Transitional care of older patients utilising community pharmacists via the dMUR service

by

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ABSTRACT

Background: Post-discharge Medicines Use Reviews (dMURs) were introduced into the English community pharmacy contract in 2011, with the aim of improving understanding and use of medication by patients who have experienced changes to their medicines in hospital. Early evidence showed uptake of dMURs to be poor. Furthermore, despite being a nationally commissioned service, there is little evidence of the benefit of dMURs to patients.

In light of the documented medication problems that occur in older people on transfer of care, a randomised controlled feasibility study was devised to investigate the feasibility and potential outcomes of a transitional care service for older patients which utilises community pharmacists via the dMUR service

Methods: Hospital pharmacists identified in-patients aged over 65 years who could potentially benefit from a dMUR. Participants were randomised to be referred for a dMUR with their usual community pharmacist or to receive standard discharge care.

Results and Contribution: This study is the first to report on patient outcomes following dMUR referrals. Through interventions made by community pharmacists, referrals may provide a 4-fold return on investment to the NHS in terms of improved quality of care. There were trends towards a shorter length of stay on readmission and reduction in A&E visits in the months following dMUR, and they may also prevent medication related admissions and deterioration in medication adherence and physical health over time.

However this work revealed significant challenges in providing dMUR referral services to older patients. Being housebound due to poor mobility or health is a major barrier, due to difficulties experienced by community pharmacists with providing domiciliary dMURs. Carer management of medication is another. It is proposed that the provision of domiciliary dMURs should be facilitated by simplifying and clarifying the process for community pharmacists. Proxy dMURs with carers should be allowed in certain cases.

Another key proposal is that the dMUR service should be re-designed to involve at least two parts. Remuneration should reflect the complexity and time needed for dMURs compared to 'standard' MURs.

Lack of time of hospital pharmacists is a barrier to recruiting appropriate patients for dMUR referral and making good quality referrals. Electronic referral from hospital to community pharmacy may assist and should be implemented more widely. It is also suggested that hospital pharmacies should be remunerated for making referrals.

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LIST OF ABBREVIATIONS

A&E	Accident and Emergency department
ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
AfC	Agenda for Change
BGS	British Geriatrics Society
CCG	Clinical Commissioning Group
CHSEO	Centre for Health Service Economics and Organisation
COM-B	Capability, Opportunity, Motivation – Behaviour
COPD	Chronic Obstructive Pulmonary Disease
CQC	Care Quality Commission
DMR	Discharge Medicines Review
dMUR	Post-discharge Medicines Use Review
DoH	Department of Health, now the Department of Health and Social Care
DRP	Drug Related Problem
EAU	Emergency Admissions Unit
ED	Emergency Department
FA	Framework Analysis
GP	General Practitioner
HCP	Healthcare Professional
HES	Hospital Episode Statistics
HIMR	Hospital Initiated Medication Review
HMR	Home Medication Review

HR-QoL	Health Related Quality of Life
HSCIC	Health and Social Care Information Centre, now NHS Digital
ITT	Intention To Treat
LTC	Long Term Condition
MAQ	Medication Adherence Questionnaire
MCA	Multidose Compliance Aid
MCI	Medication Regimen Complexity Index
MDT	Multidisciplinary Team
MMAS	Morisky Medication Adherence Scale
MUR	Medicines Use Review
NAO	National Audit Office
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NMS	New Medicines Service
NPSA	National Patient Safety Agency
PAS	Patient Administration System
PbR	Payment by Results
PCO	Primary Care Organisation
PEI	Patient Enablement Index
PIL	Participant Information Leaflet
PIN	Participant Identification Number
PP	Per Protocol
PPI	Patient and Public Involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta Analyses

PSNC	**Pharmaceutical Services Negotiating Committee**
RCT	**Randomised Controlled Trial**
RPS	**Royal Pharmaceutical Society**
ScHARR	**School of Health and Related Research**
SF-12v2	**Short Form 12 health survey, version 2**
SF-36	**Short Form 36 health survey**
SONT	**Southport and Ormskirk NHS Trust**
SPA	**State Pension Age**
UK	**United Kingdom**
USA	**United States of America**
5YFV	**Five Year Forward View**

CHAPTER 1: INTRODUCTION

In recent years there has been increased recognition of the problems faced by older people on discharge from hospital, including those related to medication (1-8). In late 2011, I had been a qualified pharmacist for four years and, having recently completed my post-graduate diploma in clinical pharmacy, was working on the care of the elderly ward and the emergency admissions unit at Southport District General Hospital. I became frustrated by the frequency with which I saw recently discharged, elderly patients re-admitted without the changes to their medication from the original admission having been enacted properly or followed up in the community.

At this time, post-discharge Medicines Use Reviews (dMURs) had recently been introduced into the English national community pharmacy contract, with the aim of improving the understanding and use of medication by patients who had experienced changes to their medicines in hospital (9). Shortly after this, the Royal Pharmaceutical Society (RPS) early implementer sites for medicines related transfer of care were established. Early feedback from these sites showed minimal uptake of dMURs, even after signposting by hospitals (10). Furthermore, despite being a nationally commissioned service, there was no evidence of the benefit of such reviews to patients. In fact, previous research on the role of pharmacists in transitional care generally has shown inconsistent effects on outcomes and at the time there was little published research on the contribution community pharmacists could make (11). I therefore became determined to set up a service that would refer patients directly to their nominated community pharmacist for a dMUR, and to evaluate this service in terms of both its feasibility and the potential benefits on specific patient orientated outcomes.

Overall Aim of thesis: *To investigate the feasibility and potential outcomes of a transitional care service for older patients which utilises community pharmacists via the dMUR service*

My specialism in care of the elderly led me to focus my research on older patients, as I was acutely aware of the potential for medication related problems in this group. These problems are related not only to the polypharmacy which has

become an inevitable consequence of the prevalence of multiple long-term conditions in the older population, but the changes in the ability of the aging body to handle many medications, and the impact of changes in manual dexterity, visual acuity, mobility and cognition, on the day-to-day management of medicines by a larger proportion of older people then in the general population (12,13).

Despite having taken over seven years to complete, the work represented in this thesis is as important now as it was when it began. Over this period of time, many relevant primary research reports, review articles and national policy documents and guidelines have been published. Indeed, the findings in this thesis have already resulted in the publication of three papers in peer reviewed journals, which themselves form part of the current pool of knowledge on the subject of medicines related transfer of care:

Ramsbottom HF, Fitzpatrick R, Rutter P. Post discharge medicines use review service for older patients: recruitment issues in a feasibility study. International Journal of Clinical Pharmacy 2016 Apr;38(2):208-212.

Rutter P, Ramsbottom H, Fitzpatrick R. Community pharmacist perceptions of delivering post-hospital discharge Medicines Use Reviews for elderly patients. International Journal of Clinical Pharmacy 2017 Feb;39(1):33-36.

Ramsbottom H, Rutter P, Fitzpatrick R. Post discharge medicines use review (dMUR) service for older patients: Cost-savings from community pharmacist interventions. Research In Social & Administrative Pharmacy 2018 February;14(2):203-206.

In terms of current health policy, this thesis focuses closely on the aims of the 2014 government document *Transforming Primary Care,* part of a national strategy to provide proactive, joined-up care for older people, co-ordinating services and providing proactive follow-up support on discharge (14). Many of the themes explored within this thesis also receive special mention in the 2018 government document *Prevention is Better than Cure* and the 2019 *NHS Long Term Plan*, the latter published only weeks before this thesis was submitted for examination (15,16). These include the need to make greater use of community pharmacists' skills, to better support patients to take control of their own care and get the best from their medicines and to reduce delayed discharges from hospital. These documents include a special focus on the aging population, reiterating that people

are living longer now than ever before, but that these extra years are not always spent in good health. The need to improve the support given to carers of older people is mentioned specifically in the *Long Term Plan*, which is also a finding of this thesis.

Other projects are being undertaken around the UK to improve the transfer of medicines related discharge information to community pharmacies and increase the uptake of dMURs. This PhD study was ongoing at the same time as several of these were being implemented and/or evaluated, including electronic referral systems in East Lancashire, North-East England and Wessex and the Welsh Discharge Medicines Review (DMR) service (17-20). However the findings contained within this thesis make a unique contribution to this body of work, through the focus on patient experience and outcomes, laying a foundation for future service improvements and evaluation.

The chapters to follow start with a contextual Chapter 2, which defines the target population for this research in more detail and provides a background to the problem this work addresses. Chapter 3 then discusses the specific problems that can occur with medicines when older people are discharged from hospital, why they happen and their consequences. The need for mechanisms to improve medicines related transfer of care in the elderly is identified and some possible mechanisms to achieve this are introduced. This is followed by the formal literature review, Chapter 4, which defines previous and ongoing research into interventions that support medicines related transfer of care for older people discharged from hospital, either led by or involving pharmacists. Methodological considerations, including the rationale behind selecting a mixed methods approach, potential study designs, operational aspects and ethical considerations are discussed in Chapter 5, before the final methods chosen for recruitment, data collection and analysis are presented in Chapter 6. Chapter 7 presents the results of the data collected during this PhD project, relating both to process measures and participant outcomes. These are then discussed in the context of other recent and ongoing research and national health policy in Chapter 8. Chapter 9 presents the conclusions of this thesis, the implications of which are embodied in the recommendations for both research and practice in Chapter 10.

CHAPTER 2: CONTEXT

This chapter defines the target population for this research and provides a background to the problem it addresses. The changing demographics of the United Kingdom (UK)'s population and the increasing 'medicalisation' of healthcare are placing significant demands on the country's health and social care systems. Consequences such as medication errors and emergency hospital admissions are more common in older people and contribute to an increasing pressure on hospital beds. This has led to a national drive towards increased collaboration between secondary and primary care, and supporting people to self-care and stay well in the community following discharge from hospital. The role the pharmacy profession can play in this integrated care is under-developed and this highlights a gap for evidence based services to be introduced to support medicines-related transitional care of older people.

2.1 WHAT CONSTITUTES OLD AGE?

For over a century, the chronological age of 65 years has been accepted as a definition of an 'elderly' or older person in developed countries. This somewhat arbitrary value is often associated with the age at which one can begin to receive pension benefits (21). However, with advances in medical and health science during the late 20th and early 21st centuries, the average population lifespan has increased rapidly. The increasing life expectancy across the Western world has led to a recognition that there may be a need to re-define what constitutes old age (22).

To add further complexity to the challenge of defining who is elderly, the use of a calendar age to mark the threshold of old age assumes that this is equivalent to biological age. However, it is now generally accepted that these two are not necessarily synonymous (21,22). The ageing process is not uniform across the population due to differences in genetics, lifestyle, and overall health (22). In 1975, Norman Ryder was the first to use the concept of remaining life expectancy, rather than years lived, to re-consider the measurement of old age, selecting the arbitrary

period of 10 years of remaining life expectancy to define the point of entry into old age (23).

More recently, the concept of frailty, a distinctive health state related to the ageing process in which multiple body systems gradually lose their in-built reserves, has emerged (24). An older person living with frailty is at a higher risk of a sudden deterioration in their physical and mental health. The British Geriatrics Society (BGS) reports that around 10% of people aged over 65 years have frailty, rising to between a quarter and a half of those aged over 85 years (24).

Taking all this into account, it is not surprising that both researchers and various national organisations such as the Office for National Statistics, the Health and Social Care Information Centre (HSCIC), the National Health Service (NHS) and the DoH use different age values in publications and policy when discussing older people. This makes it difficult to compare data from different publications. For example, when discussing prescription medication use, figures are presented for those aged below 60 and for those aged 60 years and over, as 60 is the age at which a person becomes eligible for free NHS prescriptions. Figures for other statistics, such as population demographics and hospital admissions, commonly use two 'age-bands' for older people, differentiating those aged between 65 and 84 from those aged 85+, although there are sometimes differences in the ranges used. The definition of an older or elderly person in the academic research reviewed in this thesis also varied.

A review of 20 Australian clinical practice guidelines relating to the use of pharmacotherapy found that three guidelines defined 'elderly' using chronological age, with two defining 'elderly' as being 65 years or older and one using the age of 75 years or more. The remaining 17 guidelines did not define 'elderly' by any specific measure (25). In England and Wales, the latest National Institute for Health and Care Excellence (NICE) guidelines for Hypertension, and for Cardiovascular Disease: Risk Assessment and Reduction, recommend different approaches to care for people aged 80 or 85 and over, respectively (26,27). NICE has, however, started to recognise the heterogeneity of the older population. For example NICE CG181 states that patient preference, co-morbidities, polypharmacy, general frailty and life expectancy should be taken into account

when making treatment decisions regarding lipid lowering therapy, as well as chronological age (27).

As no one definition of old age exists, the decision was made that, for the purposes of the work presented in this thesis, the most established convention of age 65 would be used as the cut-off for defining a person as 'older'. This may be a slightly conservative definition in today's society, but if not elderly, it may still be assumed that the majority of this population are at least 'approaching' old age. Providing support for medication use at this stage may therefore establish behaviours which will endure and remain with the person as they make the transition into 'old age' or 'frailty', possibly even delaying the point at which the transition occurs.

2.2: THE CHANGING DEMOGRAPHICS OF THE UK POPULATION

The UK has an ageing population. In 2012 there were over 7.8 million people in England aged between 65 and 84; by 2032 this number is set to increase by 39% to 10.9 million. The population aged 85+ is predicted to more than double, from 1.3 million to 2.6 million (28). This compares to an increase of 11% in the population aged 0-14, (from 9.3 million to 10.4 million) and just 7% in those aged 15-64 (from 34.7 million to 37.2 million) (28). The old age dependency ratio (the number of people over the national state pension age (SPA) for every 1000 people of working age) rose from 230 per 1000 in 1971 to 314 per 1000 in 2009, and is likely to continue to rise over the next 20 years. By 2037 there is expected to be 349 people over the SPA for every 1000 people of working age. This means that there will be fewer people of working age to support the population over the SPA (28,29).

These changes can be attributed both to ageing of the large number of people born during the post 2nd World War baby boom, and increasing life expectancy compared to previous generations (28,29). A boy born in the UK in 1981 could expect to live 84.6 years on average. For a boy born in 2017, the figure is 90.8 years and, based on current assumptions, by 2037 it is projected to be 93.6 years. Similarly, a girl born in 1981 could expect to live 88.3 years on average, rising to 93.6 years for those born in 2017 and, 96.3 years for those born in 2037 (29).

However, healthy life expectancy is not increasing as quickly; although people are living longer, they are not necessarily living these extra years in better health, resulting in proportionately greater demands on health systems including the NHS (15,29-32).

Whilst the population aged 85 and over grew by 68% between 1990 and 2010, the number of non-elective hospital admissions for this age group increased by 189% (28). With further increases expected in population within this age group during the next fifteen years, hospital workload seems likely to increase further.

Given the above, it is not surprising that the costs of health and social care are significantly greater for older people (28).

2.3 THE INCREASING MEDICALISATION OF HEALTHCARE

'Long-term conditions' (LTC) or 'chronic diseases' are conditions for which there is currently no cure, which are managed with medicines and other treatment, for example diabetes, chronic obstructive pulmonary disease (COPD), depression and hypertension (33). The prevalence of LTC is increasing; in 2012 the DoH estimated that around 15 million people in England were living with a long-term condition, accounting for 70% of the NHS budget (33). In October 2014, the *Five-Year Forward View* (5YFV), NHS England's five year strategy for the NHS, stated that growing demand, if met by no further annual efficiencies and flat real terms funding, would produce a mismatch between resources and patient needs of nearly £30 billion a year by 2020/21 (32).

The increasing prevalence of LTC is at least partly due to improvements in technology, transforming our ability to predict and diagnose disease, thereby leading to the earlier recognition of LTC, as well as the introduction of new clinical guidelines for their treatment (31-34). However, two key risk factors for developing a long-term condition are ageing and lifestyle (32). Given that ageing of the population is inevitable, the 5YFV stated that the sustainability of the NHS and the economic prosperity of Britain depended on a radical upgrade in prevention and public health, and the engagement of the public to tackle risk factors for poor health (32). This was reinforced in November 2018 by the publication of the

government policy paper *Prevention is Better than Cure*, which emphasised the need to support everyone to manage their health issues earlier and more effectively (15).

Notwithstanding the push towards lifestyle changes to prevent or delay the progression of chronic disease, once developed, many LTC are almost exclusively managed with medication. It is therefore not surprising that prescribing rates continue to rise, with prescribing a medication being the most common intervention in the NHS. For example, in 2015, just over 1 billion prescription items were dispensed by community pharmacies in England, representing a 50% increase in the 10 years since 2005 (31).

The Quality and Outcomes Framework, the annual reward and incentive programme for general practice in the UK, has resulted in more consistent adherence to evidence-based treatment guidelines (35,36). While this is in many ways positive, with the intention of encouraging high quality care and reducing variations in practice, it also encourages greater use of medicines (35,36).

Other factors driving up prescribing rates may include patient expectation, biased reporting in medical journals and a lack of understanding of health statistics and risk (36).   It is easy to misunderstand health statistics, and doctors can find themselves needing to manage unrealistic expectations of patients who may find it difficult to obtain reliable information. Communicating relative risks as opposed to absolute risk or numbers needed to treat can unintentionally lead both doctors and patients to overestimate the benefits of a treatment (36). The UK's Academy of Royal Medical Colleges suggests that the onus on doctors to "do something" at each consultation may have bred unbalanced decision making (36). This could result in patients sometimes being offered treatments that have only minor benefit and minimal evidence despite the potential for substantial harm and expense.

2.4: LONG TERM CONDITIONS AND OLDER PEOPLE

Age is a major non-modifiable risk factor for a number of LTC. Fifty-eight per-cent of people aged over 60, and 70% aged over 80, have at least one long-term condition, compared to 14% of those aged under 40 (33).

In 2013, the global burden of disease study concluded that ageing of the world's population is leading to a substantial increase in the numbers of individuals living with sequelae of diseases and injuries (30). Chronic disease is now so common that healthcare systems are increasingly focused on people with more than one long-term condition (36,37). The presence of two or more LTC is referred to as 'multi-morbidity'. In this context, LTC include symptom complexes such as frailty and chronic pain and sensory problems such as sight and hearing loss, as well as clinical conditions (37). Whilst not exclusively a condition of the elderly, the presence of multi-morbidity increases with age, with a quarter of people aged 60 or over, and a third of people aged 80 or over living with multi-morbidity (30).

2.5: POLYPHARMACY AND ITS RELATIONSHIP WITH AGE

As a population, older people take more medications than younger ones. This situation is unsurprising when we consider that, if each one of their LTC is treated according to national guidelines, older people may end up taking a complex combination of medicines, a situation termed polypharmacy (38). The management of risk factors for future disease can also contribute to polypharmacy and be a major treatment burden for older people with multi-morbidity (37).

Studies indicate that almost half of people aged 65 or older in England take 5 or more regular medicines, a figure which has quadrupled over the last two decades (34). An analysis of more than 300,000 patients in Scotland found that 16.4% of patients aged 65 years and above took 10 or more regular medications, compared to 5.8% of the population as a whole (39).

Polypharmacy is even more prevalent in older patients admitted to hospital, with one British study finding that 60% of an inpatient population with an average age of 65 were taking five or more medicines concurrently (40). A study of six different hospitals across Western Europe found the average number of medications taken by an older inpatient population (median age 82 years) to be six (41).

