free to withdraw from the study at any stage without giving a reason.

What will happen if I take part?

The Research Fellow (Laura Bedford) will contact you one week after you receive this information sheet to discuss if you might be interested in participating in the study and to answer any questions. If you wish to participate in the study, she will arrange to meet with you at the pharmacy at a time that suits you. During this meeting, you will be given a study file containing the necessary documentation.

You will be asked to recruit a total of five patients with dementia into the study and perform a medication review and adherence check during a consultation with these patients and their carers. At the end of the study you will be asked to take part in an interview where we will ask about your experience of taking part in the intervention. The interview will be audio-recorded, transcribed and analysed by the research team. We will also ask you to record the number of patients screened, approached and recruited. You will be asked to provide information from recruited patients' pharmacy medication records (e.g. details of their regular medicines) to the researchers with patients' consent at baseline (date of medication review) and at one month after the review. On completion of the study, you will be offered a certificate of participation which could be added to your continuing professional development portfolio. You can also receive up to £1050.00 for taking part.

What are the possible risks and disadvantages of taking part?

There is a risk that poor practice may be identified during the feasibility 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. This may involve informing the appropriate professional regulatory body.

What are the benefits of taking part in the study?

Participation in this study will help to determine if the intervention needs to be refined before further evaluations can be undertaken to assess the effectiveness of the intervention in improving medicines management for PWD. The study will also contribute to the development of the evidence base regarding the role of pharmacists in the care of people with dementia

What will happen if I decide I no longer wish to take part?

You are free to withdraw from the study at any time. You do not have to give a reason why. However, if you do decide to withdraw, the data collected prior to your withdrawal from the study may still be included in the final analysis. The £1050.00 honorarium will only be paid to you in full on condition that: five patients who meet inclusion criteria, and their carers, are recruited into the study; medication reviews and adherence checking are completed during a consultation with these patients and their carers; the requested data are returned to the researchers and you take part in an interview at the end of the study.

Who will have access to my information?

All information collected as part of the study will be kept strictly confidential. Interview transcripts will be anonymised and your name will not appear in any publications. All identifiable information (e.g., consent forms) 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 General Data Protection Regulations (GDPR). In order to ensure that studies involving human participants are carried out to a high standard, the University is required to monitor on-going research studies and as a result, staff from Queen's University may need to review the information collected as part of this research.

What will happen to the study results?

The findings from this study will be used as part of a research project at Queen's University Belfast. Data may be published in academic journals and presented at conferences. Although quotes from the interviews may be used, you will not be identified personally in any report or publication. You will be provided with a summary of the results at the end of the study.

Who is organising and funding the study?

The study is organised by the School of Pharmacy, Queen's University Belfast. It is funded by the Northern Ireland Public Health Agency and The Atlantic Philanthropies.

Who has reviewed the study?

This study has been reviewed and given a favourable opinion by the Office for Research Ethics Committees Northern Ireland (18/NI/0100). The project has been peer reviewed by independent reviewers on behalf of the Public Health Agency.

What happens if there is a problem?

If you are unhappy with any aspect of the study, or the way you have been approached or treated during the course of this study, please contact the Chief Investigator, Professor Carmel Hughes.

Further information

If you would like more information, would like this leaflet in a different format, or have any queries about the study, please feel free to contact the research team:

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Head of School

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Dr. Laura Bedford

Research Fellow

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Belfast, BT9 7BL

Telephone: 028 9097 2348

Email: L.Bedford@qub.ac.uk

Thank you for considering taking part in this study

Appendix 44. Community pharmacist consent form (v1, 20.03.2018)



**QUEEN'S
UNIVERSITY
BELFAST**

School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

Participant Study ID: _____

COMMUNITY PHARMACIST CONSENT FORM

Study title: A feasibility study of an intervention to improve medicines management for persons with dementia in primary care in Northern Ireland

Please initial box

1. I confirm that I have read and understood the information sheet (<date>, <version number>) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. I understand what the study involves.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and that this will not affect my legal rights.
3. I agree to persons with dementia, and their carers, who attend my pharmacy being recruited into the study and I agree to performing medication reviews and adherence checking with the patients recruited.
4. I agree to share data with the researchers from recruited patients' medication records at the agreed time points (baseline and one month after the medication review) subject to patients providing written informed consent.

5. I agree to take part in an interview at the end of the study. I understand that quotes from the interview may be reproduced in reports and papers, but that confidentiality and anonymity will be maintained and it will not be possible to identify me in any publications or presentations.
6. I understand that what is discussed during the interview is confidential with the exception that if poor professional practice is identified, the researcher is legally obliged to pass on this information to the Chief Investigator who may refer it to the appropriate regulatory authority.
7. I understand that my personal information (including consent forms) will be held securely in the School of Pharmacy, Queen's University Belfast and handled in accordance with the provisions of the General Data Protection Regulations.
8. I understand that data collected during the study may be looked at by authorised individuals from Queen's University Belfast and from regulatory authorities, for auditing purposes. I give permission for these individuals to have access to this information.
9. I agree to take part in the above study.

Name of Participant (Please print)	Date	Signature
---------------------------------------	------	-----------

Name of Researcher (Please print)	Date	Signature
--------------------------------------	------	-----------

When completed: one copy for participant and one copy for researcher

Appendix 45. Patient screening information sheet (v1, 09.05.2018)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

PATIENT SCREENING INFORMATION SHEET

Study title: A feasibility study of an intervention to improve medicines management for people with memory problems in primary care in Northern Ireland

A research study is taking place in your local pharmacy <Pharmacy name>, which is being run with Queen's University Belfast. The purpose of the study is to help people with memory problems to manage their medicines. At this stage of the study, we are speaking to people who have come to our pharmacy to see if they might be eligible to take part. Before you decide whether or not you would like your pharmacist to check if you can take part in this study, it is important that you understand what this will involve. If anything is unclear, please speak with your pharmacist, or contact the research team, who can answer any questions you have.

Why are we doing this study?

We know from other research studies that some people with memory problems find it difficult to manage the medicines that have been prescribed for them by their GP and dispensed by their community pharmacist (chemist). We have put together a plan to try to help people manage their medicines better. This plan involves meeting with your pharmacist to talk about your medicines. Your pharmacist may recommend some changes that your GP could make to your

prescription. Your carer or family member will come to the appointment with you.

Why has my pharmacist told me about the study?

We have approached you because you take medicines that help with memory problems and you take four or more regular medicines.

Do I have to take part?

It is up to you to decide if you would like your pharmacist to check if you are eligible to take part in this study. If you would prefer that this check does not take place, you do not have to say why and it will not affect your normal care. We will respect your decision and will make no further attempts to contact you. It will not affect the health care you receive in any way.

What will I be asked to do?

If you would like your pharmacist to check whether you can take part in the study, you will be asked to sign a consent form to say that you are happy for your pharmacist to contact your GP. We will ask your GP to check if you can take part. You will be given a copy of the consent form to keep.

After you have signed your consent form, your pharmacist will send a letter to your GP telling them about the study. Your GP will also be given a copy of your consent form. Your GP will contact your pharmacist to let them know whether or not you are eligible to take part.

Who is organising and funding the research?

The study is organised by the School of Pharmacy, Queen's University Belfast. It is funded by the Northern Ireland Public Health Agency and The Atlantic Philanthropies.

Who has reviewed the study?

All studies are checked by a group of independent people called a Research Ethics Committee. They make sure that the study protects your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Office for Research Ethics Committees Northern Ireland (18/NI/0100). The project has also been reviewed by independent reviewers on behalf of the Public Health Agency.

What happens if there is a problem?

If you are unhappy about any aspect of the study, or the way you have been approached or treated, please contact the Chief Investigator, Professor Carmel Hughes on 028 9097 2147.

What should I do now?

Your pharmacist will ask you to complete a consent form to confirm that you are happy for them to contact your GP to check that you are eligible to take part. Once your pharmacist has heard back from your GP, they will contact you to let you know if you can take part. If you are able to take part, your pharmacist will tell you more about the study and what taking part would involve.

How can I contact you?