Older people are particularly vulnerable to adverse drug reactions due to changes in the handling of, and sensitivity to, many medications in the ageing body. Polypharmacy, leading to interactions between medications, may exacerbate this

problem further. In fact, older age and greater number of medicines are two of the strongest predictors of potentially harmful medication errors and hospitalisation for preventable adverse drug events, as discussed below.

In England, the PRACtICe Study, published in 2012, conducted a detailed examination of the prescribing records of 1,777 patients in general practice with the aim of identifying and learning from medication prescribing and monitoring errors (42). In this study, a prescribing error was defined as an unintentional, significant reduction in the probability of treatment being timely and effective, or increase in the risk of harm, as a result of a prescribing decision or prescription-writing process. A monitoring error was said to occur when a prescribed medicine was not monitored in the way which would be considered acceptable in routine general practice.

The PRACtICe study found a higher prevalence of prescribing and monitoring errors in elderly patients. Of patients who had received at least one medication, 38% of those aged 75 years or older experienced an error, compared to 20% of all patients. The study also found that 30 and 47% of patients receiving respectively 5 or more and 10 or more medications had prescribing or monitoring errors in the 12-month study period. Thus both older age and polypharmacy were associated with a higher rate of unsafe or inappropriate prescribing.

A meta-analysis of 68 studies reporting adverse drug reaction (ADR) related hospital admissions included 17 studies where participants were elderly (age over 65 in most cases, over 70 in one and over 75 in another) (43). In those studies, ADRs were associated with 17% of admissions, compared to 4% in the non-elderly population. Twelve of the 68 studies reported data on the preventability of admissions, two of which were studies of elderly patients. Overall, 88% of elderly admissions were judged to be preventable. The authors concluded that ADRs in the elderly result in a significant number of unnecessary hospital admissions and associated waste of money (43). A later systematic review of 25 prospective studies found that in the five studies involving older patients (aged over 60), 11% of admissions were ADR related, compared to 6% for non-elderly adults (44).

A further study conducted after these two reviews found that 6.5% of elderly admissions where related to ADRs, with almost three-quarters of the ADRs suffered classified as avoidable (45). Medications commonly reported to be involved in ADRs in elderly patients include those used to treat cardiovascular and central nervous system disorders, as well as non-steroidal anti-inflammatory drugs (NSAIDs) (43-45).

Other studies have used broader definitions when identifying hospital admissions related to medication. A review of 15 studies from seven countries reporting preventable drug related admissions (PDRA) found that where the average age of patients was over 70 years, the rate of PDRA was approximately twice that of studies where patients were younger (7.6% vs 3.9%) (46). A further recent large prospective study conducted in two hospitals in England found very similar results: 7% of admissions in patients aged 65 or over were PDRA, nearly twice the proportion found in younger adult patients (4%) (40).

2.6: PRESSURE ON HOSPITAL BEDS

Rates of emergency hospital admission (those which are not planned and happen at short notice because of perceived clinical need) continue to rise. In response to the growth in emergency admissions, the 'emergency marginal rate' rule was introduced into the national tariff of payment to NHS hospitals (Payment by Results, PbR) in 2010/11, in an attempt to lower the rates of emergency admission and encourage acute providers to work with other stakeholders to reduce demand for emergency care (47). This rule sets a baseline monetary value for emergency admissions at provider level. A provider is then paid only a percentage of the national price for any increases above this baseline.

In October 2013, the National Audit Office (NAO) produced a report examining emergency hospital admissions (48). Despite the adjustments to the national payment tariff, the report stated that in 2012-13, there were 5.3 million emergency admissions to hospitals in England. These admissions costed approximately £12.5 billion and represented an increase of 47% in the number of emergency admissions over the preceding 15 years.

The NAO report identified that the main factor in the increase in long-stay admissions is the increasingly frail elderly population who are living with one or multiple LTC (48). This population are far more likely to have immediate or chronic health problems, to need urgent care and to go to an accident and emergency (A&E) department. Once in A&E they are more likely to be admitted into hospital, and once admitted, typically spend much longer in hospital, thereby costing the NHS more under the PbR system (48). The King's Fund Report, *Older People and Emergency Bed Use: Exploring Variation* found the average emergency length of stay increased with age, from 7 days for those aged 65–74 to 11 days for those aged 85 and over (49). This compares to the overall average length of stay following emergency admission of 5.8 days (48).

In light of the increase in emergency admissions and the increase in the elderly population, the DoH commissioned the Centre for Health Service Economics and Organisation (CHSEO) to conduct a study of recent trends in emergency hospital admissions of older people, aged 65 and over, and factors associated with these trends (50). This study found that emergency admissions for people aged 65 and above in England increased by 46% between 2001/02 and 2012/13, from 1.5 million to 2.2 million. Even when demographic population changes were taken in to account, the rate of emergency admissions of older people per thousand older population increased by almost 26% over this 11-year period.

Similar to the NAO, the CHSEO report found that all age groups had seen considerable increases in the number of short-stay admissions over their study period. When looking at emergency hospital spells of at least 2 days, they found a reasonably stable picture for people aged 20 to 84. However, amongst people aged 85 and over they found a substantial increase of 52% (50).

The CHSEO report states that the underlying demand for emergency inpatient care in old age has been affected by rising numbers of older people and by changes in the health state of the older population, but these factors explain only around one-third of the rise. It may therefore be that changes in attitudes, including rising risk aversion among the public and health and social care staff, have affected demand by lowering the threshold for seeking emergency care. The increased scope for urgent and emergency care to diagnose and treat health conditions, and

associated greater awareness may also have put upward pressure on demand (50).

All parts of the health system have a role to play in managing emergency admissions and ensuring that patients are treated in the most appropriate setting. Hospital based factors such as accessibility and internal processes can influence the likelihood of patients aged over 65 being admitted as an emergency and their subsequent speed of discharge (49). However, the current movement towards full service provision seven days a week in hospitals is not matched by community services, which can compromise attempts to prevent emergency admissions and prolong the length of stay for patients unable to access pathways out of hospital seven days a week (48,51). Older people are more likely to be affected by this as they are more likely to need support in the community (51). This is a particular concern for older people as a long length of stay is associated with poor outcomes for the elderly, especially those who are frail and suffer from dementia. With prolonged length of stay comes an increased risk of complications such as falls, delirium and hospital acquired infection. All this lowers the likelihood of a successful return to independent living (51).

Relationships between services in primary and secondary care and the extent to which they co-ordinate and work collaboratively are important. Interestingly, the King's Fund found that areas with higher proportions of people aged over 65 have lower rates of acute bed use. This suggests that in areas with a relatively high proportion of older people, more attention may have been paid to service improvements such as the development of more integrated care models. Indeed areas with well-developed, integrated services for older people (in terms of both integration between health and social care and between hospital and community care), had lower rates of hospital bed use.

2.7: NATIONAL HEALTH POLICY: THE DRIVE TOWARDS CARE IN THE COMMUNITY

Avoiding unnecessary emergency hospital admissions and managing those that are admitted more effectively is a major concern for the NHS (48). According to

the DoH, approximately 20% of emergency admissions are for known conditions that could be managed effectively in the community (14). *Transforming Primary Care*, published by the DoH in April 2014, is part of the national strategy to provide proactive, joined-up care for older people and those with complex needs. The plan states that providing these patients with personalised support outside of hospital will be critical in achieving a reduction in unplanned hospital admissions. This includes co-ordinating services and providing proactive follow up support on discharge to prevent readmission. This document makes reference to the part that pharmacy services can play, by supporting older people to use their medicines safely and effectively and to make decisions about how they can maximise their health (14).

This vision is echoed both in the 5YFV and in *Prevention is Better than Cure*, which advocate that patients with LTC should be empowered to take control of their own care, and that more care must be delivered outside of hospitals (15,32). Barriers between primary, secondary and community healthcare, and between health and social care, must be broken down. Options presented by the 5YFV to achieve this include integrated hospital and primary care providers known as Primary and Acute Care Systems, which combine general practice and hospital services, and Multidisciplinary Community Providers, combining General Practitioner (GP) services with nurses, other community health services, hospital specialists and perhaps mental health and social care to create integrated out-of-hospital care (32). The 5YFV recognises the particular challenge of providing support for frail older patients, who are more likely to have multiple LTC and increased health and social care needs (32).

The DoH's *Shared Delivery Plan*, published in February 2016, outlines its own main objectives for 2015-2020, and endorses NHS England's 5YFV. The plan focuses on the importance of supporting people to take an active role and make their own decisions regarding their health and care. A key objective is to reduce emergency hospital admissions by improving out of hospital care, with more preventative and person centred care, especially for people with LTC (52). To support the achievement of these objectives, NHS England, the Department for Communities and Local Government, the DoH and the Local Government

Association (a politically-led, cross-party organisation that works on behalf of councils to support, promote and improve local government) have set up a single pooled budget for health and social care services to work more closely together in local areas. Individual clinical commissioning groups (CCGs) and local authorities are required to pool budgets and to agree an integrated spending plan for how they will use their allocation. Now called the Better Care Fund and totalling £5.3bn, key aims of this initiative include preventing non-elective hospital admissions, reducing inappropriate admissions of older people into residential care, supporting vulnerable older people discharged from hospital through reablement or rehabilitation programmes to prevent readmissions, and reducing delayed transfers of care from hospital (53).

Delayed transfers of care and barriers to collaboration and co-ordination of care across local health economies were identified as major challenges faced by hospital trusts in the Carter Report on productivity and efficiency in English acute hospitals (54). The report states that hospital trusts, and their local health and social care partners, are currently working within a system where the incentives and processes around transfers of care are not always clear and rarely fully aligned. Greater collaboration to establish a daily cycle of early and proactive transfer out of hospital could lead to both efficiency and quality improvement opportunities but time and effort is needed to engage local health and social care partners and communities. Optimising information technology systems to allow the capture of patient data across a variety of care settings in the acute sector and the community was identified as key to delivering timely and co-ordinated transfer of care.

Pharmacy was recognised as one of the key resource areas within NHS hospitals by the Carter Report, which recommended that pharmacists and clinical pharmacy technicians should spend more time on patient facing clinical services such as medicines reconciliation, prescribing and discharge support as this increases the likelihood that medicines use is optimised (54).

2.8: SUMMARY

There is a need for pharmacy services to adopt the ethos of the national strategy to encourage integration between providers of care in different sectors. This is particularly important given the increasing number of elderly people with multiple LTC, prescribed multiple medicines. Pharmacists have the potential to support these patients and their carers to become empowered to manage their medication and make their own decisions regarding drug treatments. However, the role the pharmacy profession can play in collaborative care is under-developed and this highlights a gap for evidence based services to be introduced to support medicines-related transitional care of older people.

CHAPTER 3: MEDICINES RELATED TRANSFER OF CARE OF OLDER PEOPLE

This chapter discusses the problems that can occur with medicines when older people are discharged from hospital, why they happen and their consequences. The need for mechanisms to improve medicines related transfer of care in the elderly is identified and some possible methods to achieve this are introduced.

Transfer (or transition) of care occurs whenever patients move between care providers (55). It includes admission to and discharge from hospital, shift changes on a ward, transfers between departments in a hospital, and transition from a patient's own home to a long-term care facility (1). Moving between inpatient and outpatient settings is a routine part of patient care and is the most extensively studied transfer of care to date (1).

Hospital discharge is a period of transition from hospital to home that involves transfer in responsibility for care from the inpatient provider to the patient and the primary care team (56). Inadequate communication and insufficient care co-ordination are common challenges during transfers of care. Poor communication between inpatient and outpatient providers, together with the lack of an effective communication infrastructure, contributes to poor patient outcomes (1).

3.1: PROBLEMS WITH MEDICINES OCCURING ON DISCHARGE FROM HOSPITAL

Adverse drug events (ADEs) are adverse outcomes experienced by patients, which are caused by medication (2). A slightly broader term, drug related problem (DRP) has been used by some researchers to encompass all events or circumstances involving drug therapy that actually or potentially interfere with desired health outcomes (57). DRPs include issues with treatment effectiveness, adverse drug reactions (ADRs), and others such as patient dissatisfaction with treatment and non-adherence (57). Using these definitions, all ADEs are DRPs, but not all DRPs ultimately lead to ADEs.

Although they may occur at any time, there is a greater risk of DRPs and ADEs during care transitions (1). ADEs are the most common type of adverse event reported following discharge from hospital, occurring in 10-20% of patients after discharge (3). In one study, almost half of ADEs resulted in a visit to the family doctor or hospital emergency department (ED), or a readmission to hospital (2).

The first few weeks following discharge are a particularly high-risk interval for ADEs because patients have often experienced a recent change in health state and they have frequently had several prescription changes (2). Nearly two thirds of patients have three or more medicines changed during their hospital stay, and the likelihood that an elderly medical patient will be discharged from hospital on the same medication they were admitted on is less than 10% (4,5). Almost all ADEs occurring post discharge are caused by new or altered medication rather than those unchanged from pre-admission (2). More than half of these ADEs may be preventable or ameliorable (i.e., duration or severity could be decreased) (2).

Certain patient populations are particularly at risk of ADEs following hospital discharge, including the elderly and those taking 5 or more medicines, with patients discharged on 12 or more medicines having almost three times the risk of those discharged on 4 or less (1,2,6).

Reasons identified for post-discharge ADEs include poor communication during transitions in care, lack of monitoring and review of treatment and patients not taking their medicines as agreed (non-adherence) (3,6,56). Poor communication may occur between healthcare professionals and patients or between professionals in secondary and primary care.

This situation may be exacerbated by a condition described as 'post hospital syndrome' - a transient period of approximately one month following discharge, during which there is a generalised risk for a wide range of adverse health events. This syndrome may emerge due to the myriad of physical and cognitive stressors involved in a hospital admission, which can adversely affect health and contribute to substantial impairments during the early recovery period, an inability to fend off disease, and susceptibility to mental error (7).

3.1.1: Patient Non-Adherence

Medication adherence can be defined as 'the extent to which the patient's medication taking behaviour matches agreed recommendations from the prescriber' (12). It is estimated that between one-third and half of all medicines for LTC are not taken as recommended (58). Medication non-adherence leads to reduced clinical benefit, avoidable morbidity and mortality and medication wastage. The estimated opportunity cost of health benefits forgone because of poor adherence is over £500million per year in the UK, and with increases in life expectancies and the number of patients living with chronic illnesses, for which they are prescribed medication, this problem may well get worse in coming years (59,60).

Unintentional non-adherence refers to practical barriers to patients taking medicines as prescribed. These might include problems with memory (e.g. forgetting instructions or forgetting to the take the medication), dexterity (e.g. difficulties in opening containers or using devices such as inhalers or injections), knowledge (e.g. being unaware of how to obtain a repeat prescription) or difficulties with disruptions to normal routine (12).

Intentional non-adherence describes the way in which patients may take deliberate decisions to adjust their own medication use (e.g. not taking it at all or modifying the dose or frequency). Intentional non-adherence is thus an action that is rational in terms of patients' beliefs, circumstances, priorities, preferences and experiences, although these perceptions and actions may differ from medical expectations and rationality (12).

There is a degree of overlap between the categories of unintentional and intentional non-adherence. For example, forgetting can be unintentional but might be influenced by intentional or motivational factors such as a lack of perceived need for treatment. In contrast, practical barriers may be overcome where motivational factors are high (12).

Medication adherence therefore depends on the patient having the knowledge, motivation, skills and resources required to follow the agreed recommendations. In addition, adherence is a dynamic process, whereby the experience of adherence

or non-adherence can alter pre-disposing factors such as beliefs about medication (60). This complex interaction has been mapped to a model known as the COM-B model for human behaviour (60). COM-B hypothesises that interaction between three components, Capability, Opportunity and Motivation (COM) causes the performance of a behaviour (B) and hence can provide explanations for why a recommended behaviour (such as taking a medicine in a particular way) is not engaged in. Each component can influence behaviour directly and, in addition, opportunity and capability might influence motivation and so affect behaviour. Performance of the behaviour can in turn influence capability, opportunity and motivation (Figure 3.1). The COM-B model therefore includes and expands upon the concepts of unintentional and intentional non-adherence (60).
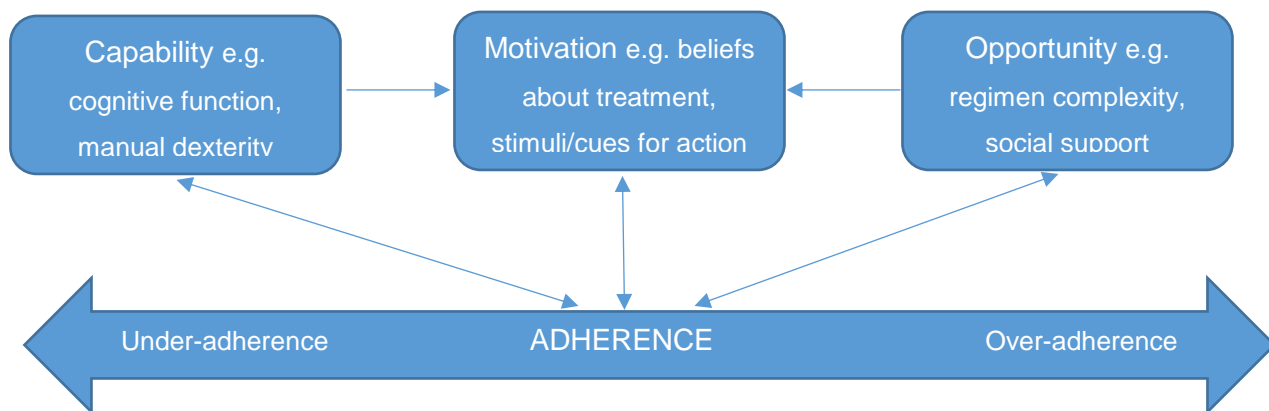
Figure 3.1: Application of COM-B to adherence, reproduced from (60).

Factors associated with unintentional non-adherence are particularly prevalent among people aged 75 years and over. These include a greater prevalence of cognitive problems, multiple pathology leading to complex polypharmacy, living alone and dexterity problems (12,13). Older people, like younger people, may also make intentional decisions to change or stop their medication without professional advice, due to side effects, symptom changes or perceived inefficacy of treatments prescribed (12).

Non-adherence and Hospital Admissions

In a large observational study of 3784 patients screened by pharmacists on a hospital medical admissions unit in England, adherence problems were the cause of 1.3% of all admissions (61). The drug class most frequently associated with admissions due to adherence problems was loop diuretics, although, antiepileptics, nitrates, corticosteroids and insulins were also associated with adherence related admissions (61).

These results are similar to those of a study in Denmark, where 1.8% of 333 admissions were found to be the direct result of adherence problems (62). The authors of this study found that non-adherent patients were prescribed more medicines than patients with no reported adherence problems, supporting the theory that polypharmacy is a risk factor for non-adherence. They also noted that as one-third of patients were admitted due to symptoms that were apparently already being treated, some of these cases may be the consequence of undetected non-adherence. Adherence in this study was assessed during patient interviews, which the authors state may be unreliable if patients under-report adherence problems. Therefore, the contribution of adherence problems to admissions may have been underestimated (62).

The role of non-adherence may be even more important in hospitalisations of the elderly. American researchers interviewed 315 consecutive elderly patients admitted to an acute care hospital and found that 11.4% were due to non-adherence (63). Again, polypharmacy was associated with a higher risk of adherence related admission, as was the involvement of multiple different physicians and poor recall of medication regimen (63).

All of the studies discussed above are now well over 10 years old. Given the aging population and increase in polypharmacy in recent years as discussed in Chapter 1, it is possible that now adherence related admissions among the elderly are even more prevalent.

Adherence Following Hospital Discharge

Patients in hospital receive nearly 100% of their prescribed medication regimen, and therefore have favourable odds of experiencing optimal therapeutic outcomes

from medicines while hospitalised. If patients deviate from the intended regimen following discharge, breakthrough symptoms may occur; leading to avoidable morbidity and hospital readmission (6).

In an American study, 147 patients aged 65 or older discharged from hospital on more than 2 medicines (mean 9.3) and receiving home health services were followed up in their homes 2 weeks after discharge (64). Forty-four percent of participants were under- or over adherent with at least one medicine. The probability of non-adherence in this study increased by 16% for each extra medication a person was taking. Patients with cognitive impairment were 2.5 times more likely to be non-adherent to at least one medication than those without.

Researchers in an Australian prospective cohort study of 68 patients discharged from hospital to their own home on more than 2 medicines utilised telephone follow-up one month after discharge to assess adherence (65). Participants had a mean age of 70 years and were prescribed a mean of 9.5 medicines. Forty percent reported non-adherence to one or more regular medications, equally split between intentional and unintentional non-adherence, with some patients displaying both types. The most common reasons for intentional non-adherence were that patients felt the medication was unnecessary, and experiencing adverse effects. Medicines intentionally discontinued by patients included respiratory drugs, gastric acid suppressants and anti-hypertensive drugs. Medicines subject to unintentional non-adherence included anti-hypertensive and lipid lowering drugs and gastric acid suppressants.

A similar study in Italy enrolled 100 patients aged 65 years of age or older (mean age 78 years) discharged from medical wards and receiving at least four medications (8). Non-adherence with at least one medication was reported for 55% of patients at 15-30 days post discharge and 70% by 3 months after discharge. Again, feeling the medication was unnecessary and fear of side effects were the main reasons for non-adherence. At the first follow-up, the mean number of drugs prescribed to non-adherent patients was significantly higher (9.5) than in patients with regular medication adherence (8.2). Diuretics, psycholeptics, analgesics and laxatives were the drugs most commonly associated with non-adherence. The authors conclude that simplifying drug regimens and reducing the

pill burden as well as boosting the patient's understanding of the prescribed medications should be considered targets for intervention to improve adherence.

No published studies from the UK could be located specifically investigating post-discharge medicines adherence. However one study conducted in Southeast England aimed to explore patients' problems with new medicines prescribed in primary care for chronic conditions (66). On telephone follow-up at 10 days, 30% of 226 patients were already non-adherent. Two-thirds of patients were experiencing one or more problems with their new medication, in terms of side effects, concerns or practical problems, and 61% had unmet information needs. As changes made to medication regimens in hospital may well be more complex than adding a single new medicine, problems with post-discharge adherence are likely to be even more prevalent than in this study.

If patients do not understand why their medications are important or the potential for negative outcomes if non-adherent, then they may be more likely to self-cease medications. This is particularly true of treatment for asymptomatic disease, as patients cannot see a tangible benefit of their medication (67).

Community pharmacists are well placed to help patients gain this understanding and support medicines adherence following discharge from hospital.

3.1.2: Poor Communication during Transitions of Care

Most errors and adverse events following discharge result from a breakdown in communication between the hospital team and the patient or primary care physician (56). In England, the 2009 Care Quality Commission (CQC) report *Managing patients' medicines after discharge from hospital* found that information shared between GPs and hospitals when a patient moved between services was often patchy, incomplete and not transferred quickly enough (68). The report stated that acute trusts needed to improve the quality of information sent to GPs in discharge summaries, and that Primary Care Organisations (PCOs, formally Primary Care Trusts, now replaced by CCGs), needed to ensure that safe processes were in place for critically reviewing medication changes and updating patients' records after discharge. Both acute trusts and primary healthcare

professionals were urged to ensure that they communicated more effectively with patients about their medicines, both at the point of discharge and after return to the community.

The need to improve discharge information and patient education around medicines was highlighted again by a Department of Health action plan to improve the use of medicines and the RPS guidelines on transfer of care and medicines optimisation (55,69,70). All of these papers make reference to the importance of post discharge medication reviews, and advise hospital pharmacists to collaborate more with patients' community pharmacists, in order to ease transitions in pharmaceutical care.

However in the UK there have historically been, and continue to be, gaps in communication regarding medicines between hospitals and primary care on hospital discharge. In a questionnaire survey of 163 UK hospitals published in 2000, 42% of respondents stated that reasons for medication changes were 'never' given on discharge summaries, and 48% that this information was only 'sometimes' given (71). Ninety-five percent of hospitals reported that they either never involved community pharmacists in the discharge process, or did so in <10% of discharges. Where this did occur the communication was usually via telephone, and restricted to patients taking unusual medicines or needing multi-dose compliance aids. Recent (2016) research involving telephone interviews with 13 chief pharmacists, or suitably qualified nominees, from North-West England found that it is still 'uncommon' for information to be sent from hospital to community pharmacy (72).

From the community pharmacists' perspective, a postal questionnaire completed by 163 community pharmacists in northern England in 2001 found that 96% would not know if a patient of theirs had recently been in hospital, which supports the findings from the questionnaire survey above (73). Eleven years later, in a survey of community pharmacists in Ireland, 91% of respondents reported no or only occasional contact by a hospital when patients were being discharged (74). Similarly, semi-structured interviews with 14 community pharmacists from one primary care organisation in England found that these pharmacists did not routinely receive information when a patient had been in hospital and often only found out via 'ad-hoc' conversations with patients or carers (75). Information that was

received was not always consistent or comprehensive. However when information was received, pharmacy staff would make an effort to communicate with patients regarding changes. Ten of the 14 pharmacists interviewed gave examples of when poor communication had compromised patient safety, for example wrong doses of medicines being taken, patients running out of medicines and incorrect repeat prescriptions being dispensed due to the lack of timely updating of records, as identified in the *Moving Patients, Moving Medicines, Moving Safely* document (76). The situation was reportedly exacerbated by the fact that discharge information was not always received or processed in a timely fashion by GP surgeries (75).

Medication Discrepancies

Medication discrepancies on discharge from hospital are differences between the medicines prescribed on discharge, and the pre-admission regimen (56). Discrepancies may also occur between the discharge prescription and the medicines actually taken by the patient following their return home (77). Reported rates of medication discrepancies on, or following, discharge vary widely, with differences between studies in the terminology and definitions used as well as study populations and methodology. For example, some studies use the discharge prescription itself to detect discrepancies, whilst others use the first prescription subsequently issued in primary care. Studies also vary in the way results are reported (e.g. percentage of patients experiencing at least one discrepancy or total number of discrepancies) (6). Some studies differentiate between intentional discrepancies (where there is a difference between pre-admission and discharge medication but this can be clinically justified with reference to discharge documentation), and unintentional discrepancies, which may lead to medication errors and ADEs in primary care if not promptly resolved (78,79).

There are numerous reasons why unintentional discrepancies between pre-admission and discharge medication may occur (56). Firstly, incomplete medicines reconciliation on admission to hospital may mean that discrepancies are present throughout the patient's admission and carried forward onto the discharge prescription. Researchers have identified unintentional error rates on hospital prescriptions at admission of between 30 and 70%, and while intensive medicines reconciliation activities by hospital pharmacists within 24 hours of admission can

dramatically reduce the number of unintentional discrepancies on discharge; this is not currently standard practice in UK hospitals (80).

Secondly, acute illness may lead to significant modification to pre-admission medication. However once the acute phase of the illness is over, many of these medicines will need to be re-started. Failure to review and resume these medicines may lead to unintentional discrepancies on discharge. Conversely, some medicines which were required during hospitalisation may be unnecessarily carried forward onto the discharge prescription (56).

In the PRACtIcE study (Section 2.5), 36 out of 37 patients were found to have discrepancies between pre-admission and discharge medication regimens when their GP records were reviewed (42). Discrepancies were found between discharge communications and subsequent GP prescriptions in 43.2% of discharged patients, including 28% of all new medicines. In a recent study of 403 discharge prescriptions processed by Dutch community pharmacies, 92% led to one or more problems with continuity of care, including 356 medication discrepancies (81). There were also 33 cases where a drug had been prescribed with an unclear indication, and the number of problems per prescription increased with increased number of prescribed drugs post-discharge.

These two studies, however, did not report on what proportion of these discrepancies was intentional. A systematic review and process mapping of medication use in primary care in the United Kingdom, published in 2009, reported that unintentional discrepancies were found in 11 to 27% items prescribed on discharge (82). Unintentional discrepancies in repeat medication subsequently received from the GP were found in around half of all items issued, affecting 57% patients. The fact that the rate of unintentional discrepancies was higher in studies of post-discharge prescriptions issued in primary care than in those evaluating discharge prescriptions directly suggests that the rate of prescribing errors post discharge could potentially be reduced by completing thorough medicines reconciliation in the community setting, before the issuing of the first post-discharge prescription by the GP.

Further highlighting the difference between intentional and unintentional discrepancies, researchers at a teaching hospital in Spain who reviewed 954 discharge documents reported that, although discrepancies were found in 87%, most were intentional and could be resolved with reference to the discharge letter (78). Only 5% of discharges contained unintentional discrepancies. It is likely to be relevant here that the authors describe a rigorous process for medicines reconciliation on admission to the hospital, and excluded any discharges where this had not been completed. It was also specified that clinicians at the study hospital made reference to the admission list of medication when preparing the discharge prescription. This is likely to reduce the number of omitted medicines from pre-admission, which is a frequent cause of discrepancies in other studies (3,79,81). This reiterates the value of thorough medicines reconciliation on admission to and discharge from hospital in reducing unintentional medication discrepancies.

Researchers at a tertiary care teaching hospital in Canada found that 41% of patients had at least one unintentional medication discrepancy on their discharge prescription (79). Thirty per-cent of the discrepancies were assessed as having the potential to cause patient discomfort or clinical deterioration. The researchers separately studied 'potential' unintentional discrepancies; situations where clear patient directions regarding the management of medication, for example the post-discharge status of a pre-admission medicine, were omitted or not explicitly documented on the discharge letter (these are likely to have been classified as discrepancies in their own right in some of the other studies discussed).   The medication listed on these discharge summaries may be correct, and discrepancies clearly intentional when interpreted by a healthcare professional with reference to the patient's reason for admission and clinical status on discharge. However, these ambiguities, affecting 55% of discharges, could cause confusion in patients without this specialist knowledge, which could then lead to unintentional non-adherence and patient harm.

This situation was demonstrated during a follow-up study of 50 elderly patients (mean age 77 years) discharged from a district general hospital in England, who were visited at home by a pharmacist after the initial supply of medicines given by

the hospital should have run out (83). Forty-five (90%) patients were following a different regimen to that prescribed on discharge: 11 were taking a different dosage, 10 had stopped medicines that were prescribed and 20 were taking medicines which had not been prescribed. This latter group included patients who were taking medicines which had been prescribed for them pre-admission but had not been noted during their hospital admission, as well as medicines that had intentionally been stopped by the hospital. Some of the differences between the discharge prescription and medications subsequently being taken were clinically unimportant (e.g. a change in brand name) or intentional (e.g. following advice from a healthcare professional subsequent to their discharge). However many of the patients had not been reviewed by their GP, and some of the discrepancies could have had serious consequences. For example, 11 patients had not obtained further supplies of medication before the supply from the hospital had run out, leading to a break in treatment.

A similar study in the United States of America (USA) focussed on the factors contributing to post-discharge medication discrepancies, which were found in 14% of 375 patients aged over 65 who were visited within 72 hours of discharge by a geriatric nurse practitioner (77). As well as being older, the participants in this study were predominantly Caucasian and all had prescription drug coverage (i.e. they did not need to pay for prescription medication), which makes them more similar to the population studied in this thesis compared to other studies reviewed. Causes of discrepancies were found to be equally split between patient and system associated factors. The most common system-associated causes of discrepancies were incomplete or ineligible instructions on how to take medication and conflicting information from different sources. The most prevalent patient-associated cause of discrepancy was non-intentional non-adherence due, for example, to patients resuming pre-discharge medication on their return home. Five medication classes accounted for half of all identified medication discrepancies: anticoagulants, diuretics, angiotensin-converting enzyme inhibitors, lipid-lowering agents and proton pump inhibitors. Two variables were significantly associated with patients having experienced medication discrepancies: the number of medications taken (patients with discrepancies were taking an average of 9

medicines whereas those with no discrepancies were taking an average of 7) and the presence of congestive heart failure. The emergency readmission rate among patients with medication discrepancies (14.3%) was significantly higher than that among patients with no medication discrepancies (6.1%).

It is notable that the rate of discrepancies was much lower in the American study than the smaller English study. Other than differences between the two countries in terms of transfer of care procedures, which may have affected results, one possible reason for the higher rate of discrepancies in the English study is that the time to follow-up was longer. Non-intentional deviation from the discharge regimen may become more prevalent once the hospital supply of medicines has run out, as patients may become confused about what to do next and this may be compounded by delays in continuity of supply or errors on subsequent prescriptions issued in primary care (83). This theory is supported by the process mapping research referred to above which found that discrepancies were more prevalent in studies of post-discharge prescriptions issued in primary care than in studies of the discharge prescriptions themselves (82). The English study also used a broader definition of discrepancy; for example changes in dose timings even if the overall dose remained the same, and changes in brand names even if these did not lead to a deviation in the actual medication usage.

However a further American study evaluating post-discharge medication discrepancies found similar high discrepancy rates as the English study. In this study, 94% of 101 patients had at least one discrepancy (84). Forty percent of patients had at least one discrepancy attributable to adherence barriers; similar to the figures reported in studies specifically investigating post-discharge adherence (8,64,65). Sixty-nine percent had one or more system related discrepancies, most commonly due to incomplete or inaccurate instructions on prescriptions, conflicting information from different sources, therapeutic duplication or incorrect dosage. The authors note that the higher number of discrepancies in their study compared to earlier American studies could be due to the complex health problems and polypharmacy among patients in their study (average number of medicines per participant was 10.4). They also note that medication history taking on admission to hospital may have been sub-optimal in their study, and that increasingly strict

formularies in the acute setting lead to extensive substitution of medications which may have increased the potential for discrepancies in the hospital to home transition. Additionally, the definition of discrepancy used in this study was broad and included situations such as non-use or dose reduction of analgesics prescribed on discharge because these were no longer needed. As already discussed, there are inconsistencies in published research as to whether such situations should qualify as discrepancies or non-adherence at all (8,65).

Patient Involvement and Education

The fact that many patient-associated medication discrepancies, knowledge gaps and adherence problems were found in the studies described above highlights the need to place the patient at the centre of their care. NICE guidance on medicines optimisation states that good communication between healthcare professionals and patients is needed for involvement of patients in decisions about medicines and for supporting adherence (85).

However, while receiving care in hospitals, patients often assume a passive or dependent role as clinical staff members address their needs, including the administration of medication (79). It has also been suggested that the brief period prior to discharge is not an ideal time to convey new and complex information to older patients, as pain, anxiety, sleep deprivation, or delirium may limit receptivity to new learning (77).   Furthermore, at hospital discharge patients may be overwhelmed with information, at a time when their primary concern is to get home as quickly as possible (81).   In spite of this, once at home, patients (and their family members) are abruptly expected to assume a significant self-management role in the recovery of their condition and in the management of their medications, for which they may feel unprepared (77).

In the Dutch study of transfer of care issues identified by community pharmacists, patients' lack of medication knowledge was illustrated by the high need for patient education (406 instances among 403 patients, with some patients having more than one knowledge deficit) (81).   In the two American studies of nurse domiciliary visits post discharge, nearly a third of the patient-level discrepancies were attributed to participants not knowing that they were supposed to take a medication

or a lack of knowledge about taking the medication as prescribed (77,84). In the Italian telephone follow-up study, 72% of patients did not understand the purpose of all their medications at the first follow-up and 75% at the second (8).

UK studies have also found that patients do not always feel adequately prepared to participate in their post-hospital care. Elderly patients in the pharmacist home-visit study recalled little information being given about medicines whilst in hospital, particularly with regards to the purpose of their medicines, how to take them and potential side effects (83). This may reflect a true lack of communication between hospital staff and patients, or patients forgetting information that had been given.

Qualitative interviews in the UK with patients aged $\geq$75 and their caregivers found that inadequate explanations about medicines at discharge were commonly reported and lead to medicines being omitted, incorrect doses being taken, confusion and anxiety (86). Better communication between staff, patients and carers could, it was felt, significantly improve the hospital discharge procedure and the value of clear, concise lists of prescribed medicines was emphasised by many participants. Participants also highlighted the need for prompt and effective communication between the hospital and their GP and community pharmacist as they felt that being given the responsibility for this was a particular burden.

In the study in North West England interviewing chief pharmacists, interviewees admitted that patients had limited involvement in their own discharge from hospital (72). Furthermore, all agreed that patients are not always counselled on medication changes and that it is unclear who is responsible for doing this. In a questionnaire survey of 104 patients on their day of discharge from one of these hospitals, only 22% of participants felt that they had been fully involved in their discharge (87). Over a third were unclear about what medicines they should be taking after discharge, calling into question the quality of information given to patients and whether it is provided at an appropriate time, thus highlighting a need for improved communication with patients regarding post-discharge medication regimens. In that study, pharmacists were the least likely healthcare professional to provide patient counselling (only 13% reported being counselled by a pharmacist). This supports previous evidence that hospital pharmacists are unlikely to be providing adequate patient counselling (72,88).

In a 2013 survey of 1218 medical inpatients at six hospitals in North-West England, only 44% of patients felt fully informed about medicines (88). The survey also enquired as to whether participants had been asked if they had any concerns about medicines; 63% answered no, or could not recall whether they had been asked or not. In a recent inpatient survey involving many of the same hospitals, 76% of participants reported receiving enough information about medicines (89). However, 16% could not recall discussing medicines with any healthcare professional and only 38.5% felt involved in the decision to make changes, indicating that there may still be gaps in the support given to hospitalised patients regarding changes to medicines. In a telephone follow-up to this survey, 31% of patients reported needing support with their medicines after discharge. Issues included not knowing which medicines to continue taking, how long to take newly prescribed medicines, dose queries, side effect queries and wanting more information in general, particularly with respect to newly prescribed medicines or significantly changed regimens.

In the most recent NHS Adult Inpatient Survey, 71% of patients reported being given clear written information regarding medicines by the hospital, and 75% stated that the purpose of their medicines and how to take then were explained in a way they could understand (90). However the extent of the information provided to patients in the NHS inpatient survey and their retention of it are not reported. When asked about the specific scenario of information pertaining to possible medication side effects, only 38% of patients in the NHS survey reported being told 'completely' about side effects to look out for.

Taken together, this research indicates that the majority of patients discharged from hospital have unmet information needs regarding medication.

3.2: EXTENT AND IMPORTANCE OF READMISSIONS IN OLDER PEOPLE

Emergency readmissions to hospital (unplanned admissions which occur within one month of the original discharge) are rising year on year, with an increase of 27% between 2002 and 2012 (91). In 2012, around 15% of patients aged over 75 were readmitted within a month of discharge (92). In 2012-13, 19% of the 5.3

million emergency admissions to NHS hospitals were readmissions, and it has been estimated that each readmission costs the NHS £2114 on average (48,93). Therefore, emergency readmissions to hospital cost the NHS over £2.1billion each year.