You can contact, <Pharmacist name>, your pharmacist by email or phone:

Tel: <Pharmacy telephone number> or **Email:** <Pharmacy/pharmacist email address>

You can also contact Laura, the researcher:

Tel: 028 9097 2348 or **Email:** L.Bedford@qub.ac.uk

Thank you for considering taking part in this study

Appendix 46. Assessment of patient capacity checklist (v1, 20.03.2018)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

ASSESSMENT OF PATIENT CAPACITY CHECKLIST

Study title: A feasibility study of an intervention to improve medicines management for people with memory problems in primary care in Northern Ireland

Yes/No

1. Does the patient understand that they can consent to or refuse to participate in the study?
2. Does the patient understand what the research is about?
3. Does the patient understand and weigh-up the benefits and risks of agreeing or refusing to take part?
4. Has the patient communicated their decision to you in any way?

If the answer is YES to each of these items, then the patient is judged to have the capacity to consent to or refuse to take part in the study. If they wish to participate proceed with taking informed consent.

If the answer is NO to any of the first three items above, then the patient is judged NOT to have the capacity to consent to or to refuse to take part in the study.

Checklist completed by: _____

Date: _____

Appendix 47. Patient screening consent form (v1, 09.05.2018)



**QUEEN'S
UNIVERSITY
BELFAST**

School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086

F 028 9024 7794

Participant Study ID: _____

PATIENT SCREENING CONSENT FORM

Study title: A feasibility study of an intervention to improve medicines management for people with memory problems in primary care in Northern Ireland

**Please
initial box**

1. I have read (or had read to me) and understood the information sheet (<date>, <version number>) for the above study. I have had the opportunity to consider the information and ask any questions. I understand what the study involves.
2. I understand that by signing this form I am agreeing to the pharmacist contacting my GP to confirm my eligibility to participate.
3. I understand that I am free to contact my pharmacist or a member of the research team should I have any questions.
4. I understand that checking my eligibility does not oblige me to participate in this study.

Name of Participant

(Please print)

Date

Signature

Name of Pharmacist
(Please print)

Date

Signature

When completed: one copy for participant, one copy for researcher, one copy

Appendix 48. GP screening letter (v1, 09.05.2018)

<To be printed on community pharmacy-headed paper>

<GP name and address>

<Date>

Dear <GP name>,

Re: A feasibility study of an intervention to improve medicines management for people with dementia in primary care in Northern Ireland

I am writing to inform you that your patient **[patient name inserted here]** has consented to eligibility screening for the above study, which is taking place in a community pharmacy in your local area **[insert pharmacy name here]**.

As part of the study, an intervention to assist community pharmacists in achieving optimal medicines management for people with dementia has been developed. The intervention is delivered through a short video demonstrating the conduct of a medication review and adherence checking between a community pharmacist, a patient with dementia, and their carer. A quick reference guide is also provided. The intervention has been developed by researchers at Queen's University Belfast. A feasibility study is being conducted with community pharmacists to test how the intervention works in practice. I am taking part in this study and have been asked to recruit a total of five patients with dementia into the study and perform a medication review and adherence check during a consultation with these patients and their carers. After the consultation, I will send you a letter and a pro forma document detailing any proposed recommendations following the review.

In order to take part, patients must have a diagnosis of **mild-moderate dementia**. If eligible, **[patient name inserted here]** and their carer will attend a medication review and adherence check at **[pharmacy name here]**. A copy of the patient's screening consent form is enclosed for your records. I have also enclosed an eligibility checklist and would be very grateful if you could complete this checklist to confirm if **[patient name inserted here]** is eligible, and return the checklist to me using the pre-paid envelope provided.

If you require any further information, or wish to discuss, please do not hesitate to contact me by telephone: <Pharmacy telephone number> or by email: <Pharmacist email address>.

Alternatively, if you wish to speak with a member of the research team who developed the study, you can contact the Chief Investigator, Professor Carmel Hughes, at Queen's University Belfast on 028 9097 2147 or c.hughes@gub.ac.uk.

Yours Sincerely,

<Signature>

<Printed Name of Pharmacist> at <Printed Name of Pharmacy>

Appendix 49. Patient eligibility screening checklist to be used by GPs (v1, 09.05.2018)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

SCREENING CHECKLIST

Study title: A feasibility study of an intervention to improve medicines management for people with memory problems in primary care in Northern Ireland

PATIENT ELIGIBILITY

Please answer the following questions when determining the patient's eligibility to participate in the above study:

PATIENT CHARACTERISTICS

Yes/No

1. Does the patient have a diagnosis of mild-moderate dementia?
2. Is the patient capable of undertaking a medication review with a pharmacist and a separate interview with a researcher?

If the answer is YES to all of the questions above, then the patient is eligible to participate in the study. Please inform the pharmacist whether or not the patient is eligible using the contact details provided below.

PHARMACIST CONTACT DETAILS (to be completed by Pharmacist)

Name: _____

Telephone number: _____

Appendix 50. Patient and carer invitation letter (v1, 20.03.2018)

<To be printed on pharmacy headed paper>

<Date>

Dear **[write patient and carers names here]**,

I am writing to you as researchers from Queen's University Belfast are running a study to help people with memory problems to manage their medicines. We are speaking to a number of people who have visited our pharmacy to ask if they would be interested in taking part in this study.

I have enclosed an information leaflet, which tells you what taking part in the study would mean. As part of the study, you will both meet me at the pharmacy at a time that suits you. First, a researcher from Queen's University Belfast will complete some surveys with you. After you have completed the surveys, we will talk about your medicines and discuss whether you are getting the best from them. You will be asked to bring your medicines with you. The appointment will last about an hour. Two weeks after the appointment, the same researcher will visit you in your home at a suitable time for you to interview you both and ask what you thought of the appointment. You will each receive £50 for taking part in an interview. One month after your appointment, the researcher will visit you again and you will complete the same surveys that you did at the appointment. I have enclosed a leaflet, which tells you what taking part in the study would involve, and some more detailed information on what will happen during the medication review.

It is important that you are fully aware that taking part in this study is voluntary. You do not have to take part if you do not want to and you do not have to give a reason why. Your care will not be affected if you decide not to take part.

If you require further information, you can contact me directly on <Pharmacy telephone number> or the researcher, Dr. Laura Bedford, on 028 9097 2348. We will be happy to answer any questions you have.

Yours Sincerely,

<Signature>

<Printed Name of Pharmacist> at <Printed Name of Pharmacy>

On behalf of the research team:

Prof. Carmel Hughes, Dr. Heather Barry, Dr. Laura Bedford, Ms. Máiréad McGrattan, Prof. Cristín Ryan, Prof. Peter Passmore, Prof. Louise Robinson, Dr. Gerry Molloy, Ms. Carmel Darcy, Dr. Hilary Buchanan

Appendix 51. Patient information sheet – after screening (v1, 09.05.2018)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

PATIENT INFORMATION SHEET

Study title: A feasibility study of an intervention to improve medicines management for people with memory problems in primary care in Northern Ireland

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 done and what you will be asked to do. If anything is unclear, please contact the research team who can answer any questions you have.

Why are we doing this study?

We know from other research studies that some people with memory problems find it difficult to manage the medicines that have been prescribed for them by their GP and dispensed by their community pharmacist (chemist). We have put together a plan to try to help people manage their medicines better. This plan involves meeting with your pharmacist to talk about your medicines. Your pharmacist may recommend some changes that your GP could make to your prescription. Your carer or family member will come to the appointment with you.

Why have I been chosen?

We have asked you to take part because you are living in your own home and are taking four or more medicines every day.

Do I have to take part?

It is up to you to decide if you would like to take part in this study. If you do decide to take part, you will be asked to sign a consent form at your appointment at the pharmacy, and you will be given a copy of the form to keep.

You can stop taking part in the study at any time. You do not have to say why and it will not affect your normal care. If you decide not to take part we will respect your decision and will make no further attempts to contact you. This will not affect the health care you receive in any way.

What will I be asked to do if I take part?

You will be asked to attend an appointment at your local pharmacy that you usually go to. It will be held at a suitable time for you and your carer or family member. At the start of the appointment, a researcher from Queen's University Belfast will complete some surveys with you, which ask about taking your medicines, your quality of life, and looking after your health. Your carer or family member will complete some surveys too. After the surveys are completed, you will talk with your pharmacist about your medicines. The appointment will last about an hour. After the appointment, your pharmacist will send a letter and form to your GP telling them what you talked about. Your pharmacist might recommend some changes that could be made to your medicines. It is important for you to know that pharmacists cannot make changes to a patient's prescription. Any suggested changes have to be checked and made by your GP. The GP might make the changes or they might decide that the changes are not needed at this time.

Two weeks after the appointment, the researcher will visit you at home to ask you what you thought of the appointment. This interview will be audio recorded. It is important that we find out this information to see if the pharmacist appointment is helpful to people. You will be paid £50 for taking part in this interview. What you say to the researcher will be kept confidential and your pharmacist will not be told anything that you say in the interview. One month

after your appointment with the pharmacist, the researcher will visit you again and you will complete the same surveys for a second time.

We will ask your pharmacist what they thought of the appointment. They might talk about problems that you discussed in relation to your medicines and any changes they suggested making to your medicines. You will not be identified in any reports or publications.

What are the risks or disadvantages of taking part?

There is little risk to you if you take part in the study. It is possible that taking part may make you think about your medicines and the conditions for which you take your medicines. If you find this distressing, you can stop at any time.

What will happen if I decide I no longer wish to take part?

You are free to stop taking part in the study at any time and you do not have to say why. If you decide to stop taking part, the information recorded up until the time you leave 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.

What are the benefits of taking part?

Taking part will give you an opportunity to discuss your medicines with a pharmacist (chemist). You will also be providing us with information that will help us to see if the pharmacy appointments work and improve the service for other people in the future.

What will happen to the information I give you?

All information will be kept strictly confidential and will only be accessible to the research team. Your name will not appear in any publications or reports. Information collected during the study, including your signed consent forms, will be stored securely at Queen's University Belfast. These will be kept for five years and then destroyed. This is required by law. However, if you say something during the study that suggests that you have had the wrong

treatment or that a healthcare professional has not acted in a proper way, then we may need to report this to the healthcare professional who cares for you, or to another authority.

In order to make sure that studies involving patients are carried out to a high standard, the University will sometime do checks on studies that are on-going. This means staff from Queen's University Belfast may need to see the information collected. If this happens, you will not be identified in any way. All of your information will be kept be strictly confidential.

What will happen to the results of the study?

The findings from this study will be used as part of a research project at Queen's University Belfast. The results may be published in academic journals or used in talks. We may use quotes from what you told the researcher in your interview but your name will not be given with any of the quotes. We will send you a summary of the results when the study has finished.

Who is organising and funding the research?

The study is organised by the School of Pharmacy, Queen's University Belfast. It is funded by the Northern Ireland Public Health Agency and The Atlantic Philanthropies.

Who has reviewed the study?

All studies are checked by a group of independent people called a Research Ethics Committee. They make sure that the study protects your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Office for Research Ethics Committees Northern Ireland (18/NI/0100). The project has also been reviewed by independent reviewers on behalf of the Public Health Agency.

What happens if there is a problem?

If you are unhappy about any aspect of the study, or the way you have been approached or treated during the course of this study, please contact the Chief Investigator, Professor Carmel Hughes on 028 9097 2147.

What should I do now if I would like to take part?

Your pharmacist will call you seven days after they have sent you this information to discuss whether you would like to take part in the study. If you would like to speak with someone sooner, you can contact your pharmacist or the researcher.

How can I contact you?

You can contact, <Pharmacist name>, your pharmacist by email or phone:

Tel: <Pharmacy telephone number> or **Email:** <Pharmacist email address>

You can also contact Laura, the researcher:

Tel: 028 9097 2348 or **Email:** L.Bedford@qub.ac.uk

Thank you for considering taking part in this study

Appendix 52. Carer information sheet – after screening (v2, 09.05.2018)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

CARER INFORMATION SHEET

Study title: A feasibility study of an intervention to improve medicines management for people with memory problems in primary care in Northern Ireland

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 done and what you will be asked to do. If anything is unclear, please contact the research team who can answer any questions you have.

Why are we doing this study?

We know from other research studies that some people with memory problems find it difficult to manage the medicines that have been prescribed for them by their GP and dispensed by their community pharmacist (chemist). We have put together a plan to try to help people manage their medicines better. As part of this plan, you and your family member/person you care for will meet with your pharmacist to talk about the person's medicines. The pharmacist may recommend some changes that their GP could make to their prescription.

Why have I been chosen?

We have asked you to take part because you are the family member or carer of a person with memory problems and you help them with their medicines.

Do I have to take part?

It is up to you to decide if you would like to take part in this study. If you do decide to take part, you will be asked to sign a consent form at the appointment at the pharmacy, and you will be given a copy of the form to keep.

You can stop taking part in the study at any time. You do not have to say why and it will not affect your health care. If you decide not to take part we will respect your decision and will make no further attempts to contact you. This will not affect the health care you receive in any way.

What will I be asked to do if I take part?

You will be asked to attend an appointment at the local pharmacy that you usually go to. It will be held at a suitable time for you and the person you care for. We will let the person's GP know that they are part of this study.

At the start of the appointment, a researcher from Queen's University Belfast will complete some surveys with you. One survey will ask you about your experiences of looking after the health of the person you care for. The other two surveys ask about the symptoms that the person you care for may experience and their quality of life. Your family member/person you care for will complete some surveys too. The surveys will ask them about taking their medicines, their quality of life, and looking after their health. After the surveys are completed, you will both talk with your pharmacist about the person's medicines. The appointment will last about an hour. After the appointment, the pharmacist will send a letter and form to the person's GP telling them what you talked about. The pharmacist might recommend some changes that could be made to their medicines. It is important for you to know that pharmacists cannot make changes to a patient's prescription. Any suggested changes have to be checked and made by a patient's GP. The GP might make the changes or they might decide that the changes are not needed at this time.

Two weeks after the appointment, the researcher will visit you both to ask you what you thought of the appointment. This interview will be audio recorded. It is important that we find out this information to see if the pharmacist appointment is helpful to people. What you say to the researcher will be kept confidential and

your pharmacist will not be told anything that you say in this interview. You will each receive £50 for taking part in an interview. One month after your appointment with the pharmacist, the researcher will visit you again and you will complete the same surveys.

We will ask your pharmacist what they thought of the appointment. They might talk about problems that you discussed in relation to the person your care for/family member's medicines and any changes they suggested making to their medicines. You will not be identified in any reports or publications.

What are the risks or disadvantages of taking part?

There is little risk to you if you take part in the study. It is possible that taking part may make you think about the person your care for/family member's medicines and the conditions for which they take their medicines. If you find this distressing, you can stop at any time.

What will happen if I decide I no longer wish to take part?

You are free to stop taking part in the study at any time and you do not have to say why. If you decide to stop taking part, the information recorded up until the time you leave the study may still be included in the study.

What are the benefits of taking part?

Taking part will give you an opportunity to discuss the medicines of the person you care for with a pharmacist (chemist). You will also be providing us with information that will help us to see if the pharmacy appointments work and improve the service for other people in the future.

What will happen to the information I give you?

All information will be kept strictly confidential and will only be accessible to the research team. Your name will not appear in any publications or reports. Information collected during the study, including your signed consent forms, will be stored securely at Queen's University Belfast. These will be kept for five years and then destroyed. This is required by law. However, if you say something during the study that suggests that the person you care for has had

the wrong treatment or that a healthcare professional has not acted in a proper way, then we may need to report this to the healthcare professional who cares for the person, or to another authority.

In order to make sure that studies involving patients are carried out to a high standard, the University will sometime do checks on studies that are on-going. This means staff from Queen's University Belfast may need to see the information collected. If this happens, you will not be identified in any way. All of your information will be kept strictly confidential.

What will happen to the results of the study?

The findings from this study will be used as part of a research project at Queen's University Belfast. The results may be published in academic journals or used in talks. We may use quotes from what you told the researcher in your interview but your name will not be given with any of the quotes. We will send you a summary of the results when the study has finished.

Who is organising and funding the research?

The study is organised by the School of Pharmacy, Queen's University Belfast. It is funded by the Northern Ireland Public Health Agency and The Atlantic Philanthropies.

Who has reviewed the study?

All studies are checked by a group of independent people called a Research Ethics Committee. They make sure that the study protects your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Office for Research Ethics Committees Northern Ireland (18/NI/0100). The project has also been reviewed by independent reviewers on behalf of the Public Health Agency.

What happens if there is a problem?

If you are unhappy about any aspect of the study, or the way you have been approached or treated during the course of this study, please contact the Chief Investigator, Professor Carmel Hughes on 028 9097 2147.

What should I do now if I would like to take part?