According to an analysis published by the DoH in 2008, there is no single explanation for the increase in readmissions, but a number of possible contributing factors are cited (94). These include increasing number of patients admitted from A&E departments (increasing the overall number of admissions, some of which will be readmissions), changes in patient expectations (so they will re-present if they feel the original problem was not adequately dealt with or experience side effects from treatment), the quality of community health and social care services and transitional care between providers. Increased prevalence of LTC, particularly those associated with high healthcare usage such as heart disease and COPD, may also be contributing to the rise in readmission rates. In the context of the elderly, multiple co-morbidities and an increased likelihood of suffering the adverse effects of treatments increases both the likelihood and length of stay on readmission. The average length of stay following emergency readmission for patients aged 75 or over in 2006-7 was more than twice that of those aged 16-74; 13.9 days compared to 6.4 days (the overall average length of stay for all patients following emergency admission at that time was 7.6 days (48)). The DoH's report also suggests that a move towards treating less severe or complex cases in the community, when in the past they would have been admitted, may also mean that the patients treated in (and discharged from) hospital are more severely unwell than they were in the past. In such a scenario, an increase in the proportion of patients requiring readmission would not be surprising (94).

Emergency readmissions are included in the NHS Outcomes Framework as an indicator of quality care in the NHS (95). To provide the most suitable care for patients when they leave hospital (and therefore reduce the likelihood of readmission), hospitals need to have robust discharge planning arrangements in place. The NHS tariff of payment to secondary care providers specifically recommends more collaborative working and better coordination of clinical intervention with community and social care providers (96). It also states that

hospitals should co-ordinate with the patient's family and GP regarding medication as part of the discharge plan, to reduce the risk of readmission.   In addition to this, financial penalties have now been introduced for hospital trusts when emergency readmissions occur. These are determined locally following a clinical review of a sample of 30-day readmissions to determine the proportion that could have been prevented through actions that might have been taken by the hospital, primary care team, community health services or social services (96). The aim of the review is not to identify poor quality care in hospitals, but to identify actions that could have been taken to prevent readmission. The review leads to the setting of a 'threshold' level of readmissions, above which the hospital will not receive any payment. Where money is retained from not paying for emergency readmissions, this should be reinvested by the commissioner in post-discharge services that support rehabilitation and reablement and, in turn, may help to prevent avoidable readmissions (97).

However, determining the preventability of a readmission is challenging. Reports in the literature vary widely but overall, approximately one-third of readmissions may be preventable (98,99). Importantly, the preventability of medication related readmissions has consistently been judged to be higher than this, as will be discussed below, and therefore investment in improving medicines related transfer of care may represent a rational 'first step' in reducing the risk of readmission.

3.3: THE IMPACT OF MEDICATION ON READMISSIONS AMONG OLDER PEOPLE

In 2012, Age UK, the country's largest charity for older people, commissioned a piece of research in order to understand the causes and effects of emergency readmissions from the perspective of older people who had experienced them (100). Eighteen older people were asked to share their experience, beginning from their first admission to hospital through to the discharge and return home, and then their experience of the readmission to hospital. Several interviewees had a poor experience of being discharged from hospital, including a lack of information about how to take medication, and a lack of co-ordination between secondary and

primary care settings impeding access to supplies of medication post-discharge. Some interviewees also expressed a desire for a more person centred experience and to be more involved regarding decisions about their care. Where connections were made between their first admission and the readmission, these tended to be related either to the first admission not addressing the underlying health problem, or a lack of clarity at the point of discharge leaving them confused about the care they should be receiving once they left hospital, including how to take their medication.

Four senior stakeholders, whose role or organisation was connected to the issue of emergency hospital readmission amongst older people, were also interviewed for Age UK's study. Stakeholders agreed that an important component of discharge is the provision of information, the development of a care plan for the patient's care in the community, or simply the provision of advice for self-care. Variable care in the community, including communication failure between the acute and community settings, was also raised as a potential contributing factor to emergency readmissions.

As well as communication deficits between hospital staff and the patient and primary care team, taking more than 5-6 medicines on discharge has been identified as an independent risk factor for emergency readmission (101,102). Medicines most frequently implicated in preventable drug related readmissions include diuretics, antihypertensives and non-steroidal anti-inflammatories (including low-dose aspirin) (102-105).

A meta-analysis of 15 studies of preventable drug related hospital admissions found that studies reporting only readmissions assessed 14% as related to medication, approximately four times higher than those including first admissions as well (46). An audit of readmissions occurring during a 1-week period in 2012 at a teaching hospital in North-East England identified medicines as a causative or contributing factor in 20% of 81 cases (102). Three-quarters of these were judged to be medicines related and avoidable, meaning that 15% of all readmissions were related to preventable DRPs. A much larger, prospective study of patients discharged from a hospital in North-West England found similar results; approximately one-fifth of 403 patients re-admitted within one year had an ADR as

a contributing factor to re-admission, and of those approximately half (ie 10% of the total) were definitely or possibly avoidable (103). Increasing age was a significant risk factor for ADR related readmission; the median age of patients readmitted due to ADR was 74 years, as opposed to 68 years for all readmitted patients and 56 years for those who were not readmitted.

An American study of 100 patients discharged from an acute medical unit and readmitted within 60 days assessed that 64% of readmissions were related to a DRP (106). Increasing age and missing a follow-up appointment were associated with an increased risk of readmission, whilst the presence of a clinical pharmacy consultation during the original admission was associated with a reduced risk. The high number of medication related readmissions in this study compared to those above may be due in part to the broad definition used, which encompassed lack of treatment effect, adverse effects and factors related to treatment costs. The study authors also note that the hospital used in the study did not routinely reconcile medication on admission or discharge, which may increase the number of ADEs following discharge and hence the number of readmissions.

Medication related readmission rates have consistently been found to be higher in the elderly. In a UK observational study of 108 consecutive emergency readmissions of patients aged 75 or over, 38% were assessed to be related to medication and 61% of these were considered to be preventable (ie 23% of all readmissions were judged to be due to preventable ADEs) (104). Reasons identified for the preventable medication-related readmissions included poor documentation of changes to medication and associated lack of follow-up (accounting for 10% of all readmissions) and unrecognised poor adherence (accounting for 6.5% of all readmissions). A similar study in Australia found that 18% of all readmissions among a patient population of average age 79 were due to preventable ADEs (105). Nearly half of these were attributed to inadequate communication and/or monitoring of medication (accounting for 8.2% of all readmissions). Adherence problems were found in 53% of readmitted patients, including both under-adherence (usually due to side effects) and over-adherence (due to a belief the dose or frequency were not effective). This prevalence is within

the range reported previously in studies of post-discharge adherence problems (8,64,65).

3.4: POSSIBLE MECHANISMS TO IMPROVE MEDICINES RELATED TRANSFER OF CARE

Moving Patients, Moving Medicines, Moving Safely suggests a variety of interventions that can be put in place by hospitals to improve medicines related transfer of care (76). Among these are thorough medicines reconciliation on admission and discharge, improved pharmaceutical counselling accompanied by written information or reminder charts, pharmacist written discharge summaries, providing community pharmacists with information regarding discharge medication and the use of a pharmaceutical care plan or 'pharmacy discharge sheet' as a means of communication between hospital and community sectors regarding medication needs in the post-discharge period. The guideline recommends that these interventions are integrated with initiatives to improve electronic information transfer between sectors (76).

Many of these suggestions were used as the basis for projects initiated by the RPS transfer of care guidelines' 'early adopter sites', although the success of these projects has been varied (10,107). Other hospital initiated mechanisms that have been studied as a means of improving medicines related transfer of care include involving a pharmacist in a multi-disciplinary discharge planning team, telephone helplines manned by hospital pharmacy staff, and pro-active telephone, clinic or home follow-up from hospital based staff (108).

The CQC report *Managing patients' medicines after discharge from hospital* stated that PCOs should evaluate the level of pharmacist support available to them, focussing on medicines management after discharge, to improve safety and efficacy (68). This evaluation was to include a review of the number and deployment of pharmacy staff providing direct support to GP practices to provide a greater focus on post-discharge medication reviews and adherence support, particularly for complex or older patients. PCOs were also asked to evaluate the level of MURs carried out by community pharmacies, how these were targeted,

and improving feedback on outcomes when reviews were carried out. MURs are patient-pharmacist consultations, designed to assess any problems patients have with their medicines and to help develop the patient's knowledge of their medicines. In 2011, NHS Employers and the Pharmaceutical Services Negotiating Committee (PSNC) stipulated that 50% of MURs provided by community pharmacies should target patients in pre-defined groups identified as being at risk of medication related problems or poor adherence. In 2015 this proportion was increased to 70%. Patients recently discharged from hospital were identified as one of these groups, along with patients with respiratory conditions, those taking particular 'high risk' medications, and as of 2015, patients with cardiovascular disease or risk factors (9).

3.5: SUMMARY

Older patients are particularly at risk of DRPs following discharge from hospital. Reasons identified for this include poor communication regarding medicines on transfer of care, lack of monitoring and review of treatment, and patient non-adherence to medication. If not promptly addressed, some DRPs may ultimately lead to preventable readmissions to hospital.

The most effective intervention strategies to improve medication adherence involve regular monitoring, follow up and feedback for patients, and there is no reason why post-discharge adherence should be any different (56). Encouraging older patients to visit their community pharmacist for review soon after leaving hospital could be a simple way of developing a regular monitoring and support system for discharge medication regimens, improving adherence and reducing readmissions. A more comprehensive literature review of the role of the pharmacist in improving the transition from hospital to home, with a particular focus on community pharmacy, is covered in the next chapter.

CHAPTER 4: LITERATURE REVIEW

4.1: SEARCH STRATEGY

In order to define previous and ongoing research into interventions that support medicines related transfer of care for older people discharged from hospital, either led by or involving pharmacists, a comprehensive literature search was undertaken. Databases searched included the Cochrane Library, Embase, Medline, CINAHL, Web of Science, PubMed, Database of Abstracts of Reviews of Effects (DARE), NHS Economic Evaluation Database (NHS EED), National Institute for Health Research Dissemination Centre, Health Management Information Consortium (HMIC), Electronic Theses Online System (EThOS), NHS Evidence and the ClinicalTrials.gov Registry. In addition the website of the Pharmaceutical Journal (www.pharmaceutical-journal.com) was searched as its material, whilst being highly relevant to the practice of pharmacy in Britain, is not referenced in many mainstream databases. A full reproduction of the search strategies employed is found in Appendix 1.

Reference lists of the articles identified via the above resources were reviewed to identify further papers not identified in the main search. In addition, related papers 'suggested' by websites such as PubMed and Science Direct were also considered; this presented a further means of locating relevant research. Finally, other research known to the author, for example from networking at conferences or knowledge developed through experience of working as a specialist care of the elderly pharmacist in a district general hospital was reviewed for inclusion.

In order to gather the fullest base of literature to evaluate, all apparently relevant titles were reviewed, whether they related to controlled or uncontrolled trials, service evaluations, conference abstracts or review articles. Following initial title screening, the abstracts of papers which appeared relevant were reviewed and where these met inclusion criteria, every effort made to access the full, English version of the paper.

Inclusion criteria for review:

- Evaluation of intervention(s) to improve transfer of medication related care on discharge from hospital

- Intervention(s) delivered in full or part by pharmacists

- Focus on patients aged $\geq$65

Practice guidelines and government policy papers including recommendations for improving the quality of medicines related transitional care on discharge from hospital were also collated and will be discussed in the context of the research papers reviewed in Sections 4.2 - 4.4 of this chapter.

During this literature review a more narrative approach is taken than might be expected in a full systematic review, and meta-analysis was not appropriate due to the heterogeneity of papers reviewed. However where applicable Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria were followed; for example reproduction of search strategy, inclusion and exclusion criteria, reporting of study characteristics and results, consideration of limitations of studies reviewed, summary of evidence and interpretation of the results in the context of this thesis (109). Figure 4.1 represents a flow diagram describing the literature search based on the PRISMA template.

Reasons for excluding papers from review:

- Unable to access full version of paper in English

- Average age of participants <65 (unless study evaluated older participants during subgroup comparison)

- Study recruited only those who were:

  - Surgical patients

  - Cognitively impaired

  - Discharged to residential care

- Study focused on specific clinical condition only (e.g. heart failure, diabetes, COPD)

- Pharmacist not involved in transfer of care intervention

- Intervention limited to inpatient services without a transfer of care element

- Published after 2013. Later publications could not have informed the design of the study, which forms the basis of this thesis, as all study planning was complete and approvals gained by the early part of 2014. Instead, these papers will be reviewed in Chapter 8 (Discussion) of this thesis, placing the author's work in the context of current developments.

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┌─────────────────────┐   ┌─────────────────────┐
│ 4104 records        │   │ 40 records identified│
│ identified through  │   │ through other sources│
│ database searching  │   │                     │
└─────────────────────┘   └─────────────────────┘

        ┌─────────────────────┐   ┌─────────────────────────┐
        │ 4144 records        │→→→│ 3812 records excluded   │
        │ screened            │   │ (duplicates or not      │
        │                     │   │ relevant following title│
        │                     │   │ screening)              │
        └─────────────────────┘   └─────────────────────────┘

        ┌─────────────────────┐   ┌─────────────────────────┐
        │ 332 abstracts       │   │ 129 records excluded    │
        │ screened            │→→→│ from literature review as│
        │                     │   │ published after 2013 (but│
        │                     │   │ will be reviewed for    │
        │                     │   │ inclusion in discussion)│
        └─────────────────────┘   └─────────────────────────┘

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                                →→→│ 102 records excluded    │
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        ┌─────────────────────┐   ┌─────────────────────────┐
        │ 101 full text papers│→→→│ 30 papers excluded      │
        │ assessed            │   │                         │
        └─────────────────────┘   └─────────────────────────┘

        ┌─────────────────────┐
        │ 73 papers remaining │
        └─────────────────────┘

        ┌─────────────────────┐   ┌─────────────────────────┐
        │ 47 papers reviewed in│→→→│ 26 papers not included  │
        │ Chapter 3           │   │ as duplicated findings  │
        │                     │   │ already discussed       │
        └─────────────────────┘   └─────────────────────────┘
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Figure 4.1: PRISMA flow diagram of literature search

Database searches were performed from the earliest date available for each database at various stages throughout the progression of this PhD to inform study design and evaluation. A final search was run in April/May 2017, to present an overview of how this field of research has expanded over recent years. The growing importance of the transfer of care agenda is also reflected in the increasing number of national policy and practice guidelines published in this area (68,69,110-112). As shown in Figure 4.2, there has been a sharp increase in activity in this field since 2011, when the project described in this thesis was first conceived.
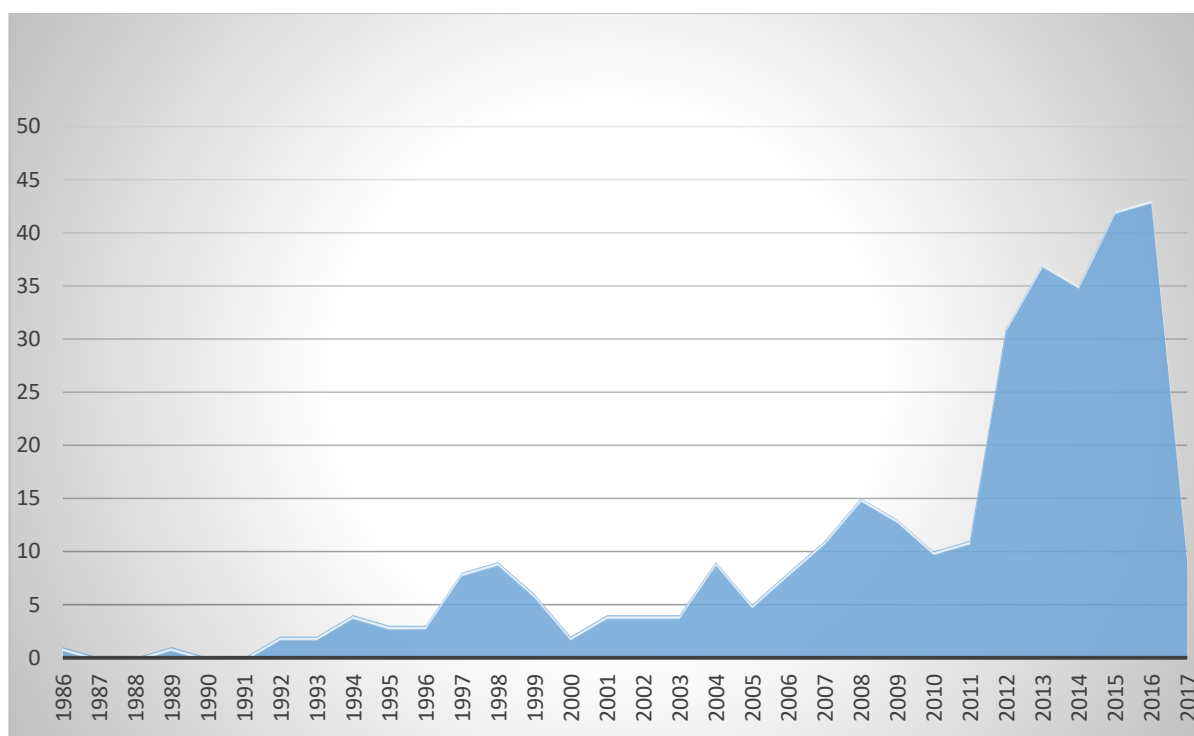
Figure 4.2: Number of papers relevant to medicines related hospital discharge care of older people, by year of publication

4.2: PAPERS PUBLISHED BEFORE 2000

The first papers reporting on pharmacist involvement in the transfer of care of elderly patients from hospital to the community were published in the mid-late 1990s. The inception of this research area in the UK was influenced by a number of factors, including the publication of the DoH's Community Care Act 1990, which aimed to improve the provision of services and support for people affected by

problems associated with aging, mental illness or physical/sensory disability, to allow them to live as independently as possible (113). Integration of primary and secondary care was identified as an important aspect of this type of care provision, and in a RPS policy statement on the pharmaceutical aspects of community care, the development of patient held documentation relevant to inpatient treatment and discharge and the improvement of links between hospital and community pharmacists were key recommendations (114).

Around the same time there was a recognition of the growing problem of medication non-adherence and ADEs amongst the elderly post-discharge population and rising numbers of potentially preventable readmissions. This coincided with the development of the concept of pharmaceutical care and the role of the clinical pharmacist, with subsequent identification of the potential of the pharmacy profession to provide support in addressing these problems (115-119).

4.2.1: Pharmaceutical Discharge Counselling and Follow-up

One early paper, published in 1994, reports on a small pilot study conducted over five months on three care of the elderly wards at Ryhope General Hospital, North-East England (115). This before and after study aimed to evaluate provision of an inpatient pharmaceutical care service and a pharmacy discharge care plan as a means of communication between the hospital and community sectors. Not all patients recruited received all elements of the service, which included medicines reconciliation on admission (n=38), performing a pharmaceutical assessment (n=38), counselling the patient before discharge (n=42) and providing the patient's GP and nominated community pharmacist with their medication details (including details of therapy changes and recommendations for ongoing pharmaceutical care, n=43). The study found that drug knowledge increased from baseline scores performed at the time of recruitment, and 73% of patients demonstrated 100% medication compliance assessed by tablet count. Whilst only half the recommendations for action by the GP or community pharmacist were followed, the authors acknowledged that the service was new, and in their opinion the more important recommendations had been actioned. The service was noted to be time consuming for hospital pharmacists to deliver, with the authors recommending targeting those most likely to benefit, for example the elderly on multiple drug

therapy.

The first RCT of a pharmacy-led transitional care service for older patients was conducted in the USA, and also published in 1994 (Table 4.1, page 84) (116). Clinical pharmacists provided intervention group patients with counselling on discharge medication prior to leaving hospital, followed by four follow-up consultations over three months. Medication adherence, assessed using a questionnaire administered via telephone, was found to be significantly higher in the intervention group post discharge. In addition, polypharmacy was reduced in the intervention group.

This study, however, failed to show a difference in hospital readmissions between groups after 6-month follow-up, with approximately one-third of both groups being readmitted at least once. The authors suggested that their study population (n=706) was too small to detect a significant difference in overall readmissions and that several thousand patients might be needed to do so. They also suggested replication of their study among 'high-risk' patients, such as those taking particular medicines that are known to be associated with serious ADEs, prescribing errors or poor adherence.

The concept of tailoring transfer of care interventions to patients anticipated to be at high risk of readmission was explored during a 1998 Australian RCT involving 762 discharged patients (Table 4.1) (117). All intervention group participants (n=381) received discharge counselling from either a pharmacist or nurse regarding compliance with medication and detection/reporting of worsening in their clinical condition. In addition, intervention patients deemed at high risk of readmission (defined as 2 or more of the following criteria: age $\geq$60, prescribed 2 or more medicines, admission within the previous 6 months, living alone or possessing limited English language skills) received a home visit one-week post discharge from a hospital pharmacist and nurse (n=314). At this home visit, the pharmacist assessed compliance and medication knowledge and made interventions where problems were identified, ranging from education, provision of compliance aid or medicines chart, organisation of daily medication monitoring by carers or referral to the patient's regular community pharmacist for ongoing support. The nurse then assessed participants' physical and psychosocial status

and referred for community based support as needed.

At six-month follow-up, there was a significantly lower number of readmissions and out-of-hospital deaths in the intervention group. However, the number of patients in whom these endpoints occurred was not significantly different between groups. Post-hoc analysis suggested that patients particularly likely to benefit from home-based intervention included those with chronic heart failure or respiratory disease, and those who were at risk of poor medication adherence or ADEs (e.g. those prescribed more than 5 medicines).

It should be noted that the above study involved a pharmacist and nurse working together to provide an intervention, and it is not possible to clarify the relative contributions of the actions of each to the reported positive results. Similarly, as the 'high-risk' subset accounted for 82% of the intervention group patients (who therefore went on to receive the home visit) it was not possible to clarify the relative contribution of the discharge counselling component of the intervention.

The effects of discharge counselling and post-discharge domiciliary follow-up were assessed in two 1997 UK RCTs of hospital generated pharmaceutical care for older patients (Table 4.1) (118,119). One study, by Smith et al, involved 53 patients aged $\geq$65, identified by ward pharmacists as being at risk of DRPs following discharge (118). Intervention group participants received pharmacist discharge counselling and a written care plan, which they were instructed to show to their GP and community pharmacist. They were also provided with a telephone helpline number for any medicines related queries. Control group patients received standard pharmaceutical care, including a medicine record card containing a summary of when to take their medicines together with a copy of their discharge prescription. All participants were visited 7-10 days post discharge for follow-up assessment and resolution of any identified DRPs. At this visit, compliance (as assessed by interview and tablet count) was significantly higher in the intervention group. However unintentional medication discrepancies between discharge and home medication regimens were common in both groups (almost half of the intervention group and two-thirds of the control group) and some form of DRP was identified for three-quarters of intervention group patients and 96% of controls. No participants contacted the helpline with a medicines related query.

This study suggested that, although pharmacist discharge medication counselling and provision of a written care plan may lead to improved adherence among older patients, the potential for DRPs after discharge is still high and patients cannot be relied upon to identify and tackle these problems on their own. It should be acknowledged that limitations of this study, such as its small size and short follow-up period, prohibited any assessment of the effects of the intervention on subsequent health service usage. It is also not reported what percentage of intervention group patients actually showed their medication care plan to their community pharmacist, and what, if any, subsequent actions were taken by the pharmacists to support these patients.

The second study, by Begley et al, was an RCT of a post-discharge domiciliary pharmacy visit involving 190 patients discharged from 3 hospitals in one UK health authority (119). Eligible participants were aged $\geq$75 years and prescribed at least 3 medicines, with one or more having a twice daily or higher dosage frequency. Intervention participants received 5 visits between 1-2 days and 12 months following discharge, during which the pharmacist reviewed their medicines use and storage and offered solutions where problems were identified. In order to determine any placebo effect of receiving a visit on participants' medicating behaviour, this study utilised 2 control groups, one which received 5 visits to collect follow-up measures but no intervention, and one which received one baseline visit 1-2 days post discharge and one final visit at 12 months to collect follow-up measures only.

Adherence, measured by tablet count, was higher in the intervention group at all follow-ups, and inappropriate drug storage and hoarding decreased over the 12-month study period, whereas there was no change in these behaviours in the control groups. The number of GP visits was also lower in the intervention group, although this only reached statistical significance between the 3 and 12 month visits. As with the previous study, readmissions were not studied.

Summary

Collectively these early studies indicated that transfer of medicines related care for older patients could be improved by pharmacist interventions involving discharge

counselling in association with post-discharge follow-up, or repeated follow-up. This is evidenced by improvements in medication knowledge and/or compliance in patients who received these interventions. Targeting 'high-risk' patients such as those with complex polypharmacy, particular clinical conditions such as heart failure or respiratory disease, or those at risk of DRP after discharge, may increase the potential for success of these interventions. Collaborative working with other healthcare professionals (HCPs), such as nurses, to provide a holistic package of care, may also increase their value.

Data regarding healthcare usage following pharmacist interventions in transfer of care were however lacking in these early studies. Although improved compliance and drug knowledge are worthy objectives they are only really proxy outcomes in improving patient health and quality of life. Demonstrating a reduction in readmissions and A&E visits would be valuable both in terms of reducing healthcare costs and improving patient outcomes. In order to detect differences in these outcomes though, larger sample sizes are likely to be needed than were achieved in most of these early studies.

4.2.2: Information Transfer and the Role of the Community Pharmacist Pre-2000

Whilst the above studies, in the main, focused on hospital generated care and follow-up, other early research focused on improving information transfer between secondary and primary care regarding medication changes made in hospital and associated patient needs. Some researchers hypothesised that community pharmacy could be the 'missing link' in reducing DRPs after discharge. A quasi-experimental study conducted by Duggan et al in East London, UK, and published in 1998, aimed to reduce prescribing discrepancies post hospital discharge by providing 264 intervention group patients with a list of their discharge medication to pass to their community pharmacist (Table 4.1) (120). Eighty-nine percent of these patients handed the information to their community pharmacist, and the study reported a reduced rate of medication discrepancies in the intervention group after 2 weeks (32.1% of drugs had an unintentional discrepancy vs 52.7% in the control group, P<0.001). Almost all (96%) of the community pharmacists involved were enthusiastic about the service; the only criticism was the clarity of some of the

information received from the hospital, with electronic transfer of information suggested as a possible solution. Although the vast majority of patients in this study did deliver the information to their pharmacist, it should be noted that the study only recruited patients up to the age of 79, and nearly half were aged under 65. Older patients, who are the focus of this thesis, may have reduced mobility and find it more difficult to deliver the information to the pharmacy, and indeed other studies have found much lower rates of patient self-referral to community pharmacy post discharge (10,107,121,122).

A different approach to transferring discharge information was taken by a hospital-community pharmacy liaison service for patients from medical and elderly wards at Airedale general hospital in West Yorkshire, UK. During a 6-month pilot, the hospital pharmacy faxed details of medication changes, reason for admission, special needs, discharge medication and any other relevant information for 82 patients to their community pharmacy upon discharge (123). Fifty-four potential DRPs were identified by community pharmacists, the largest proportion (one-third) of which were related to patient compliance, and a quarter of which related to GPs medication records not being updated before the first post-discharge prescription was generated, leading to prescribing errors or missing items.

The authors of this service evaluation concluded that faxed discharge sheets can offer a better level of communication and co-operation between hospital and community pharmacists, and provide an opportunity to resolve medication problems before a patient arrives at the community pharmacy.   However, they also note that the successful transfer of information between hospital and community pharmacy relies on patient 'loyalty' to one particular community pharmacy; as evidenced by the fact that in over a third of cases the patient did not visit their nominated pharmacy, and the pharmacists were unable to make contact to resolve potential problems. This is in contrast to other studies where high (86-90%) levels of patient loyalty were observed (120,124).

Around the same time, researchers in the USA evaluating a hospital-community pharmacy referral form conducted 120 interviews with 91 participating community pharmacists (121). Initially the forms had been given to patients to hand in to their community pharmacist, but after finding that the majority of patients did not do this,

forms were also posted to the community pharmacy. Like Duggan, these authors suggested electronic transfer of information from the hospital pharmacy to address this problem.

Eighty-five percent of interviewed pharmacists indicated that the referral form provided information that resulted in a benefit to the patient through enabling tailored counselling regarding their medicines. Eighty-seven percent of interviewees felt the information provided had a positive impact on patient-pharmacist interactions, and 62% were able to incorporate the information into a database to direct future patient care. The most useful aspect of the form was felt to be the discharge medication list, although some pharmacists called for greater emphasis being placed on discontinued medicines.   Suggestions for improvements included intended duration of use of the medicines, the follow-up plan, extent of discharge counselling provided, name and telephone number of the attending physician (equivalent to consultant in the UK), and the patient's prognosis. Despite this enthusiasm for information, many pharmacists indicated that drug-dispensing functions occupied too much of their time to allow them to use the forms to improve patient care.

A further early trial of enhanced transfer of information regarding medicines on discharge in Aberdeen, UK involved 90 patients sequentially assigned to intervention or control groups (125). Intervention patients were given a pharmacy information letter providing details on their discharge medication, along with verbal counselling. A copy of the letter was sent to the patient's GP, community pharmacist and community nurse by post or fax.

This study found that, compared to control group patients (who had received discharge counselling as part of 'standard care'), fewer intervention group patients had problems managing their medicines within the first 2 weeks post discharge (22% vs 46%, p<0.05). The commonest problems identified were related to adherence (usually unintentional due to a lack of understanding of the discharge medication regimen) and the complexity of medication regimens. This indicates that verbal discharge counselling alone in this study was not enough to prevent DRPs, possibly due to poor patient recall and the low level of counselling of care givers, who were involved in home medication management of many of the

participants. These findings support the need for multiple component interventions, with reinforcement post discharge as identified in the studies by Smith and Begley above, and the involvement of care-givers where appropriate (118,119).

The contribution of community pharmacists in this study was limited by the fact that, similar to the Airedale study, only 54% of patients presented their first post-discharge prescription to their nominated pharmacy.

Summary

Most early studies involving patients' regular community pharmacist in their transfer of care had small sample sizes and were non- or quasi-experimental in design. This, together with a limited range of outcome measures (for example no data on healthcare resource usage or participants' quality of life are reported in any of the studies reviewed in this section) limits the conclusions that can be drawn from their results.

Where these early studies are valuable is in providing a background on which future transfer of care services could be built; for example the unreliability of requesting patients to transfer their own discharge information to their pharmacist, and the type of information required by community pharmacists on referral. These studies also provide 'proof of concept' that, when discharge information is received by community pharmacists, it can be used to identify medication discrepancies and detect other DRPs.

4.3: TRANSFER OF MEDICINES RELATED CARE AFTER 2000

4.3.1: Studies Involving Patients' Regular Community Pharmacists

Around the turn of the millennium, there was a reduction in the number of new papers reporting on transfer of care interventions involving pharmacists. However, in 2001 the first UK RCT of co-ordinated discharge planning by hospital and community pharmacists was published by Nazareth et al (Table 4.1) (126). Patients aged $\geq$75 were assessed and their medicines rationalised by a hospital pharmacist, given discharge counselling and a medication discharge plan, which

was also provided to their carers, GP and community pharmacist. The community pharmacist then conducted a home visit 7-14 days post discharge to reconcile medicines, check patient understanding and adherence and intervene where necessary. Second or third visits could be provided at the community pharmacist's discretion.

Despite the comprehensive and time-consuming nature of this care package, there were no significant differences between intervention and control groups in readmissions, death, outpatient attendances, GP visits, medication adherence, general wellbeing or satisfaction with care at 3 or 6-month follow-up. Looking to explain the lack of effect, the authors note that the average age of their participants was 84, most had at least 3 LTC and all were prescribed complex medication regimens. Moreover, the baseline level of adherence was high, offering little room for improvement. It is worth noting that community pharmacists were unable to visit 22% of the patients referred to them, and it is possible that this cohort were different in some way to the patients who were visited, making them more likely to benefit.

Further research was published the following year by Stowasser et al, who conducted an RCT to evaluate the benefits of a medication liaison service (MLS) in Australia (Table 4.1) (127). The MLS pharmacist liaised with intervention group patients' GPs and community pharmacists at the point of admission to reconcile medicines and prepared a comprehensive discharge summary including details of all medication changes and recommendations for follow-up. This information was provided to the GP and community pharmacist within 24 hours of discharge. Participants were randomly selected from the daily admission list and no inclusion criteria in terms of age, number of medicines or likelihood of DRPs were set. Although younger than the participants in most of the other studies reviewed here (mean age 66.5 years), participants did experience a high degree of polypharmacy (mean 7.6 medicines per patient), which as addressed in earlier chapters does increase the risk of DRPs following discharge.

At 30-day follow-up, there were numerically fewer patients readmitted in the intervention group (12 (11%) vs 17 (13%)), although this did not reach statistical significance (p=0.076). Intervention group patients also required significantly fewer

HCP visits during this time period (7.54 vs 9.94 per patient, P<0.05). Functional health and wellbeing, measured using the Short-Form 36 health survey (SF-36), tended to improve more from baseline in the intervention group, for all components other than vitality. The authors argue that as their sample size was relatively small (n=240) and the overall rate of readmission fairly low, the observed reduction in readmissions probably did represent a true effect of the intervention, but that a larger study would be required to confirm this. This limitation has been identified in other studies reviewed here (116,118,122,125,128-133).

It is disappointing that this study did not report on the actions taken by community pharmacists following receipt of discharge information from the hospital. As such it is difficult to characterise the impact that this transfer of information had as distinct from the other elements of the MLS (e.g. improved medicines reconciliation in the hospital and provision of the enhanced discharge information to the GP).

A further Australian RCT, this time focusing more on the post-discharge element of transitional care, was published in 2003 by Naunton and Peterson (Table 4.1) (128). This study evaluated home-based follow-up of high-risk elderly patients within 5 days of discharge. Eligible patients were randomised to a home visit or standard care. Patients had to be aged $\geq$60 with $\geq$2 LTCs and at least 4 regular medicines. A full clinical medication review was provided to intervention group patients, including review of the need for all medicines and monitoring requirements, and where issues were identified the patient's GP and community pharmacist were contacted.

At the initial visit, 179 DRPs were identified for the 57 intervention group patients. By 90-day follow-up, there were significantly fewer readmissions in the intervention group (p=0.05), better self-reported compliance and significantly fewer DRPs. This suggests that older patients (median age 75.5) with complex medical conditions (median=5) and polypharmacy (median = 8 medications) could benefit from a home visit by a suitably qualified pharmacist who has the ability to liaise with the patients' GP, community pharmacist and hospital following discharge. The findings from Naunton's study need to be interpreted with caution however as it was relatively small (n=121).

A similar Australian RCT was published in 2008 by Vuong (129). To be eligible, patients had to have one or more risk factors for DRPs (Table 4.1). Dedicated community liaison pharmacists (CLPs) received a blinded handover from ward pharmacists and provided a home visit to intervention group patients within 5 days of discharge. During the home visit, the CLP provided education and information to the patients and/or their carers, monitored techniques with administration devices, assessed medication supplies and storage, removed obsolete medicines and evaluated discrepancies with the regimen prescribed at discharge. Any difficulties, problems or potential problems experienced by the patients were rectified or highlighted for primary care provider intervention. A report from each visit was produced and faxed to the GP, community pharmacist and other relevant primary HCPs.

Unfortunately, recruitment to this study (n=316) did not reach the sample size required for comparison of readmission rates, which are not reported. In fact 73% of patients referred to the service were either excluded or chose not to participate, which appeared to stem primarily from the burdensome recruitment process. Despite the sample size being smaller than planned, this study did demonstrate a greater improvement in medication adherence in the intervention group compared to the controls (p=0.028), as measured using a modified Morisky scale (a tool that quantifies self-reported medication adherence). The impact of liaison with participants' regular community pharmacist, and any subsequent actions taken by the community pharmacists was not evaluated.

Another RCT, by Holland et al in 2005, of a home-based medication review following discharge, focussed on patients aged $\geq$80 (the HOMER study, Table 4.1) (134). They recruited 872 patients, across 10 UK hospitals, who were randomised to standard care or to be visited at home by a pharmacist approximately 1 week after discharge. Pharmacists assessed patients' ability to self-medicate and medicine adherence, educated the patient and carer, removed out of date medicines, reported possible drug reactions or interactions to the GP, and reported the need for a compliance aid to the community pharmacist. One follow-up visit occurred at 6-8 weeks after recruitment to reinforce the original advice.

This study found that at 6-month follow-up there was a higher readmission rate and number of GP visits in the intervention group; however there was a trend towards fewer deaths in this group. One possible explanation for these findings proposed by Holland et al is that pharmacists did help patients to understand their conditions better, leading them to recognise warning signs and seek help earlier. This positive view is weakly supported by the non-significant decrease in deaths observed in the intervention group. Another explanation is that by improving adherence to prescribed medication, this study actually increased the rate of iatrogenic illness to which this elderly group of patients (mean age 85.5) may have been particularly vulnerable; however the actual aetiology of the readmissions and GP visits was not explored. Finally, by visiting patients at home and spending relatively long periods of time there the researchers acknowledge that they may simply have added to the complexity of care, creating confusion or causing patients to focus more on their problems.

These latter two factors hint at the importance of focussing on the patient's agenda during medication review. By ascertaining what the patient actually wants and needs to know about their medicines (as opposed to what we think they ought to know) we can avoid the situation of 'information overload' and patient confusion. By encouraging open discussion regarding baseline adherence to medication and being aware of the potential consequences of increased adherence (for example hypotension and falls if previously unused blood pressure medicines are suddenly re-started), we can minimise (or at least be alert to) iatrogenic adverse effects as a result of improved adherence. This view is supported by other commentary on this study, which suggests that the medication reviews carried out were not holistic, were limited by lack of access to clinical records and means to verify the correctness of the discharge medication list, and that the additional training received by the pharmacists involved may not have been adequate in relation to their previous clinical level of practice (135,136).

Recruiting patients from 10 different hospitals and using 22 different pharmacists to deliver the intervention could be viewed as a positive factor as it may make the results more generalisable to the 'real world' situation. However the heterogeneity of the pharmacists and the patient population (for example the intervention group

included more patients with dementia) should perhaps be taken as an indication that the results of HOMER do not necessarily mean that home medication review by pharmacists is ineffective or detrimental, but that more work is needed to ascertain target patients and the most appropriate form of the review and level of training required by the pharmacists involved.

Holland et al themselves called for research into more effective forms of medication review, possibly based in general practice with full access to clinical notes and a close working relationship with the patient's GP. In Naunton's study above, the importance of liaising with other practitioners was also emphasised. It may be worth noting that Naunton's patients were, on average, 10 years younger, so may have had more potential to benefit from the intervention and been less vulnerable to iatrogenic adverse effects (128).