The pharmacist will call you seven days after they have sent you this information to discuss whether you would like to take part in the study. If you would like to speak with someone sooner, you can contact the pharmacist or the researcher.

How can I contact you?

You can contact, <Pharmacist name>, your pharmacist by email or phone:

Tel: <Pharmacy telephone number> or **Email:** <Pharmacist email address>

You can also contact Laura, the researcher:

Tel: 028 9097 2348 or **Email:** L.Bedford@qub.ac.uk

Thank you for considering taking part in this study

**Appendix 53. Medication review information for patients and carers (v2,
09.05.2018)**



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

Reviewing your medicines

You have been invited to a meeting with your pharmacist to discuss whether you are getting the best from your medicines. This meeting is called a **medication review**. Your carer or family member will attend this meeting with you.

At this meeting your pharmacist will:

- Check all the medicines you are taking and check what they are for
- Check that you understand why you are taking your medicines
- Find out how you feel about taking your medicines
- Check that you still need all the medicines you are taking
- Ask whether you are having problems with any of your medicines
- Ask whether you have had or currently have any risk factors for developing a side effect from your medicines.

Involving you:

It is your right to be involved in making choices about your medicines. People often find they are happier with their care, and more likely to stick with any treatments or care plans, when they make decisions jointly with their healthcare professional.

Involving your carer or family member:

At the meeting, your carer or family member can be involved in decisions about your medicines if you want them to be.

Before you see your pharmacist:

- Write down any questions you want to ask. You can do this with your carer or family member.
- Think about what you both would like to get out of the meeting.

When you see your pharmacist:

- Ask if you need more information or if you don't understand something.
- Let them know if you need information in a different way, such as large print.
- If you don't understand any words, you can ask for the pharmacist to write them down and explain them to you.
- If you think it might be helpful, you can take notes, or you can ask your carer or family member to take notes.
- Check what should happen next, and when.
- Find out who to contact if you have any problems or questions.

After the meeting:

- When the meeting is over, your pharmacist will send a letter and form to your GP to tell them what you talked about. The pharmacist might suggest some changes that your GP could make to your medicines.
- It is important for you to know that pharmacists cannot make changes to your prescription. Any suggested changes have to be checked and made by your GP as they will have access to your full medical record.

- Your GP might make the changes or they might decide that the changes are not needed at this time. If you want to discuss this further with your GP, you can make an appointment to go and see them at the practice.

Appendix 54. Patient consent form (v1, 09.05.2018)



**QUEEN'S
UNIVERSITY
BELFAST**

School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

Participant Study ID: _____

PATIENT PARTICIPANT CONSENT FORM

Study title: A feasibility study of an intervention to improve medicines management for people with memory problems in primary care in Northern Ireland

**Please
initial box**

1. I have read (or had read to me) and understood the information sheet (<date>, <version number>) for the above study. I have had the opportunity to consider the information and ask any questions. I understand what the study involves.
2. I agree to have my medicines reviewed and checked by my pharmacist and to my carer or family member being present.
3. I understand that my pharmacist cannot make changes to my prescription. My pharmacist can suggest changes, which have to be checked and made by my GP. The GP might make the changes or they might decide that the changes are not best for me at this time.
4. I agree to allow my pharmacist to share information from my pharmacy medication record with the researchers at the time of my appointment and one month after my appointment.
5. I agree to an interview with the researcher about my appointment with the pharmacist. I agree to the interview being audio-recorded. I understand that quotes from the

interview might be used in reports and papers but it will not be possible to identify me in any publications.

6. I understand that what is discussed in the interview with the researcher is confidential with the exception that if I disclose information that indicates poor practice by a healthcare professional, the researcher is legally obliged to tell the Chief Investigator.
7. I agree to my GP being informed that I am taking part in this study and to my GP being informed if I become upset or distressed during the study.
8. I agree to allow my pharmacist to provide feedback to the researchers on the medication review appointment.
9. I understand that I may stop taking part in the study at any time without giving a reason. If I stop taking part, it will not affect my normal medical care.
10. I understand that my personal information (including consent forms) will be kept confidential and stored safely in the School of Pharmacy at Queen's University Belfast. I am aware that results from the study will be anonymous.
11. I understand that information collected during the study may be looked at by authorised individuals from Queen's University Belfast. I give permission for these individuals to have access to this information.
12. I agree to take part in this study.

Name of Participant (Please print)	Date	Signature
---------------------------------------	------	-----------

Name of Pharmacist (Please print)	Date	Signature
--------------------------------------	------	-----------

When completed: one copy for participant, one copy for researcher and one copy for pharmacist; one copy for GP

Appendix 55. Carer consent form (v2, 09.05.2018)



School of Pharmacy
Queen's University Belfast
Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

T 028 9097 2086
F 028 9024 7794

Participant Study ID: _____

CARER PARTICIPANT CONSENT FORM

Study title: A feasibility study of an intervention to improve medicines management for people with memory problems in primary care in Northern Ireland

**Please
initial box**

1. I have read and understood the information sheet (<date>, <version number>) for the above study. I have had the opportunity to consider the information and ask any questions. I understand what the study involves.
2. I agree to attend the medication review appointment with the pharmacist
3. I understand that the pharmacist cannot make changes to prescription of the person I care for. The pharmacist can suggest changes, which have to be checked and made by the GP. The GP might make the changes or they might decide that the changes are not best at this time.
4. I agree to meet with a researcher to talk about the appointment with the pharmacist. I agree to the meeting being audio-recorded. I understand that quotes from the meeting might be used in reports and papers but it will not be possible to identify me in any publications.

5. I understand that what is discussed in the meeting is confidential with the exception that if I disclose information that indicates poor practice by a healthcare professional, the researcher is legally obliged to tell the Chief Investigator.
6. I agree to allow the pharmacist to provide feedback to the researchers on the appointment.
7. I understand that I may stop taking part in the study at any time without giving a reason.
8. I understand that my personal information (including consent forms) will be confidential and stored safely in the School of Pharmacy at Queens University Belfast. I am aware that results from the study will be anonymous
9. I understand that information collected during the study may be looked at by authorised individuals from Queen's University Belfast. I give permission for these individuals to have access to this information.
10. I agree to take part in this study

Name of Participant (Please print)	Date	Signature
---------------------------------------	------	-----------

Name of Pharmacist (Please print)	Date	Signature
--------------------------------------	------	-----------

When completed: one copy for participant, one copy for researcher and one copy for the pharmacist

Appendix 56. Clinical record form (v1, 20.03.2018)



**Improving medicines management for people with dementia
COMMUNITY PHARMACY MEDICATION REVIEW – CLINICAL RECORD FORM**

Patient ID No: _____

Patient details		GP details	
<i>Title:</i>	<i>First name:</i>	<i>Surname:</i>	<i>GP name:</i>
<i>Date of Birth:</i>	<i>Telephone/mobile number:</i>		<i>Practice name:</i>
<i>Address:</i>		<i>Address:</i>	
<i>Date of review:</i>		<i>Name(s) of other people present:</i>	<i>Written informed consent obtained:</i> Yes <input type="checkbox"/> No <input type="checkbox"/>
Action plan			
Issue	Recommendation		

Pharmacy details

<i>Pharmacist name:</i>	<i>Registration number:</i>	<i>Email:</i>	<i>Pharmacist signature:</i>
<i>Pharmacy address:</i>		<i>Telephone number:</i>	

Current medicines (both prescribed and not prescribed)		Does the patient use the medicine as directed?	Does the patient and/or their carer know why they are using the medicine?	Has further information been provided on use of medicine?	Is the formulation appropriate?	Are side-effects reported by the patient or their carer?	General comments relating to advice, side-effects or other issues
1	<i>Name/dosage form/strength:</i>	Yes <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	<i>Dose:</i>	If no, specify:					
2	<i>Name/dosage form/strength:</i>	Yes <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	<i>Dose:</i>	If no, specify:					
3	<i>Name/dosage form/strength:</i>	Yes <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	<i>Dose:</i>	If no, specify:					
4	<i>Name/dosage form/strength:</i>	Yes <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	<i>Dose:</i>	If no, specify:					

Total number of medicines being used by the patient

Prescribed:

OTC and complementary therapies:

Issues identified during the medication review

- | | |
|---|---|
| <input type="checkbox"/> Patient not using medicine(s) as prescribed (non-adherence) | <input type="checkbox"/> Problem with pharmaceutical form of a medicine or use of a device |
| <input type="checkbox"/> Potentially inappropriate prescribing identified | <input type="checkbox"/> Patient/carer reports side-effects or other concern about a medicine |
| <input type="checkbox"/> Patient and/or carer reports need for more information about a medicine or condition | <input type="checkbox"/> Concerns about antipsychotic drug use warranting review |
| <input type="checkbox"/> Other matter and/or notes on above | |

Action taken/to be taken by pharmacist (where appropriate, more than one may apply)

- | | | |
|---|---|--|
| <input type="checkbox"/> Information/advice provided | <input type="checkbox"/> Yellow card report submitted to MHRA | <input type="checkbox"/> Patient referred to GP or other healthcare professional |
| <input type="checkbox"/> Other action and/or notes on above | | |

Lifestyle advice provided: (more than one may apply)

- | | | | |
|--|----------------------------------|--|--|
| <input type="checkbox"/> Diet and nutrition | <input type="checkbox"/> Smoking | <input type="checkbox"/> Physical activity | <input type="checkbox"/> Alcohol consumption |
| <input type="checkbox"/> Other advice provided and/or notes on above | | | |

Appendix 57. Letter to GP (v1, 09.05.2018)

<To be printed on pharmacy headed paper>

<GP name and address>

<Date>

Dear [insert GP name here],

Re: A feasibility study of an intervention to improve medicines management for people with dementia in primary care in Northern Ireland

I am writing to inform you that your patient [**patient name inserted here**] recently took part in the above study. As part of this study, [patient name inserted here here] and their carer attended a medication review and adherence check at <pharmacy name here> on <date here>. A copy of the patient's consent form is enclosed for your records.

I have enclosed a pro forma document detailing some proposed recommendations following the medication review that has been undertaken. If you require any further information, or wish to discuss anything further, please do not hesitate to contact me by telephone: <Pharmacy telephone number> or by email: <Pharmacist email address>.

Yours Sincerely,

<Signature>

<Printed Name of Pharmacist> at <Printed Name of Pharmacy>

Appendix 58. Proforma document detailing pharmacist's recommendations (v1, 20.03.2018)



Improving medicines management for people with dementia
COMMUNITY PHARMACY MEDICATION REVIEW – COMMUNICATION FORM

Patient ID No: _____

To the GP:			
This patient recently received a medication review as part of the study entitled: 'A feasibility study of an intervention to improve medicines management for people with dementia in primary care in Northern Ireland'. Please consider the proposed recommendations, outlined in the action plan below.			
Patient details			GP details
Title:	First name:	Surname:	GP name:
Date of Birth:	Telephone/mobile number:		Practice name:
Address:			Address:
Date of review:		Name(s) of other people present:	Written informed consent obtained: Yes <input type="checkbox"/> No <input type="checkbox"/>
Action plan			
Issue	Recommendation		

Pharmacy details			
<i>Pharmacist name:</i>	<i>Registration number:</i>	<i>Email:</i>	<i>Pharmacist signature:</i>
<i>Pharmacy address:</i>		<i>Telephone number:</i>	

Appendix 59. Pharmacy PMR data extraction form

Data extraction form: baseline data

[Please use this form to extract data from patient's medical record on date of medication review.]

Patient name:

Study site X

   Remove and destroy text box with patient's name using the pharmacy's confidential waste disposal system **BEFORE** returning the completed data extraction form to the Research Fellow.

Patient ID: [each data extraction form will be printed with a unique patient ID number]

Date of medication review: Day/ Month/ Year

Date of data extraction: Day/ Month/ Year

Data extraction performed by:

Patient demographics

Patient's gender:

Patient's age:

Prescribed medications

Drug name	Strength and formulation type (<i>i.e.</i> tablet, liquid)	Directions	Date of last issue	Quantity prescribed
------------------	---	-------------------	---------------------------	----------------------------

Prescribed medications

Drug name	Strength and formulation type (<i>i.e.</i> tablet, liquid)	Directions	Date of last issue	Quantity prescribed
------------------	---	-------------------	---------------------------	----------------------------

Pharmacy patient medication record data extraction form (one month follow-up)

Data extraction form: follow-up data

[Please use this form to extract data from patient's medical record four weeks after date of medication review.]

Patient name:

Study site X

*✂ ✂ ✂
Remove and destroy text box with patient's name using the pharmacy's confidential waste disposal system **BEFORE** returning the completed data extraction form to the Research Fellow.*

Patient ID: (each data extraction form will be printed with a unique patient ID number)

Date of medication review: Day/ Month/ Year

Date of data extraction: Day/ Month/ Year

Data extraction performed by:

Patient demographics

Patient's gender:

Patient's age:

Prescribed medications

Drug name	Strength and formulation type (<i>i.e.</i> tablet, liquid)	Directions	Date of last issue	Quantity prescribed
------------------	---	-------------------	---------------------------	----------------------------

Prescribed medications

Drug name	Strength and formulation type (<i>i.e.</i> tablet, liquid)	Directions	Date of last issue	Quantity prescribed
------------------	---	-------------------	---------------------------	----------------------------

Appendix 60. Community pharmacist interview topic guide



Semi-structured interview guide for community pharmacists

“My name is <name of researcher>, and I’m a researcher from the School of Pharmacy, Queen’s University Belfast. Thank you very much for making the time to speak with me today.

The reason I would like to speak with you is to find out what you thought about the study, what you liked, what you didn’t like and if there are any changes that we could make to improve it.

This interview should last approximately 30-40 minutes. I will be recording the interview on a digital recorder, to ensure that we have an accurate and detailed record of what you say. The recording will be saved on a password-protected computer and only those immediately involved in the research study will listen to it. The recording will be typed up word-for-word and any names, locations, or anything else that could identify you or anyone you talk about will be removed so that the information is anonymous. After we have conducted interviews with all of the other participants we will analyse the information within the research team.

You are free to stop the interview and/or recording at any point. If there are any questions that you would prefer not to answer, just let me know and we can move on to the next question. Just to reiterate, anything you say will be kept completely confidential and you will not be identified in any way.

Have you any questions before we start the interview?”

[Turn the digital recorder on]

Questions

- To start with, could you tell me how many years it has been since you qualified as a pharmacist?
1. Thinking back to before you agreed to take part in the study, what did you think of the information that you were given before you consented to take part? [copies of invitation letter and information sheet provided if required]

[Prompt: Is there anything else you would have liked to have known about the study beforehand?]

2. You were provided with this folder at the start of the study [copy of folder shown].
 - How far did you get through it?
 - What did you think about it?

[Prompts: if satisfied, why? If not, what do you feel should have been included?]

I would now like to ask you some questions about the video and quick reference guide and how you used them.

3. We used software called 'Articulate' to deliver the video and reference guide [print-out of all the slides will be available if required].
 - What did you think about the video and reference guide?

[prompts: Did you experience any problems accessing the video or using the reference guide?

When you did access it, did you find it easy to navigate? Was it visually appealing?]

4. How many times did you watch the video/read the guide?
5. What did you like most about the video/quick reference guide?
6. Are there any aspects of the video and reference guide that could be improved or anything else that could be included?

[prompt: are there any changes that could be made to the content/delivery format?]

Now that we've talked about the video and quick reference guide, I'd like to ask some questions about your experiences of screening patients for potential inclusion in the study. [At this point, pharmacist is shown the table outlining the two-stage screening process].

7. You started the screening process and were able to approach some patients about the study.
 - How did you find the screening and recruitment process?

- Can you describe any difficulties you experiences during screening and recruitment?

[prompts: Can you tell me more about that? What worked? What didn't work? In hindsight, what timeframe do you think might have been more realistic for screening and recruitment? Is there anything that the research team could have done to support you better?]

I would now like to finish up with a few questions about your overall experience of taking part in the study.

8. Thinking about the video and quick reference guide, would you recommend them to a colleague? *[If yes, why? If no, why not?]*
9. What could the research team have done to support you better throughout the course of this study?
10. How have you found the level of communication with the research team during the study?
11. Is there anything else that you think community pharmacists could do to improve medicines management in patients with dementia?
 - Is there any future training or information that you would like to have concerning medicines management for patients with dementia?

End of interview

"We have now come to the end of the interview. Before I switch off the recorder, is there anything else that you would like to tell me about the study? Do you have any additional comments that you would like to make?"