It would be interesting to recreate Holland's study using the patients' regular community pharmacist, who they were perhaps more used to interacting and discussing medication related problems with. This may have made the intervention seem less confusing and more part of routine practice by avoiding the introduction of yet another HCP to their care. The same could be said for the domiciliary visits in the studies by Naunton and Vuong above. Empowering the regular community pharmacist would also give them a platform from which to provide ongoing pharmaceutical care in the long term, which research or hospital based pharmacists are unable to do.

Another study which involved, but did not focus on, patients' regular community pharmacists, was a quasi-experimental study by Al-Rashed et al who reported on the value of pharmaceutical counselling of elderly patients prior to discharge (Table 4.1) (122). Eligible patients were aged $\geq$65, taking 4 or more medicines, and at risk of DRPs post discharge in the professional opinion of the ward pharmacists who referred them. Intervention group patients received comprehensive medication discharge counselling. All patients then received a visit from a research pharmacist at 2-3 weeks and 3-months post discharge, who collected follow-up measures and provided advice on the correct use of medication.

The intervention group in this study displayed better medication knowledge and

compliance than the control group at both follow-ups, with a significant increase in compliance between first and second follow-up in the intervention group only. GP visits and readmissions were also significantly lower in the intervention group. This study involved fewer patients than the others evaluated here (n=83) and caution is required in interpreting the results as the participants were not randomised but instead two different hospital wards were used for intervention and control groups. Although older than those in Stowasser and Vuong's studies, participants were slightly younger than in Nazareth's and Holland's (mean age 80 vs 84 vs 85.5 years) but were prescribed more medicines on average (7 vs 6 vs 6) and all had been identified as at risk of DRPs. It could be that this study population had more to gain from the pharmacy intervention than Nazareth's (who were already highly compliant with their medication), or Holland's. This indicates the importance of targeting patients who have the potential to benefit from interventions as well as (or in preference to) those who are 'high risk' due to demographic factors.

A further observation from this paper is that despite being explicitly instructed to do so, only 4.4% of patients showed their discharge summary and medication reminder card to their community pharmacist, casting further doubts on the feasibility of relying on patients to transfer discharge information to those expressed above. This low rate of information transfer also meant that any opportunity for the community pharmacist to contribute to improved patient outcomes in this study was minimal.

The Australian home medicines review (HMR) programme was introduced in 2001 and involves an accredited pharmacist visiting patients in their homes to identify drug-related problems and make recommendations to optimise medication management. HMRs organised for patients post-discharge have been shown to improve the transfer of medicines information between hospital and community practitioners and improve communication between patients and their health professionals (137-139). However, conducting timely post-discharge HMRs has proved problematic. A pilot study investigating whether hospital-initiated medication reviews (HIMRs) could be implemented in a more timely manner than HMRs demonstrated that when at-risk patients with a mean age of 75 were referred directly to accredited pharmacists on discharge from hospital, HIMRs were

conducted in a mean of 11.6 days post-discharge (140). Issues raised by pharmacists during HIMRs were awarded a rank of clinical significance by an expert panel, with 43% judged to have a significant impact on patient care. However, the impact on actual patient outcomes was not studied, which limits determination of the true benefits of the service. After the HIMR, the patient's GP and community pharmacist were given copies of the report, but in common with many of the studies above, actions subsequently taken by the community pharmacists are not reported.

More opportunity was provided for community pharmacists to contribute to post discharge care in a 2004 RCT of a hospital-community liaison pharmacy service by Bolas et al (130). This study was based in Northern Ireland, UK, and involved 162 participants aged >55 (mean = 74) prescribed at least 4 medicines (mean = 6.8) who were randomised to receive the liaison pharmacist care package or standard discharge care. The care package included an inpatient review of medicines use, discharge counselling, medicines record sheet informing patients how to take their drugs and a discharge letter detailing the changes made to drug therapy which was faxed to the GP and community pharmacist on discharge. A medicines helpline was available to all patients following discharge. Results showed that at 10-14 day follow-up, there were fewer discrepancies in the intervention group between medicines prescribed on discharge and those taken at home, and medication knowledge had increased. At 3 months' post discharge there was no difference in readmissions between groups, although the small sample size in this study is likely to have limited its power to detect such a difference. As with Smith's 1997 study there was a low uptake on the use of the helpline with only 11 calls within a 10-month period.

Bolas also surveyed GPs and community pharmacists and found that 57% of GPs and 95% of community pharmacists considered the discharge letter had improved the standard of information exchange at discharge. However, in common with Stowasser's study, no data was collected with regards to what interventions, if any, were made by community pharmacists following receipt of this information.

Further studies by this research group published in 2007 and 2012 demonstrated how integrated medicines management (IMM) from admission through discharge

was associated with a reduction in readmissions, increased time to readmission and reduced length of stay on readmission (Table 4.1) (141,142). Their service included a comprehensive medication record sheet given to the patient and faxed to the GP and community pharmacist on discharge. Both these studies involved larger numbers of participants (n=762 and n=833 in the 2007 and 2012 studies respectively) than most of the studies discussed thus far. However, it is important to note that neither of the studies were RCTs. Both were limited by their quasi-experimental design and by capacity issues in delivering the service – not all intervention group patients received all components of the IMM service, and there was likely under-recording of the interventions that were conducted. This makes it difficult to discern if there were key interventions which contributed to its success, results may have been different if delivery and recording of the intervention were more complete. Additionally, in the 2012 study the small size of the comparison group may reduce the validity of the results. Again no data was collected regarding interventions made by community pharmacists in these two studies, although all 27 community pharmacists who completed a satisfaction questionnaire in the 2007 study felt that the faxing of the discharge details improved the information exchange between the health care sectors, and 92% believed the process to be beneficial to the care delivery to their patients.

In the Netherlands, discharge prescriptions are supplied by a community pharmacy; usually the discharge prescription is sent directly from the hospital to the pharmacy where the patient is registered (143). The regular community pharmacist therefore plays an important role in transfer of care. In 2001, the Association of Amsterdam Community Pharmacists adopted a programme (the IBOM-1 intervention) to improve the pharmaceutical care of patients who were discharged on 5 or more medicines.

Evaluation of this programme involved thirty-seven community pharmacies (self-selected as control or intervention) (Table 4.1). Each was asked to recruit 20 consecutive patients discharged from hospital. Intervention pharmacies provided counselling to 92% of patients, a daily medication intake scheme to 82.7%, a 'medication passport' to 38.7%, removed redundant home supplies of medication for 25.6% and synchronised medication for 11%. Twenty-one percent of

intervention patients also received some form of follow-up counselling. In contrast, only 19% of patients received counselling as part of usual care, and additional interventions were provided to only 4.2%.

Despite this intervention, there were no significant differences between study groups in persistence (i.e. time to discontinuation) with long-term medicines or mortality at 9 months. The authors note that despite the importance of a home visit as part of the IBOM protocol, less than two-thirds of intervention group patients received a home visit, thus reducing the potential effect of the intervention. The authors also suggest that one of the factors accounting for the lack of effectiveness of the IBOM protocol could be the unstructured nature of the medication review by the pharmacists, who were not trained for this specific task. Additionally, they argue, in most cases, only one visit was provided whereas repeated follow-up may be necessary to impact on outcomes such as readmissions. The authors recommended a further trial involving more intensive medication review and repeated follow-up over a period of 1 year from discharge.

Such a trial was published in 2012 by Ahmad et al, involving 340 patients aged $\geq$60, discharged from hospital in the Netherlands taking 5 or more medicines (Table 4.1) (144). Community pharmacies were randomised as control or intervention pharmacies. Pharmacists working at intervention pharmacies were given training in medication review and pharmacy technicians were trained in counselling using cognitive behavioural technique (145). Intervention pharmacists and technicians worked together to provide a post-discharge medication review and 5 follow-up consultations over a period of 12 months. At 12-month follow-up, the number of DRPs per patient had decreased in the intervention group, but increased in the control group (p=0.05), with the effect being more pronounced among patients with hypertension or heart failure. Effects on other outcomes, such as ADEs, readmissions, A&E visits and quality of life are not reported, making the overall impact of this intervention difficult to assess. This is disappointing as this study could potentially answer many of the questions previously raised by other authors. For example, repeated counselling over a prolonged period, although advocated by several researchers, has not been studied elsewhere according to the findings of this literature search. Specific training for community pharmacists

has also been called for but not widely adopted or evaluated. Additionally, utilising pharmacy technicians to provide ongoing follow-up, if effective, could be valuable in freeing pharmacist time and reducing costs.

In Canada discharge prescriptions are also dispensed by community pharmacies. A 2008 Canadian study investigated the effect on post-discharge discrepancies of supplying a medication discharge plan (MDP) to community pharmacists (Table 4.1) (146). The MDP was given to all patients and also to the community pharmacists of intervention group patients only. It included many of the elements called for by community pharmacists in previous studies, including contact details of the hospital pharmacist and physician, admission medication with status at discharge of each of these, intended duration of new medication, and any recommendations made by the hospital pharmacist (121,130). To be eligible for this study, patients had to have at least 2 changes to drug therapy during admission. All patients (intervention and control) received comprehensive pharmaceutical care during admission, including medicines reconciliation, case discussion with physicians and discharge counselling.

Discrepancies between the MDP and community pharmacy dispensing records were found for just over two-thirds of patients in both groups one week after discharge, whilst discrepancies between the MDP and patient reports of medications taken were found in over half. Just over one-third of discrepancies in the community pharmacy records were judged independently by a clinical pharmacist and family medicine doctor to be significant but not life-threatening, whilst 48% of patient discrepancies were in this category. Interestingly, the rate of serious patient discrepancies was higher in the MDP group (13.5% vs 0.7%, p=0.02).

The researchers therefore concluded that provision of the MDP to community pharmacies was not effective in reducing post-discharge medication discrepancies. Suggested reasons for these results included incomplete medicines reconciliation in the hospital setting and failure of community pharmacists to incorporate all the information in the MDP into their dispensing records. Further training of hospital and community pharmacists and incorporating the MDP into the discharge prescription itself were suggestions for improvement.

Summary

The studies discussed above suggest that the role of the community pharmacist in the transfer of care of older patients has been hampered by a lack of information transfer from hospitals and a deficit of time or skill to act on this information effectively when received (121,143,146). Most studies providing post-discharge follow-up used domiciliary visits, which are reported as being time consuming to deliver (122,126,128,129,134). Domiciliary visits by community pharmacists in the UK, whilst not prohibited by the current contractual arrangements, are restricted by the need to apply separately for each visit conducted and restrictions on the time they may be away from the pharmacy premises. Additionally, not all studies which involve community pharmacists actually report on the role they play following enhanced communication from secondary care, instead utilising hospital, research or other specially trained pharmacists to provide the majority of post-discharge follow-up. Indeed, only 5 of the (quasi) experimental studies discussed in Sections 4.2.2 and 4.3.1 involved the community pharmacist as a 'main player' (120,126,143,144,146). None of these studies demonstrated a reduction in readmission, ED visits or medicines adherence versus a comparison or control group, although medication discrepancies were reduced in one study and DRPs in another (120,144). Therefore, there remains a gap in the evidence base around the effectiveness of enhanced information transfer and subsequent medication review by community pharmacists for older patients discharged from hospital.

Support for community pharmacists to become more effectively involved in the transfer of care of older patients is needed, such as detailed referrals from secondary care for identified, appropriate patients, the facility to provide continued follow-up (ideally via home visit and possibly with the assistance of pharmacy support staff), training on the more clinical aspects of medication review and the provision to work in conjunction with other members of the multidisciplinary team (MDT) in secondary and primary care.

4.3.2: Studies Not Involving Patients' Regular Community Pharmacists

As discussed in Chapter 3, not all readmissions are drug related and not all ADEs and drug related admissions are preventable, so a more realistic outcome measure

of the success of pharmaceutical transfer of care interventions might be to reduce the number of preventable ADEs occurring post discharge. An improvement in this outcome was demonstrated by Schnipper et al, who conducted an RCT of 152 patients who were randomised to receive pharmacist medication review and counselling at discharge and a telephone consultation 3 to 5 days later, or standard care (Table 4.1) (131). The telephone call focussed on adherence to medication and follow-up appointments, detection of medication discrepancies, signs of early side effects and providing patient counselling and/or primary care physician feedback when appropriate.

At discharge, changes to medication regimens were recommended in 60% of intervention group patients. Despite this, by the 3-5 day telephone call, 29% of intervention group patients had unintentional discrepancies between their discharge regimen and medicines they were currently taking. These findings back up earlier research that medication review and counselling on discharge are not enough on their own to prevent DRPs post discharge (118,119,125). By 30-day follow-up, unexplained discrepancies were similar in both control and intervention groups (65% and 61%, respectively), again indicating that repeated follow-up may be necessary.

Despite the high number of discrepancies at 30-day follow-up, preventable ADEs had occurred in only 1% of the intervention group and 11% in the control (p=0.01), whilst the rate of preventable, medication-related ED visits or hospital readmissions was 1% in the intervention group and 8% in the control (p=0.03). Total ADEs and healthcare utilisation did not differ between groups. These results highlight the importance of selection of outcome measures when evaluating the contribution of pharmacists to medicines related transfer of care. As the role of the pharmacist is to optimise the management of medicines, it may be unrealistic to expect a reduction in overall healthcare utilisation from a pharmacist intervention without using a very large sample in order to obtain sufficient power; therefore focussing on medication related events may be more suitable. It would also be unrealistic to expect such an intervention to prevent unpreventable ADEs; therefore evaluation of preventable events as a primary outcome might avoid a true effect of the pharmacist intervention being missed.

A similar RCT published in 2009 by Gillespie et al involved 368 patients aged ≥80 (Table 4.1) (132). Intervention group patients received medicines reconciliation on admission, education and monitoring throughout admission as well as discharge counselling. Recommendations on therapy were made to physicians throughout admission by the pharmacist. Pharmacists also prepared detailed medicines related discharge information for the primary care physician of all intervention group patients, and contacted the patients 2 months after discharge to ensure adequate home management of medicines and answer any questions. Control group patients received no pharmacist input. As in Schnipper's study, there was no significant difference in overall readmissions between control and intervention groups after 12 months, however ED visits were reduced by 47% in the intervention group relative to the control (49 vs 93 visits respectively). When drug related readmissions (12.3% of the total readmissions) were studied, 9 were in the intervention group and 45 were in the control group, equating to an 80% relative risk reduction. These results may indicate that focussing on outcomes which pharmacists can be expected to impact (i.e. drug related readmissions rather than overall admissions) are more likely to reveal positive results.

The authors of this study note that mortality rates were high at 32% over the 12-month follow-up (no difference between intervention and control). This is perhaps not surprising given the mean age of participants was 86.6 years. However, it is a point to consider when designing research studies with very elderly patients – sample sizes may need to be increased accordingly when a prolonged period of follow-up is planned. Polypharmacy was more prevalent in the intervention group (mean 8.7 vs 7.3 medicines, p=0.004). This might mean the intervention group were more at risk of adverse outcomes and therefore the effect of the intervention may have appeared less. Alternatively, the increased burden of polypharmacy in the intervention group may reflect a greater opportunity for pharmacists to contribute positively to the management of these patients, providing evidence for targeting of patients for pharmacist intervention based on the number of medicines prescribed.

Support for this theory was provided by a 2013 USA study evaluating a discharge medicines reconciliation and counselling service (Table 4.1) (147).   Subgroup

analysis found that among patients prescribed $\geq$5 medicines, 30-day readmission rates for the intervention group were reduced more significantly compared to control (17.7% vs 29.5%, p=0.002) than when the whole study population was evaluated (16.8% vs 26%, p=0.006). These findings were even more pronounced when patients prescribed $\geq$10 medicines were considered (19.5% intervention vs 42.5% control group patients readmitted within 30 days, p<0.001). Participants aged $\geq$65 were also more likely to benefit from the intervention, with readmission rates of 10.9% for older intervention group patients vs 31.4% for older controls (p=0.001). These findings provide some background in targeting patients who have the most to gain from pharmacist interventions.

A key limitation of this study was that it was not randomised; the pharmacist was asked to target patients who were prescribed problem medicines or major polypharmacy ($\geq$10 medicines). Not surprisingly, therefore, the intervention group contained significantly more such patients than the control group, although age and gender mix was similar. However, as with Gillespie's study, if anything this makes the reduction in readmission rate in the intervention group more impressive, as it comprised a higher risk population.

Another study involving elderly patients with polypharmacy was a pilot RCT conducted in 2009 in the USA. Koehler et al investigated the effects of a care bundle provided by a nurse and clinical pharmacist on 30 and 60-day readmissions and ED visits combined (Table 4.1) (133). To be eligible, patients needed to be aged $\geq$70, take $\geq$5 medicines, have $\geq$3 LTCs and require assistance with activities of daily living. The pharmacist reconciled medicines for intervention group patients on admission and discharge, provided clinical medication review and medication counselling throughout admission and on discharge, and made a follow-up telephone call at 5-7 days post-discharge. At 30 day post-discharge fewer intervention group patients had been readmitted or visited the ED (10% vs 38.1%, p=0.04). However, by 60 days the difference was not significant (30% vs 43%, p=0.52). The authors suggest that an optimal intervention would capitalise on the hospital based staff's ability to improve short term readmission/ED visit rates while linking patients to longer term care to extend these outcomes. Pertinently, a retrospective comparison study from the USA published by Kilcup et al in 2011

reported how a telephone call 3-7 days post discharge to reconcile and review the use of medicines discharge reduced readmissions at 7 and 14 days, but the effect had dissipated by 30 day follow-up (Table 4.1) (148). This provides more evidence that repeated follow-up may be necessary to produce a sustained effect on outcomes post-discharge.

Koehler's study was limited by its small sample size (n=41), which, like in Vuong's study above, was attributed by the authors to recruitment difficulties related to the onerous informed consent process (129). However, the results do support the role of a targeted, interdisciplinary care bundle provided on both sides of the secondary-primary care interface in improving patient outcomes.

Another recent American study evaluated the effect of a pharmacist discharge counselling service on 30-day readmissions (Table 4.1) (149). Patients were stratified according to their risk of readmission; high risk patients had to have 5 or more risk factors, medium risk patients had 4 risk factors and low risk patients had 3 or less. Patients who received the pharmacist service were compared to a retrospectively selected comparison group of patients admitted during the study period who had not received the service. The evaluation found a lower 30-day readmission rate among medium risk intervention patients only (3.8% vs 18.9% in the comparison group, p=0.033).

The criteria for defining risk in this study were more stringent than in the others discussed in this chapter, where only one or two risk factors were required. Although the results of this non-experimental study must be interpreted with caution, it might be that in today's population there are some patients whose needs are so complex that pharmaceutical interventions alone will not significantly affect the risk of readmission, reinforcing the need to target patients appropriately to a particular intervention.

This concept is supported by a recent service evaluation of the introduction of a Medicines Care Plan (MCP) for patients discharged from elderly care wards at a large English teaching hospital (150). Initially, hospital pharmacists used the PREVENT screening tool to identify high-risk patients but it was felt that the majority of patients screened were high-risk using this tool (151). Therefore

clinical judgement was used instead, whereby the identification of a specific medicines-related post-discharge need acted as the trigger for recruitment of the patient to the project and creation of a MCP. Patients and carers were also educated and signposted to HCPs in Primary Care for follow-up where appropriate. These included community pharmacists, practice pharmacists, GPs, district nurses, community matrons and practice nurses. Evaluation found that 16% of the 204 MCP patients were re-admitted within 30 days compared to 22% of 1161 comparison patients. However as this was not designed or powered to be a research project, and the difference in size between the intervention and comparison groups was so large, the significance of these results is not clear.

Summary

Many of the interventions in the studies discussed above have aspects in common, but there is significant variation in the results reported. Commonly, interventions involve some degree of input from a hospital pharmacist whilst participants are inpatients, comprising one or more of: medicines reconciliation, medication review, discharge counselling and provision of medication related discharge information to the patient, carers and community care providers. Follow-up interventions may then be provided by hospital or research pharmacists or the patient's own community pharmacist. The nature and intensity of these follow-up interventions is also variable, with some being by telephone and others by home visit, some providing a clinical medication review whilst others are more adherence focussed. Some studies involve repeated follow-up whilst others investigate one follow-up contact only. Studies also involve varying degrees of multidisciplinary working and levels of training for the pharmacists providing the interventions.

It may be that nuances in how the various components of transfer of care interventions are combined and delivered can explain some of the differences in results reported. Most of the studies reporting significant benefits in terms of reduced readmissions, ED visits, DRPs, or improved medication adherence involved either a combination of pre- and post-discharge components (so-called 'bridging' interventions), repeated review post discharge with the benefit of hospital discharge information to support these follow-ups, or full clinical review post-discharge with liaison with primary HCPs to solve identified problems

(128,129,131,133,144,149). Both telephone and domiciliary reviews have been associated with positive outcomes, although telephone reviews may be more suitable for younger patients or to reinforce education already provided in a face-to-face setting (132). This was the view taken by the patient and public involvement (PPI) group for this study, who voiced concerns regarding discussing a subject as complex and personal as their medication regimen over the phone (see Appendix 2).

The populations in the research reviewed above also varied between studies. Even studies limiting recruitment to 'older' patients reported a range of mean participant ages, and whilst it was shown by at least one study that patients aged $\geq$65 benefitted more from the intervention than younger patients, other researchers who failed to demonstrate a positive effect on outcomes have suggested that the advanced age of their participants ($\geq$84), may be one of the factors explaining the lack of benefit of their intervention (126,134,147). Participant groups also varied in terms of the number of medicines taken, with a higher degree of polypharmacy being associated with a greater effect of the intervention by some researchers (132,147). A number of studies only recruited patients who were 'at risk' of readmission or DRPs, and even these definitions varied widely, from the clinical judgement of ward pharmacists to meeting a pre-specified number of criteria from a specific list (122,126,128-130,133,141,142,144,149). Most studies targeting 'at risk' patients showed positive results in terms of readmissions, ED visits, DRPs and/or adherence (122,128-130,133,141,144). Studies that did not show positive results tended to have less stringent criteria for defining risk, for example studies that used age and number of medicines only were less likely to produce significant results unless the average number of medicines taken was $\geq$6 (126,130,134,144). However in Still's study, where very stringent criteria were used, the finding that only 'medium risk' patients appeared to benefit suggests that a balance may be needed to target interventions to patients who can benefit from pharmacist transfer of care interventions without having such complex needs that specialist care packages are required (149).

Table 4.1: Studies of interventions involving pharmacists in transfer of care of older people at discharge

First Author	Year / Location	Design	Intervention	Study population	Follow-up period	Outcomes
Ahmad	2012 Netherlands	Quasi-experiment	Post discharge medication review by specially trained community pharmacist Counselling using cognitive behavioural therapy by pharmacy technicians at 1, 3, 6, 9 and 12 months post discharge	340 (180 intervention, 160 control) Age >60. No. meds $\geq$5	12 months	**DRPs**: mean number per patient decreased from baseline to follow-up in the intervention group compared to control (p<0.05)
Al-Rashid	2002 UK	Quasi-experiment	Discharge medication counselling. Medication reminder card and medication and information discharge summary sheets (MIDS) given to all participants for themselves and their GP and community pharmacist	83 (43 intervention, 40 control), identified by ward pharmacists as being at risk of DRPs. Age >65 (mean 80). No. meds $\geq$4 (mean = 7.1)	2-3 weeks 3 months	**Medication knowledge**: better in intervention group at both follow-ups (p<0.01) **Adherence**: higher in intervention group at both follow-ups (p<0.01) **GP visits**: fewer in intervention group at both follow-ups (p<0.05) **Readmissions**: fewer in intervention group at both follow-ups (P<0.05) **Other:** 34.6% of patients showed a copy of their MIDS to their GP; 4.4% showed it to their pharmacist

Begley	1997 UK	RCT	5 home visits over 12 months post discharge for review of medicines use. 2 control groups, 1 of which received 5 visits to collect follow-up measures only (Control(V)), and 1 of which received 1 baseline visit 1-2 days post discharge and 1 visit at 12 months to collect follow-up measures only (Control(NV))	190 (61 intervention, 63 in control(V) and 66 in control(NV)) Age $\geq$75 $\geq$3 meds with at least one having twice daily dosage	2 weeks 1 month 3 months 12 months	**GP visits:** fewer in intervention group (p<0.01 for 3-12 month time period) **Adherence:** better in intervention group at all follow-ups (P<0.0001) **Medication knowledge**: NS diff **Inappropriate storage of drugs:** decreased in intervention group (p<0.01) **Drug hoarding:** decreased in intervention group
Bolas	2004 UK	RCT	Inpatient review of medication use. Discharge medication counselling. Medicines record sheet informing patient how to take their drugs. Discharge letter detailing changes made to drug therapy (faxed to GP and community pharmacist on discharge). Medicines Helpline.	162 (81 intervention, 81 control) Age >55 (mean 74) No. meds $\geq$4 (mean 6.8)	10-14 days 3 months for readmission only	**Medication discrepancies after discharge:** fewer in intervention group with respect to drug name (p<0.005) and dosing frequency (p<0.004). Dose discrepancies approached significance (p<0.07). **Medication knowledge**: greater in intervention group (p<0.001) **Readmissions:** NS diff

Duggan	1998 UK	Quasi-experiment	Copy of drugs prescribed at discharge given to patient to pass on to community pharmacist	501 (264 intervention, 237 control) Only recruited patients up to age 79 (54% were aged ≥65)	2+ weeks	**Medication discrepancies after discharge:** fewer in intervention group (P<0.001) **Other**: 89.2% took information to community pharmacist
Gillespie	2009 Sweden	RCT	Inpatient medicines reconciliation/ review Medication counselling throughout admission and on discharge. Telephone review of medicines use 2/12 after discharge.	368 (182 intervention, 286 control). Age ≥80 (mean 86.6) Mean no. meds=8.7 in intervention group, 7.3 in control	12 months	**A&E visits/ readmissions**: Fewer in intervention group (RR=0.84, 95% CI: 0.72–0.99) **A&E visits only**: Fewer in intervention group (RR=0.53, 95% CI: 0.37–0.75) **Readmissions only**: NS diff **Drug related readmissions**: Fewer in intervention group (RR=0.2, 95% CI: 0.1–0.41)
Holland	2005 UK	RCT	2 home visits over 6 months for review of medicines use	872 (437 intervention, 435 control). Age ≥80 (mean 85.5) No. meds ≥2 (mean = 5.9)	6 months	**Readmissions**: More in intervention group (RR 1.3,(CI 1.07-1.58), p=0.009) **Deaths**: Trend towards fewer in intervention group (hazard ratio = 0.75, 0.52 to 1.10; P = 0.14) **Quality of life:** NS diff

Hugtenburg	2009 Nether-lands	Quasi-experiment	Review of discharge prescriptions by community pharmacist. Post discharge medication counselling via telephone, home visit or in the pharmacy. Daily medication intake scheme. Removal of redundant home supplies Follow-up counselling. Medication synchronisation	715 (336 intervention, 379 control) Mean age intervention group = 69.7, control= 72.7 Mean no. medicines =7.8 in intervention group, 7.1 in control	9 months	**Adjustments made to the quantity of drugs dispensed:** higher in intervention group (average cost saving €19.5 per patient) **Deaths:** NS diff **Medication persistence**: NS diff
Kilcup	2011 USA	Retrospective comparison	Telephone reconciliation and review of medicines use 3-7 days post discharge	494 (243 intervention, 251 comparison) Mean age = 67 Mean no. meds = 7	7 days 14 days 30 days	**Readmissions**: fewer in intervention group at 7 days (p=0.01) and 14 days (p=0.04). NS diff at 30 days.
Koehler	2009 USA	RCT (pilot)	Care bundle provided by nurse and pharmacist. Pharmacist provided medicines reconciliation on admission and discharge, daily medication review, discharge medication counselling and telephone call 5-7 days post discharge	41 (20 intervention, 21 control). Age $\geq$70, (mean = 78.5) No. medicines $\geq$5 LTC $\geq$3 Required assistance with ADLs	30 days 60 days	**A&E visits/ readmissions:** fewer in intervention group at 1st follow-up (p=0.04) but difference not significant by 2nd follow-up (p=0.52)
Lalonde	2008 Canada	RCT	Medication discharge plan (MDP) sent to community pharmacies (who dispense discharge medication) and treating physicians	83 (42 intervention, 41 control) $\geq$2 changes to meds Mean age = 71.5 Mean meds=10	1 week	**Medication discrepancies between MDP and pharmacy dispensing records/patient self report:** NS diff

Lipton	1994 USA	RCT	Discharge medication counselling. Four consultations over 3/12 post discharge (mainly telephone). Simplification of medication regimen. Pharmacists consulted with physicians at all stages.	706 (350 intervention, 356 control). Age $\geq$65 Meds $\geq$3	6-8 weeks 12-14 weeks 6 months	**Readmissions**: NS diff. **Adherence**: Higher in intervention group at 1st (p<0.035) and at 2nd (p<0.001) follow-up. **Polypharmacy**: NS diff at 1st follow-up, intervention group taking fewer medicines at 2nd follow-up (p<0.001)
Naunton	2003 Australia	RCT	Home visit 5 days after discharge for full clinical medication review. All participants received home visit 90 days after discharge.	121 (57 intervention, 64 control) Age $\geq$60 (median 75.5) LTC $\geq$2 Meds $\geq$4 (median=8)	3 months	**Readmissions:** fewer in intervention group (p=0.05) **Deaths:** NS diff **DRPs:** fewer in intervention group (P<0.01) **Adherence:** higher in intervention group (p<0.001) with significant increase between initial visit and 90 day visit in intervention group. **Polypharmacy:** NS diff

Nazareth	2001 UK	RCT	Assessment and rationalisation of medication. Discharge medication counselling. Medication discharge plan given to patient and sent to GP, community pharmacist, carers and any other relevant party. Home visit by community pharmacist 7-14 days post discharge for review of medicines use.	362 (181 intervention, 181 control) Age $\geq$75 (mean = 84) Meds $\geq$ 4 (mean=6)	3 months 6 months	NS diff in: **Readmissions**, **Death**, **Outpatient attendance, GP visits, Hospital bed days, Medication adherence or knowledge, General wellbeing** or **Satisfaction**
Pal	2013 USA	Prospective cohort study	Discharge medicine reconciliation and counselling.	769 (537 intervention, 192 control) Mean age = 55.5 years	30 days	**In patients aged $\geq$65, readmission rate was 10.9% intervention vs 31.4% control, p=0.001**
Schnipper	2006 USA	RCT	Discharge medication counselling. Telephone call 3-5 days post discharge for review of medicines use.	152 (79 intervention,73 control) Mean age = 66 Mean no. meds = 8	30 days	**ADEs**: NS diff overall but fewer **preventable** in intervention group (p=0.01). **A&E visits/ readmissions:** NS diff overall but fewer **preventable medicines related** in intervention group (p=0.03)

Scullin	2007 UK	Service evaluation with random-isation	Inpatient medicines reconciliation/ review Medication counselling throughout admission and on discharge. Comprehensive meds record sheet given to patient, GP and community pharmacist.	762 (371 intervention, 391 control). Mean age 70. $\geq$1 of: meds $\geq$4, high risk drug, admission in last 6/12, age$\geq$65 and on anti-depressant	12 months	**Readmissions**: fewer in intervention group (p=0.027). **Length of stay on readmission:** trend towards shorter in intervention group (p=0.068). **Time to first readmission:** longer in intervention group (*P*=0.0356)
Scullin	2012 UK	Naturalistic experiment	Inpatient medicines reconciliation/ review Medication counselling throughout admission and on discharge. Comprehensive meds record sheet given to patient, GP and community pharmacist.	833 (749 intervention, 84 control). Mean age 70.5. $\geq$1 of: meds $\geq$4, high risk drug, admission in last 6/12	12 months	**Readmissions**: NS diff in number. **Length of stay on first readmission:** shorter in intervention group (p=0.013). **Time to first readmission:** trend towards being longer in intervention group
Smith	1997 UK	RCT	Discharge medication counselling and care plan. Telephone help line. Home visit for all participants 7-10 days post d/c for follow-up assessment and resolution of DRPs	53 (28 intervention, 25 control), identified by ward pharmacists as being at risk of DRPs. Age $\geq$65. Average no. meds = 5.3	7-10 days	**Adherence**: better in intervention group (p<0.01). **Unintentional discrepancies**: NS diff. **Other:** Pharmaceutical counselling required during home visit in fewer intervention group patients (p<0.01).

Stewart	1998 Australia	RCT	Discharge counselling (medicines and clinical condition) by nurse / pharmacist. Home visit one week post discharge by nurse and pharmacist for high risk patients)	762 (381 intervention, 381 control) Mean age = 66	6 months	**Readmission/ death**: lower in intervention group (p<0.001). **Readmission days**: less in intervention group ($P < 0.001$). **A&E visits**: Lower in intervention group (< 0.001).
Still	2013 USA	Retrospective comparison	Discharge medication counselling and provision of medication list. Patients targeted for intervention were high risk for readmission or were identified by hospital staff as in need of medication counselling Comparison patients were predominantly medium and low risk	748 (228 intervention, 520 comparison). Mean age of intervention group (62) was younger than high (70) or medium risk (68) comparison patients	30 days	**Readmissions:** Medium risk intervention patients had lower readmission rate then medium risk controls (p=0.033)
Stowasser	2002 Australia	RCT	Medicines reconciliation on admission. Preparation of 'Medication Liason Service communication' (enhanced medication care plan) and faxing of this to GP and community pharmacist on discharge.	240 (113 intervention, 127 control) Mean age = 66.5 Mean no. meds = 7.6	30 days	**Readmissions:** Trend towards fewer in intervention group **Healthcare professional visits**: fewer in intervention group (p<0.05) **Functional health and wellbeing (SF-36):** Intervention group tended to improve more on all components apart from vitality

Vuong	2008 Australia	RCT	Home visit within 5 days of discharge to review medicines use	316 (152 intervention, 164 control) Mean age = 72 Mean no. meds = 10.5	8-12 weeks	**Adherence:** improved more in intervention group (p=0.028)

NS diff – no significant difference between groups
RR = risk ratio
CI = confidence interval
ADLs = activities of daily living
HF = heart failure
Meds = medicines

4.4: TRANSFER OF CARE INTERVENTIONS INVOLVING PHARMACISTS: SYSTEMATIC REVIEWS

A number of systematic reviews reporting on the effectiveness of transfer of care interventions involving pharmacists have been published, both prior to and since the commencement of the study which is the focus of this thesis (11,108,152-162). As with the studies reviewed above, each review has a slightly different focus, but the vast majority of the studies discussed are included in at least one of these reviews. Below, the findings of the most relevant of the reviews published before 2014 will be discussed in the context of this thesis and in light of the studies reviewed above.

A 2012 systematic review of 36 RCTs aiming to improve handovers between hospital and primary care considered the effect of interventions on a range of outcomes, including readmissions and ED visits as well as patient satisfaction and quality of life, and outcomes related to the improvement of continuity of care after discharge (for example, timeliness and accuracy of discharge information) (152). Not all interventions involved pharmacists but of those that did, 6 of the studies reviewed in Section 4.3 were included (126,129-131,133,146). The reviewers found that effective interventions comprised components that focussed on structuring and reconciling discharge information, coordinating follow-up care, and direct and timely communication between providers. In particular interventions involving medicines reconciliation were frequently associated with significant effects. The following year, a review of 47 studies investigating the effects of hospital initiated transitional care interventions on clinical adverse events, ED

visits, and readmissions was published (108). Nine of the studies discussed in this chapter were included, 4 of which were also included in the earlier review (116,117,122,126,130-133,141). The second review drew the conclusion that nearly all interventions which had a positive effect on outcomes used a 'bridging' strategy, involving both pre- and post- discharge components. This finding supports the conclusions drawn from the primary research studies in this chapter.

In the same year, a systematic review focussing specifically on improving continuity of care in medicines management included 14 studies, 10 of which are reviewed in this chapter (11,118,120,122,126,127,129-131,143,146). The conclusions drawn were similar to those presented here; that patient education and counselling provided upon discharge and reinforced after discharge, sometimes together with improved communication between HCPs, was shown to reduce the risk of ADEs and hospital re-admissions in some studies, but that the effect was not consistent.

One explanation for this inconsistency in results from published studies could be the methodological limitations and inconsistencies identified by reviewers, the majority of which have been discussed earlier in this chapter. These include heterogeneity in intervention types (including number and intensity of patient contacts), patient populations enrolled (including level and definition of risk for post-discharge adverse events) and outcomes measured, which precluded the reviewers from arriving at clear conclusions (11,108,152). The reviewers also note that some of the outcome measures selected may not be sensitive enough to demonstrate the effectiveness of the interventions, or that the primary studies were underpowered to show significant benefits. This is also consistent with the analysis presented in Section 4.3.2, which discussed that sometimes the selection of arguably more relevant outcome measures by researchers (such as drug related readmissions as opposed to all readmissions) lead to a greater apparent benefit of the intervention (131,132).

In Rennke et al's 2013 review in particular, it is suggested that in the race to reduce hospital readmissions, there has been a lack of attention to the potential additional benefit of strategies to reduce specific post discharge adverse events, including ADEs (108). The reviewers argue that these events should be targeted

because they still represent significant failures to ensure patient safety, even if they do not ultimately lead to ED visits or readmissions. The reviewers considered that medication safety interventions led by clinical pharmacists seem to be a promising approach, indicating a need for larger trials with an explicit plan to measure clinically significant adverse events.

Importantly from the community pharmacy perspective, even among the most comprehensive intervention strategies reviewed by Rennke et al there was little evidence of active engagement of primary care providers in the transitional care planning process. This again is in line with the findings discussed in this thesis chapter, where community pharmacists were either not involved in interventions at all, or only involved 'after the fact' when the vast majority of the intervention had already been provided elsewhere (117,118,122,125,127,128,130-134,141,142,147-149). The reviewers point out that primary care providers may be best positioned to detect and prevent adverse events before an ED visit or readmission, and thus their active engagement in discharge safety efforts may prove fruitful.

Also published in 2013 (and since updated in 2016) was a Cochrane review of 24 RCTs investigating individualised discharge planning (153,161). The reviewers concluded that a discharge plan tailored to the individual patient probably brings about reductions in hospital length of stay and readmission rates for older people admitted to hospital with a medical condition. These reviewers excluded trials evaluating interventions where discharge planning was not the main focus of a multifaceted package of care (for example those focussing on pharmacist interventions only), and therefore only included 2 of the trials reviewed in this chapter (126,130). However, the findings of the Cochrane review are still relevant, as medicines management is an important part of discharge planning, and from the research presented above, the integration of pharmacists into the MDT appears key to their contribution to the success of transfer of care interventions.

Summary

Overall, these systematic reviews indicate that there is a lack of high-quality research, disproportionate to the magnitude of the problem of discontinuity during

care transitions. The heterogeneity in design of many studies limits interpretation and may explain why there is no consistent evidence that pharmacist interventions can improve patient outcomes following transfer of care.