Thank you very much for making the time to speak with me today."

General prompts to use throughout interview

- What did you think about that...
- Can you please tell me more about that....
- Can you give me an example of....

Appendix 61. Interview guide for PwD and carers following intervention delivery



Semi-structured interview guide for patients and carers

Note for REC: This is an interview guide. The questions given below will form the basis of the guide but the exact questions will be formulated throughout the conduct of the study as well as being based on the individual's responses to previous questions during the interview and on the basis of the preceding interviews with other participants. This iterative process is required when using qualitative methods in order to explore themes fully.

"My name is <name of researcher> and I am a researcher from the School of Pharmacy, Queen's University Belfast. Thank you very much for making the time to speak with me today.

As part of this research study, you had an appointment with your pharmacist where you discussed your medicines and talked about whether you are getting the best from them. The reason I would like to speak with you today is to find out what you thought about the pharmacy service, what you liked, what you didn't like and if you would like to see any changes to it for other people in the future.

This interview should last approximately 30 minutes. I will be recording the interview on a digital recorder, to ensure that we have an accurate and detailed record of what you say. The recording will be saved on a password-protected computer and only those immediately involved in the research study will listen to it. The recording will be typed up word-for-word and any names, locations, or anything else that could identify you or anyone you talk about will be removed so that the information is anonymous. After we have conducted interviews with all of the other participants, we will analyse the information within the research team.

We will also ask your pharmacist what they thought of the appointment. They might talk about problems that you discussed in relation to your medicines and any changes they suggested making to your medicines. You will not be identified in any way.

You are free to stop the interview and/or recording at any point. If there are any questions that you would prefer not to answer, just let me know and we can move on to the next question. Just to reiterate, anything you say will be kept completely confidential and you will not be identified in any way.

Before we start I need to just check that you understand what the study involves <assessment of patient capacity to provide consent>. Have you any questions about the study before we start the interview?"

[Turn the digital recorder on]

Questions for both patients and carers

1. I would like you to think back to the day when the pharmacist first approached you to tell you about the study. They will have given you a letter and information sheet, which told you what taking part in the study involved [show documents and check that patient and carer remember receiving them]. Thinking about what the pharmacist said to you about the study and what was in the information sheet, what did you think about the information you received about the appointment? Is there anything else that you would have liked to have known beforehand?
2. I now have a few questions to ask you about the appointment itself. If someone asked you what the appointment was like, based on your experience, how would you describe it to them?
3. Can you tell me what you liked best about the appointment? [Prompts: *why did you like that best? can you please tell me more about that...*]
4. As I mentioned before, we need to find out if there is anything that we could change about the service so that we can improve it for other people in the future. Can you tell me what you think could be done differently to make things better? [Prompts: *can you tell me more about that? Could you give me an example of how you think we could change things?*]
5. If you were offered another medicine review appointment with your pharmacist, would you go? [Prompts: *If yes, why? If no, why not?*]

6. I have one last question. We asked you to complete some surveys before the start of the appointment. The surveys asked about taking medicines, looking after your health, and quality of life. How did you find filling in these surveys?

End of interview

“We have now come to the end of the interview. Before I switch off the recorder, is there anything else that either of you would like to tell me about the service? Do you have any additional comments that you would like to make?”

Thank you very much for making the time to speak with me today.”

General prompts to use throughout interview

- What did you think about that....
- Can you please tell me more....
- Can you give me an example of....

Appendix 62. Measures of adherence

Instructions for completing the questionnaire

- This questionnaire is about all of the medicines you are prescribed by your doctor for your medical conditions.
- It should take about 5 minutes to complete.
- **Please answer all questions as honestly as you can. There are no right or wrong answers.**
- The researcher will be very happy to help in any way that they can if you are experiencing any problems.
- You may be taking (or using) a lot of medicines. This can include tablets, capsules, inhalers, creams, eye drops, nasal sprays, patches etc. When answering the following questions, try to think about **all of these medicines**.

Many people are not able to take all of their medicines as prescribed by their doctor. Rate your ability to take ALL of your prescribed medicines in the last month (please tick only ONE box) (Lu *et al.*, 2008):

- Very poor
- Poor
- Fair
- Good
- Very good
- Excellent

Medication Adherence Report Scale (MARS-5) (Thompson *et al.*, 2000)

- Many people find a way of using their medicines which suits them.
- This may differ from the instructions on the label or from what their doctor has said.
- We would like to ask you a few questions about how you use your medicines.

Here are some ways in which people have said that they use their medicines

For each of the statements, please tick the box which best applies to you

Your own way of using your medicines	Always	Often	Sometimes	Rarely	Never
I forget to take them					
I alter the dose					
I stop taking them for a while					
I decide to miss out a dose					
I take less than instructed					

Appendix 63. Patient quality of life measure (DEMQOL)

Study ID

DEMQOL (version 4)

Instructions: Read each of the following questions (in bold) verbatim and show the respondent the response card.

I would like to ask you about your life. There are no right or wrong answers. Just give the answer that best describes how you have felt in the last week. Don't worry if some questions appear not to apply to you. We have to ask the same questions of everybody.

Before we start we'll do a practise question; that's one that doesn't count. (Show the response card and ask respondent to say or point to the answer) In the last week, how much have you enjoyed watching television?

a lot quite a bit a little not at all

Follow up with a prompt question: Why is that? or Tell me a bit more about that.

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For all of the questions I'm going to ask you, I want you to think about the last week.

First I'm going to ask about your feelings. In the last week, have you felt.....

- | | | | | |
|--|--------------------------------|--------------------------------------|-----------------------------------|-------------------------------------|
| 1. cheerful? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 2. worried or anxious? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 3. that you are enjoying life? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 4. frustrated? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 5. confident? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 6. full of energy? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 7. sad? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 8. lonely? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 9. distressed? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 10. lively? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 11. irritable? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 12. fed-up? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 13. that there are things that you wanted to do but couldn't? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |

Next, I'm going to ask you about your memory. In the last week, how worried have you been about.....

- | | | | | |
|--|--------------------------------|--------------------------------------|-----------------------------------|-------------------------------------|
| 14. forgetting things that happened recently? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 15. forgetting who people are? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 16. forgetting what day it is? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |

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17. **your thoughts being muddled?** a lot quite a bit a little not at all
18. **difficulty making decisions?** a lot quite a bit a little not at all
19. **poor concentration?** a lot quite a bit a little not at all

Now, I'm going to ask you about your everyday life. In the last week, how worried have you been about.....

20. **not having enough company?** a lot quite a bit a little not at all
21. **how you get on with people close to you?** a lot quite a bit a little not at all
22. **getting the affection that you want?** a lot quite a bit a little not at all
23. **people not listening to you?** a lot quite a bit a little not at all
24. **making yourself understood?** a lot quite a bit a little not at all
25. **getting help when you need it?** a lot quite a bit a little not at all
26. **getting to the toilet in time?** a lot quite a bit a little not at all
27. **how you feel in yourself?** a lot quite a bit a little not at all
28. **your health overall?** a lot quite a bit a little not at all

We've already talked about lots of things: your feelings, memory and everyday life. Thinking about all of these things in the last week, how would you rate.....

29. **your quality of life overall? **** very good good fair poor

** items that need to be reversed before scoring

Appendix 64. Carer quality of life measure (DEMQOL – Carer)

Study ID

DEMQOL - Carer (version 4)

Instructions: Read each of the following questions (in bold) verbatim and show the respondent the response card.

I would like to ask you about _____ (your relative's) life, as you are the person who knows him/her best. There are no right or wrong answers. Just give the answer that best describes how _____ (your relative) has felt in the last week. If possible try and give the answer that you think _____ (your relative) would give. Don't worry if some questions appear not to apply to _____ (your relative). We have to ask the same questions of everybody.

Before we start we'll do a practise question; that's one that doesn't count. (Show the response card and ask respondent to say or point to the answer). In the last week how much has _____ (your relative) enjoyed watching television?

a lot quite a bit a little not at all

Follow up with a prompt question: **Why is that?** or **Tell me a bit more about that.**

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For all of the questions I'm going to ask you, I want you to think about the last week.

First I'm going to ask you about _____ (your relative's) **feelings**. In the last week, would you say that _____ (your relative) has felt _____.

- | | | | | |
|--|--------------------------------|--------------------------------------|-----------------------------------|-------------------------------------|
| 1. cheerful? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 2. worried or anxious? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 3. frustrated? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 4. full of energy? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 5. sad? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 6. content? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 7. distressed? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 8. lively? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 9. irritable? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 10. fed-up | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 11. that he/she has things to look forward to? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |

Next, I'm going to ask you about _____ (your relative's) **memory**. In the last week, how worried would you say _____ (your relative) has been about _____.

- | | | | | |
|---|--------------------------------|--------------------------------------|-----------------------------------|-------------------------------------|
| 12. his/her memory in general? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 13. forgetting things that happened a long time ago? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 14. forgetting things that happened recently? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 15. forgetting people's names? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 16. forgetting where he/she is? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 17. forgetting what day it is? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |

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18. his/her thoughts being muddled? a lot quite a bit a little not at all
19. difficulty making decisions? a lot quite a bit a little not at all
20. making him/herself understood? a lot quite a bit a little not at all

Now, I'm going to ask about _____ (*your relative's*) everyday life. In the last week, how worried would you say _____ (*your relative*) has been about _____.

21. keeping him/herself clean (eg washing and bathing)? a lot quite a bit a little not at all
22. keeping him/herself looking nice? a lot quite a bit a little not at all
23. getting what he/she wants from the shops? a lot quite a bit a little not at all
24. using money to pay for things? a lot quite a bit a little not at all
25. looking after his/her finances? a lot quite a bit a little not at all
26. things taking longer than they used to? a lot quite a bit a little not at all
27. getting in touch with people? a lot quite a bit a little not at all
28. not having enough company? a lot quite a bit a little not at all
29. not being able to help other people? a lot quite a bit a little not at all
30. not playing a useful part in things? a lot quite a bit a little not at all
31. his/her physical health? a lot quite a bit a little not at all

We've already talked about lots of things: _____ (*your relative's*) feelings, memory and everyday life. Thinking about all of these things in the last week, how would you say _____ (*your relative*) would rate ..

32. his/her quality of life overall? ** very good good fair poor

** items that need to be reversed before scoring

Appendix 65. Neuropsychiatric Inventory (NPI) questionnaire

npITEST

**The Neuropsychiatric Inventory
Questionnaire:
Background and Administration**

By Jeffrey L. Cummings, MD

The Neuropsychiatric Inventory–Questionnaire: Background and Administration

The Neuropsychiatric Inventory–Questionnaire (NPI-Q) was developed and cross-validated with the standard NPI to provide a brief assessment of neuropsychiatric symptomatology in routine clinical practice settings (Kaufer et al, *J Neuropsychiatry Clin Neurosci* 2000, 12:233-239). The NPI-Q is adapted from the NPI (Cummings et al, *Neurology* 1994; 44:2308-2314), a validated informant-based interview that assesses neuropsychiatric symptoms over the previous month. The original NPI included 10 neuropsychiatric domains; two others, Nighttime Behavioral Disturbances and Appetite/Eating Changes, have subsequently been added. Another recent modification of the original NPI is the addition of a Caregiver Distress Scale for evaluating the psychological impact of neuropsychiatric symptoms reported to be present (Kaufer et al, *JAGS*, 1998;46:210-215). The NPI-Q includes both of these additions.

The NPI-Q is designed to be a self-administered questionnaire completed by informants about patients for whom they care. Each of the 12 NPI-Q domains contains a survey question that reflects cardinal symptoms of that domain. Initial responses to each domain question are "Yes" (present) or "No" (absent). If the response to the domain question is "No", the informant goes to the next question. If "Yes", the informant then rates both the Severity of the symptoms present within the last month on a 3-point scale and the associated impact of the symptom manifestations on them (i.e. Caregiver Distress) using a 5-point scale. The NPI-Q provides symptom Severity and Distress ratings for each symptom reported, and total Severity and Distress scores reflecting the sum of individual domain scores.

Most informants will be able to complete the NPI-Q in 5 minutes or less. It is recommended that responses to the NPI-Q be reviewed for completeness by a clinician and for clarifying uncertainties after each administration. The first time an informant completes the NPI-Q, it may be useful to verbally review the instructions. In some instances, it may be necessary to conduct the NPI-Q in part or entirely as an interview.

The NPI and NPI-Q are both copyright-protected by Jeffrey L. Cummings, MD. The NPI-Q was developed by Daniel Kaufer, MD with permission. **Use of the NPI or NPI-Q in investigational studies sponsored in whole or part by for-profit entities is prohibited without express written consent.**

For inquiries regarding the NPI-Q, contact:

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Mary S. Easton Center for Alzheimer's Disease Research
10911 Weyburn Ave; #200
Los Angeles, CA 90095
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The NPI-Q can be found at:
www.NPitest.net

Please answer the following questions based on changes that have occurred since the patient first began to experience memory problems.

Circle "Yes" only if the symptom(s) has been present in the last month. Otherwise, circle "No". For each item marked "Yes":

a) Rate the **SEVERITY** of the symptom (how it affects the patient):

1 = Mild (noticeable, but not a significant change)

2 = Moderate (significant, but not a dramatic change)

3 = Severe (very marked or prominent, a dramatic change)

b) Rate the **DISTRESS** you experience due to that symptom (how it affects you):

0 = Not distressing at all

1 = Minimal (slightly distressing, not a problem to cope with)

2 = Mild (not very distressing, generally easy to cope with)

3 = Moderate (fairly distressing, not always easy to cope with)

4 = Severe (very distressing, difficult to cope with)

5 = Extreme or Very Severe (extremely distressing, unable to cope with)

Please answer each question carefully. Ask for assistance if you have any questions.

Delusions Does the patient have false beliefs, such as thinking that others are stealing from him/her or planning to harm him/her in some way?

Yes No SEVERITY: 1 2 3 DISTRESS: 0 1 2 3 4 5

Hallucinations Does the patient have hallucinations such as false visions or voices? Does he or she seem to hear or see things that are not present?

Yes No SEVERITY: 1 2 3 DISTRESS: 0 1 2 3 4 5

Agitation/Aggression Is the patient resistive to help from others at times, or hard to handle?

Yes No SEVERITY: 1 2 3 DISTRESS: 0 1 2 3 4 5

Depression/Dysphoria Does the patient seem sad or say that he /she is depressed?

Yes No SEVERITY: 1 2 3 DISTRESS: 0 1 2 3 4 5

Anxiety Does the patient become upset when separated from you?
Does he/she have any other signs of nervousness such as shortness of breath, sighing, being unable to relax, or feeling excessively tense?

Yes No SEVERITY: 1 2 3 DISTRESS: 0 1 2 3 4 5

Elation/Euphoria Does the patient appear to feel too good or act excessively happy?

Yes No SEVERITY: 1 2 3 DISTRESS: 0 1 2 3 4 5

Apathy/Indifference Does the patient seem less interested in his/her usual activities or in the activities and plans of others?

Yes No SEVERITY: 1 2 3 DISTRESS: 0 1 2 3 4 5

Disinhibition Does the patient seem to act impulsively, for example, talking to strangers as if he/she knows them, or saying things that may hurt people's feelings?

Yes No SEVERITY: 1 2 3 DISTRESS: 0 1 2 3 4 5

Irritability/Lability Is the patient impatient and cranky? Does he/she have difficulty coping with delays or waiting for planned activities?

Yes No SEVERITY: 1 2 3 DISTRESS: 0 1 2 3 4 5

Motor Disturbance Does the patient engage in repetitive activities such as pacing around the house, handling buttons, wrapping string, or doing other things repeatedly?

Yes No SEVERITY: 1 2 3 DISTRESS: 0 1 2 3 4 5

Nighttime Behaviors Does the patient awaken you during the night, rise too early in the morning, or take excessive naps during the day?

Yes No SEVERITY: 1 2 3 DISTRESS: 0 1 2 3 4 5

Appetite/Eating Has the patient lost or gained weight, or had a change in the type of food he/she likes?

Yes No SEVERITY: 1 2 3 DISTRESS: 0 1 2 3 4 5

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NPI-Q SUMMARY

	No	Severity	Caregiver Distress
Delusions	0	1 2 3	0 1 2 3 4 5
Hallucinations	0	1 2 3	0 1 2 3 4 5
Agitation/Aggression	0	1 2 3	0 1 2 3 4 5
Dysphoria/Depression	0	1 2 3	0 1 2 3 4 5
Anxiety	0	1 2 3	0 1 2 3 4 5
Euphoria/Elation	0	1 2 3	0 1 2 3 4 5
Apathy/Indifference	0	1 2 3	0 1 2 3 4 5
Disinhibition	0	1 2 3	0 1 2 3 4 5
Irritability/Lability	0	1 2 3	0 1 2 3 4 5
Aberrant Motor	0	1 2 3	0 1 2 3 4 5
Nighttime Behavior	0	1 2 3	0 1 2 3 4 5
Appetite/Eating	0	1 2 3	0 1 2 3 4 5
TOTAL			

Appendix 66. Multimorbidity Treatment Burden Questionnaire (MTBQ) to be administered to patients

Name.....

Date.....

THE EFFORT OF LOOKING AFTER YOUR HEALTH

We are interested in finding out about the effort you have to make to look after your health and how this impacts on your day-to-day life.

Please tell us how much difficulty you have with the following:

(Please tick the box that most applies to you)

	Not difficult	A little difficult	Quite difficult	Very difficult	Extremely difficult	Does not apply
1. Taking lots of medications	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
2. Remembering how and when to take medication	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
3. Collecting prescription medication	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
4. Monitoring your medical conditions (eg. checking your blood pressure or blood sugar, monitoring your symptoms etc)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
5. Arranging appointments with health professionals	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
6. Seeing lots of different health professionals	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
7. Attending appointments with health professionals (eg. getting time off work, arranging transport etc)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
8. Obtaining clear and up-to-date information about your condition	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
9. Making recommended lifestyle changes (eg. diet and exercise etc)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
10. Having to rely on help from family and friends	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆

Appendix 67. Multimorbidity Treatment Burden Questionnaire (MTBQ) to be administered to carers

Name.....

Date.....

Looking after the health of the person you care for.

We are interested in finding out about the effort you have to make in order to look after the health of the person you care for, and how this impacts on your day-to-day life.

Please tell us how much difficulty you have with helping the person you care for with the following: (Please tick the box that most applies to you.)

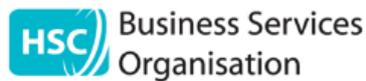
	Not difficult	A little difficult	Quite difficult	Very difficult	Extremely difficult	Does not apply
1. Taking lots of medications	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
2. Remembering how and when they need to take their medication	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
3. Paying for their prescriptions, over the counter medication or equipment	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
4. Collecting their prescription medication	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
5. Monitoring their medical conditions (eg. Checking their blood sugar, monitoring symptoms etc)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
6. Arranging their appointments with health professionals	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
7. Seeing lots of different health professionals	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
8. Attending appointments with health professionals (eg. getting time off work, arranging transport etc)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
9. Getting health care for them in the evenings and at weekends	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
10. Getting them help from community services (eg. physiotherapy, district nurses etc)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
11. Obtaining up-to-date information about their medical conditions	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
12. Making recommended changes to their lifestyle (eg. Diet, exercise etc)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆

Please tell us how difficult you have found the following:

(please tick the box that most applies)

	Not difficult	A little difficult	Quite difficult	Very difficult	Extremely difficult	Does not apply
13. Having to rely on help from family and friends	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
14. Arranging respite care for the person you care for	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
15. The financial impact of being a carer (e.g. having to give up work, relying on benefits etc)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
16. Adjusting your own lifestyle so that you can look after the person you care for	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆

Appendix 68. Ethical approval received for Phase 3



*Office for Research Ethics Committees
Northern Ireland
(ORECNI)*

Customer Care & Performance Directorate

Lissue Industrial Estate West
5 Rathdown Walk
Moir Road
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BT28 2RF
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Health and Social Care Research Ethics Committee A (HSC REC A)

08 June 2018

Professor Carmel M Hughes
Head of School
Queen's University Belfast
School of Pharmacy
97 Lisburn Road
Belfast
BT9 7BL

Dear Professor Hughes

Study title: A feasibility study of an intervention to improve medicines management for people with dementia in primary care in Northern Ireland

REC reference: 18/NI/0100

IRAS project ID: 248050

Thank you for your letter of 6 June 2018, 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 Acting Chair, Dr Alastair Walker.

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 hra.studyregistration@nhs.net outlining the reasons for your request.

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:

1. The Carer's Participant Information Sheet (PIS), contains a reference to their healthcare not being affected by a withdrawal which is not appropriate. Therefore, under the section heading entitled 'Do I have to take part?' the following words must be removed 'and it will not affect your healthcare'.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make 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 must be obtained from each host organisation prior to the start of the study 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 HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at 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 request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be

registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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).

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 to REC]		09 May 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Indemnity certificate]		15 July 2018
Interview schedules or topic guides for participants [Interview guide]	1	29 March 2018
IRAS Checklist XML [Checklist_10052018]		10 May 2018
IRAS Checklist XML [Checklist_06062018]		06 June 2018
Letter from funder [Letter from HSC PHA confirming award]		14 August 2014
Letter from sponsor [Sponsor letter]		09 May 2018
Letters of invitation to participant [Invitation letter (community pharmacist)]	1	20 March 2018
Other [Referee report or other scientific critique report (Referee ID 20522)]		
Other [Referee report or other scientific critique report (Referee ID 20350)]		
Other [Video script]	1	20 March 2018
Other [Quick Reference Guide]	1	20 March 2018
Other [Patient information sheet 1]	1	09 May 2018
Other [Assessment of patient capacity checklist]	1	20 March 2018
Other [Patient consent form 1]	1	09 May 2018
Other [GP screening letter]	1	09 May 2018
Other [Eligibility screening checklist]	1	09 May 2018
Other [Patient and carer invitation letter]	1	20 March 2018
Other [Medicine review information for patients and carers]	2	09 May 2018
Other [Validated questionnaire (Multimorbidity Treatment Burden Questionnaire)]	2.0	29 March 2017
Other [Validated questionnaire (Dementia quality of life carer proxy-report measure)]		
Other [Validated questionnaire (Carer Treatment Burden Questionnaire)]	2.0	07 October 2014
Other [GP courtesy letter]	1	09 May 2018
Other [Patient consent form 2]	1	09 May 2018
Other [Validated questionnaire (Dementia quality of life)]		
Other [Validated questionnaire (The Neuropsychiatric Inventory Questionnaire)]		
Other [Clinical record form]	1	20 March 2018
Other [GP letter to accompany pro forma document]	1	09 May 2018
Other [GP pro forma document detailing recommendations]	1	20 March 2018
Other [Pharmacy patient medication record data extraction]	1	20 March 2018

forms]		
Other [Data extraction template]	1	20 March 2018
Other [Community pharmacist certificate of participation]	1	20 March 2018
Other [Letter to patients not eligible to take part]	1	09 May 2018
Other [Actor consent form]	1	20 March 2018
Other [Lone worker procedure and related documents]	1	20 March 2018
Other [Protocol for handling patient upset or distress during the study]	1	09 May 2018
Other [Letter to GP to inform of participant distress]	1	09 May 2018
Other [Protocol for handling pharmacist upset or distress during the study]	1	09 May 2018
Other [Brief CV Dr Laura Bedford]		15 March 2018
Other [Unfavourable opinion letter]		01 May 2018
Other [Patient information sheet 2]	2	06 June 2018
Other [Carer information sheet]	3	06 June 2018
Other [Carer consent form]	3	06 June 2018
Other [Response to provisional opinion]		06 June 2018
Participant consent form [Community pharmacist consent form]	2	06 June 2018
Participant information sheet (PIS) [Participant information sheet (community pharmacist)]	1	20 March 2018
REC Application Form [REC_Form_10052018]		10 May 2018
Referee's report or other scientific critique report [Referee ID 20173]		
Research protocol or project proposal [Phase 3 Protocol]	3	06 June 2018
Summary CV for Chief Investigator (CI) [Brief CV Prof. Carmel Hughes]	1	01 February 2018
Validated questionnaire [Measures of adherence]		

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.

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/>.

18/NI/0100	Please quote this number on all correspondence
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With the Committee's best wishes for the success of this project.

Yours sincerely



pp
Dr Alastair Walker
Acting Chair

Email: RECA@hscni.net

Enclosure: After ethical review – guidance for researchers

Copy to: Dr Paula Tighe, Queens University, Belfast