4.5: CURRENT TRANSFER OF CARE RESEARCH AND HEALTH POLICY PRIORITIES IN BRITAIN

Spinewine's 2013 systematic review of interventions to improve continuity of care in medicines management suggested that future studies should fit within initiatives that are promoted at the national level (11). It is important to consider how the research conducted in this programme of study will fit in with DoH and NHS agendas to promote high quality transfer of medicines related care. This will ensure that the intervention developed, if successful, will be more smoothly incorporated into routine practice.

Following the publication in 2009 of the CQC Report *Managing patients' medicines after discharge from hospital,* the RPS campaign "*Keeping patients safe when they transfer between care providers — getting the medicines right*" was launched in 2011 (68,110). This led to the publication of good practice guidance, and the inception of an "early adopter" programme to help organisations put the guidance into practice at a local level (10,55). The guidance included a suggested core content of records for medicines when patients transfer care providers, and indicated that it would be good practice for patients' community pharmacists to receive a copy of this information.

As discussed in Section 3.4, 2011 also saw the introduction of 'target groups' for the nationally contracted community pharmacy MURs, including patients recently discharged from hospital. The RPS guidance suggested that secondary care providers should ensure that patients discharged from hospital who have had changes made to their medicines are aware that they can request a post-discharge MUR (dMUR) from their community pharmacist (55). Furthermore, hospitals should work with community pharmacists to evaluate the impact of these reviews.

Around the same time, guidelines to support closer collaboration between hospital and community pharmacists, including a template hospital to community

pharmacist referral form, were published by the NHS (163). An action plan released by the DoH steering group on improving the use of medicines in October 2012 identified routine referral from hospitals for dMURs in appropriate patients as one way in which patients can be better supported to make appropriate use of their medicines (69). However, no extra resources have been made available to hospitals to identify patients who may benefit from such a service nor have any formal mechanisms for liaison between hospital and community pharmacists been established. This lack of formal communication channels between hospital and community pharmacies was identified as a challenge by the DoH, which recommended that dedicated programmes of support should be established, so that dMURs become an integral part of the medicines pathway where appropriate.

Until this happens, the onus is on the patient to self-refer to their community pharmacy. However, early feedback from sites piloting the promotion of dMURs is that self-referral of patients is low, with less than 3% of patients 'signposted' to the service actually taking it up (10,107). This reinforces earlier concerns that signposting to community pharmacies for post discharge support is not effective (121,122). A focus group of patients in Croydon CCG, one of the RPS early adopter sites, found that patients expected community pharmacists to be able to access their discharge information electronically, rather than "*relying on the patient to supply it on a piece of paper*" (107). Another of the early adopter sites felt that part of the problem is that "*many patients come out of hospital and need time at home to recuperate, [which] is at odds with the requirement for patients to be present in the pharmacy for an MUR*" (164). An online survey exploring the provision of dMURs in March 2013 in West Yorkshire, England, found that although 76% of MURs conducted in the last month were targeted, less than 1% were dMURs (165). Key barriers to provision were not receiving discharge medication summaries and restrictions on provisions to housebound patients. Both of these barriers where tackled by a project in South Staffordshire where, as part of a multi-faceted approach to improve discharge planning, elderly patients discharged from an intermediate care unit were referred by fax to their regular community pharmacist for a domiciliary dMUR. Community pharmacists involved in this project received £25 per visit in addition to the £28 MUR fee (166). The project as

a whole resulted in fewer admissions to A&E and fewer emergency re-admissions, as well as an 81% improvement in measures of functional independence following discharge, with a net health saving of £413,819 in the first year. However the contribution of the dMUR element to this was not investigated.

Another opportunity for community pharmacists in England to support continuity of care after discharge is the New Medicines Service (NMS), which was introduced around the same time as targeted MURs (167). The NMS aims to provide support to people who are newly prescribed a medicine to manage a LTC (currently asthma, COPD, hypertension, type 2 diabetes and those prescribed antiplatelet/ anticoagulant medicines). The initial NMS intervention takes place 7-14 days after the prescription of the new medicine, and aims to identify any problems either with the treatment or otherwise in relation to the patient's self-management of their long term condition, and the need for further information or support. In a further 14-21 days a follow-up consultation takes place to identify and resolve any further or persisting medication related issues. The NMS contract allows for referral of patients who have been recently started on these medicines during a hospital admission, as well as specifying that, although face-to-face consultations are preferable, telephone consultations may be undertaken if the patient prefers (168). Along with the repeated follow-up the provision for telephone contact represents a possible advantage over the dMUR, which may only be provided on the pharmacy premises unless special permission is applied for (9). An obvious disadvantage of the NMS in the post discharge context is that often patients will have had multiple changes made to their medicines whilst in hospital, in which case a full dMUR would likely be preferable.

Very little research on post-discharge NMS could be located at the time of this literature review; however what evidence there is suggests that uptake is low. A questionnaire study of 56 eligible patients discharged from a teaching hospital in South West London revealed that only 9 (16.1%) were aware of the service and 3 (5.3%) had been referred to it (169). A pilot NMS referral service of patients from the stroke unit at one North West London hospital initially found that, in common with the research above, 'signposting' of patients (verbal and written) to their community pharmacist was not successful: at 4 week follow-up only one pharmacy

of the 65 contacted had conducted a hospital-referred NMS, and of all the patients contacted, none had remembered the NMS referral (170). 'Many' community pharmacists said they would value direct contact from the hospital and patients revealed that long-term medication management is one of a number of challenges that they face when they go home and it may not be an immediate priority for them. Therefore, the hospital pharmacy started to contact the patient's community pharmacy by telephone before discharge an asked them to telephone the patient at home one week after discharge to offer the NMS. Community pharmacists were contacted 4 weeks after discharge and of the patients referred, 33% (9/28) had received an NMS intervention. Although this represents an improvement, the authors stated that further work was needed to identify reasons for the lack of NMS uptake. However, they concluded that telephone referral for dMUR/NMS adds minimal time to the discharge process and, supported by inpatient written and verbal information to patients, could be an effective way to increase the number of patients accessing these services after hospital discharge.

It is known that other projects are in development around the country to improve the transfer of medicines related discharge information to community pharmacies and increase the uptake of dMURs/NMS. One notable example is the 'Refer-to-pharmacy' tool at East Lancashire Hospitals NHS Trust, which transfers discharge information and referrals electronically to a patient's regular community pharmacy at their time of discharge (107). However the widespread development and implementation of such a tool is likely to be resource and time intensive. In the interim, exploration of other methods for increasing referral and uptake of these services is needed in order to fulfil the national guidance.

In addition, despite the promotion of dMURs as a way to improve medicines related transfer of care, their impact on adherence and subsequent hospital readmission is currently unknown. In 2011-12, the MUR service as a whole cost the NHS £72million (171). The service has also attracted criticism, with larger organisations pressurising employee pharmacists to meet stringent targets for MUR provision, prioritising service quantity over quality and compromising the professional judgement of pharmacists over which patients to target for MUR (171-174). Before electronic referral systems are introduced on a national basis there is a need for

evidence of the benefit to patients of dMURs, to justify the investment of time and money to implement both the referral process and the dMUR itself.

Another notable initiative to support transfer of medicines related care by enhancing the role of the community pharmacist is the Welsh DMR service, implemented in November 2011 (175). The DMR service builds on the MUR and comprises a two-part intervention by the patient's community pharmacist. The first part involves medicines reconciliation by the community pharmacist between the hospital and GP lists, and the raising of any discrepancies with the GP. The second part involves an MUR style discussion with the patient and provides an opportunity to ensure any discrepancies have been rectified. An evaluation of the DMR service was being undertaken at the same time as the planning phase of this PhD study, but was not published in time to inform it.

4.6: IMPLICATIONS OF LITERATURE REVIEW FOR THIS DOCTORAL STUDY

This thesis will aim to build on the strengths of, and gaps in, previous research regarding medicines related transfer of care, replicating successful components of previous studies as interpreted from the literature. These include involving pharmacists on both sides of the hospital-primary care interface, with special emphasis on reconciling medicines and reinforcing discharge information post-discharge.

The study will focus on a patient population who are known to be at risk for ADEs following discharge (i.e. those $\geq$65 who have had medicines changed during admission). Patients will not be excluded on the basis of mild cognitive impairment or relying on carer assistance with medication (unless these factors preclude them from physically accessing the intervention under study).   Both process measures and clinical and humanistic outcomes will be studied.

4.7: FINALISED AIM AND OBJECTIVES

Overall Aim of PhD: To investigate the feasibility and potential outcomes of a transitional care service for older patients which utilises community pharmacists via the dMUR service.

Objectives of PhD:

- Identify barriers and facilitators to transfer of information between hospital and community pharmacy on discharge
- Provide a basis for the collection of evidence regarding a service which is currently nationally commissioned but the benefits of which have not yet been reported (dMUR)
- Identify appropriate outcome measures to investigate the impact of the service
- Identify ways in which the dMUR service could be improved

CHAPTER 5: METHODOLOGICAL CONSIDERATIONS

This chapter will describe the rationale behind the various methodological elements that are used within this study. An overview of the different research methods used is presented in Figure 5.1 below. A brief introduction and discussion of the importance of patient and public involvement (PPI) to this research is followed by a description of why a mixed methods approach, combining both quantitative and qualitative techniques, was chosen. Potential study designs, and the reasons for the chosen design, will then be covered. This is followed by a description of how key elements, such as sample size, follow-up periods and outcome measures were selected. Operational aspects, such as the rationale behind participant inclusion and exclusion criteria will be explained, before potential methods of data collection and analysis are discussed. The chapter finishes with a description of the ethical aspects requiring consideration during the design of this study.

Hospital Pharmacy
- Focus group
- Questionnaire

Community Pharmacy
- Questionnaire

dMUR Referral Service Evaluation - Research Methods Used

Participant follow-up
- Postal questionnaire (measuring medication adherence, health related quality of life, enablement and other medication reviews undergone)
- Semi-structured interview

dMUR Data
- dMUR provision by community pharmacies
- Delphi review of interventions made

Hospital Attendance Data
- Tracking of readmissions and A&E visits via Patient Adminsitration System
- Case note-analysis of readmissions

Figure 5.1: Research Methods Used to Evaluate the dMUR Referral Service

5.1: INTRODUCTION

As discussed in Section 4.5, the DoH action plan on improving the use of medicines recommended that a programme that promotes and supports joint working between secondary and primary care should be developed (69). Such a programme would ensure that patients recently discharged from hospitals are routinely referred to community pharmacies where appropriate, to get the support they need to take their medicines more effectively. Furthermore, the DoH plan stated that, where appropriate, dMURs should become an integral part of the medicine pathway. This is despite the lack of direct evidence of the benefit of MURs on patient outcomes.

As described in previous chapters, problems with medication on transfer of care may be particularly prevalent and have more severe consequences in older patients. Older patients taking multiple medicines may have significant potential to benefit from pharmacist intervention on transfer of care.

It is also known that older people are often excluded from clinical trials, and building a study with this population in mind may require consideration of more and different factors compared to a trial involving younger people (176,177). Older people, particularly those who have recently been acutely ill or in hospital, may be reluctant to participate in research (176). In a review of all RCTs published in the journal of the BGS over an 18 month period, none had recruited patients from an acute hospital setting (176).

Exploring the logistics of setting up the referral service, including participant recruitment, randomisation to dMUR or standard care, and data collection, as well as determining the acceptability of the new service to patients, are therefore vital initial steps in this programme of work. As no published work has assessed the impact of dMURs on patients' quality of life, medication adherence or hospital re-admissions, suitable measures and ways of capturing this data need to be investigated.

In light of this, a feasibility study is planned to investigate these factors and identify areas for improvement of the service or study design, and evaluate the potential to progress to a full RCT.

5.2: PATIENT AND PUBLIC INVOLVEMENT

A growing body of evidence suggests that patients and the wider public can be involved at most stages of healthcare, including research into new services, and that this can have a number of benefits (178), such as increasing research quality and relevance (179). The National Institute for Health Research (NIHR)'s INVOLVE programme defines public involvement in research as research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them. This includes, for example, offering advice as members of a project steering group, or commenting on and developing research materials.

As this doctoral research focuses on a direct-to-patient service (the dMUR), which requires active participation of patients when they are perhaps at their most vulnerable (i.e. shortly after a hospital discharge), it is felt that their involvement in this feasibility study is important.

Priority objectives for PPI in this research include:

- Obtaining the views of potential 'end users' as to the value of the service

- Refining eligibility criteria, particularly with regards to targeting patients who may benefit the most

- Ensuring that the methods proposed for the study are acceptable and sensitive to the situations of potential participants, for example:

  o Access to medical notes by members of the pharmacy team to complete an eligibility screen

  o Being approached to take part in the study whilst unwell in hospital

  o Being randomised to be referred for a dMUR, or to be discharged 'as usual'

  o Details of medication changes during hospitalisation being sent to their community pharmacy

- The intervention itself, i.e. attending their community pharmacy for a dMUR within 4 weeks of discharge (or having a dMUR at home or via the telephone if their community pharmacist is able/willing to offer this)

- The dMUR 'action plans' being sent back to the research team for scrutiny

- Being sent questionnaires and/or interviewed about their experiences after discharge

- Making the language and content of participant information more appropriate and accessible (for example participant information leaflets and follow-up questionnaires)

- Helping to ensure that the research uses outcomes that are important to the public

With this agenda in mind, the aim is to recruit a PPI group consisting of patients or members of the public in the target demographic (aged $\geq$65 who have had changes to medicines whilst in hospital), as well as friends, family and carers of these people. The views of this group on the topics above will then feed into the overall final study design.

5.3: ELEMENTS OF STUDY DESIGN

This study is experimental in nature as it involves assessment of the effect of an intervention - a community pharmacy based dMUR within four weeks of hospital discharge (180). A number of possible designs for experimental studies exist which needed to be considered; these are discussed in Section 5.3.2. Other important elements of study design include decisions regarding sample size, follow-up periods and the selection of outcome measures; these are discussed in Sections 5.3.4 - 5.3.6.

Underpinning all these decisions is the ontological and epistemological position of the researcher. This position drives the decision as to whether the research conducted is of a quantitative or qualitative nature, or whether a combination of the two (the 'mixed methods' approach) is appropriate. All further decisions regarding

study design follow on from this. Section 5.3.1 therefore discusses the ontological and epistemological perspective of this research and why a mixed methods approach was chosen.

5.3.1: Mixed Methods Approach

The quantitative and qualitative research paradigms are each based on a particular patterned set of assumptions concerning reality (ontology) and knowledge of that reality (epistemology). The quantitative paradigm is based on positivism, or realism – the ontological position that there is only one truth, an objective reality that exists independent of human perception, separate from the observer and waiting to be discovered. Science is characterised by empirical research; all phenomena can be reduced to empirical indicators which represent the truth. Epistemologically, the investigator and investigated are independent entities. Therefore, the investigator is capable of studying a phenomenon without influencing it or being influenced by it (181). The goal is to measure and analyse causal relationships between variables within a value-free framework. Techniques to ensure this include randomisation, blinding, highly structured protocols, and written or orally administered questionnaires with a limited range of predetermined responses (181).

In contrast, the qualitative paradigm is based on interpretivism and constructivism. Ontologically speaking, there are multiple realities or multiple truths based on one's construction of reality. On an epistemological level, there is no access to reality independent of our minds. The investigator and the object of study are interactively linked so that findings are mutually created within the context of the situation which shapes the inquiry. The emphasis of qualitative research is on process and meanings. Techniques used in qualitative studies include one-to-one and focus group interviews and participant observation (181).

Sale et al argue that qualitative and quantitative research methods have grown out of, and still represent, different paradigms (181). However, they state that the fact that the approaches are incommensurate does not mean that multiple methods cannot be combined in a single study if it is done for complementary purposes. In

this way the strengths of one method can enhance the other, although they remain independent (additive). It has been argued that mixed methods research, combining quantitative and qualitative approaches, can be particularly useful in healthcare research as only a broader range of perspectives can do justice to the complexity of the phenomena studied (182-184). By combining qualitative and quantitative findings, an overall or negotiated account of the findings can be forged, which is not possible by using a singular approach (185).

This study therefore combines quantitative and qualitative methodologies. Sequential data analysis is used, where results from each methodology are analysed in sequence with the purpose of informing, rather than being integrated with, findings from the other methodology (186). Findings are then integrated at the stage of interpretation and conclusion. Positivism is the primary ontological position of this research, coloured by a certain degree of interpretivism, as advocated by Howe (187).

Mixed Methodology within This Thesis

Analysis of a qualitative focus group is used to inform development of a quantitative survey for all pharmacists working on wards during participant recruitment.

Qualitative consensus methodology is used to provide an illustration of the potential significance of community pharmacist interventions, to complement quantitative data on hospital visits, quality of life scores, adherence and enablement scores.

Quantitative analysis of participant recruitment rates, dMUR uptake rates and dMUR 'action plans' are further explored using qualitative participant interviews.

Other parts of this study are analysed using purely quantitative techniques, for example hospital readmission rates, health related quality of life, adherence and enablement scores.

5.3.2: Possible Study Designs

<u>Randomised Controlled Trial (RCT)</u>

These are trials where participants are randomly allocated to receive either an intervention or nothing (control). If well implemented, randomisation should ensure that intervention and control groups only differ in their exposure to treatment (188). This reduces the chance of confounding variables affecting the results and gives a greater degree of confidence that any difference in outcomes between participant groups is caused by the intervention rather than inherent differences between participant groups. This increases the internal validity of the study. In view of these advantages a randomised controlled design was eventually chosen for this PhD study. Further discussion of why other designs were discounted in favour of a randomised controlled design is presented below.

Clustering in RCTs

In a cluster RCT, the unit of randomisation is a cluster of participants. For example in this study, hospital wards could be randomly assigned as control or intervention wards, with all participants from those wards allocated to the assigned study group (188). This approach will not be used as all the wards had different specialities. Therefore using hospital ward as the unit of randomisation would have been likely to result in non-comparable groups.

Blinding In RCTs

Blinding participants to the administration of the intervention in a trial can eliminate the possibility that observed effects are due to differential use of other treatments in the intervention and control groups (for example control group patients actively seeking out a medication review by other means because they know they are not going to be offered one through the study) (189). However, it is not considered feasible to blind participants in this study to their allocation to intervention or control group. Offering control group participants a 'sham' intervention of no proven worth may be seen as unethical as well as time-consuming and resource intensive to deliver in the context of a PhD project.

Blinding study personnel can prevent biased assessment or interpretation of the outcome (for example the investigator looking more carefully for outcomes in the

intervention group) (189). However it is not possible to blind the researcher who will be recruiting participants and collecting data for this study or the community pharmacists who will be delivering the intervention. This is due to lack of resource as the research student is required to receive the results of participants' study allocation, complete the referral process to the community pharmacist, follow-up dMURs which are not reported back with the community pharmacists, administer different follow-up questionnaires to intervention and control groups, and conduct qualitative follow-up interviews. It would not be possible to perform all these roles and remain blinded to participants' group allocations.

Note -the consultant who will be involved with the assessment of causality readmissions (Section 6.6.2) will be blinded to participants' allocation, which will reduce the chance of bias in this part of analysis.

Non-randomised between-groups design

These studies compare outcomes for a group of patients who received an intervention with a 'comparison' group who have been assigned by means other than randomisation. Analytic methods can adjust for baseline factors that are unequal between the two study groups, but it may not be possible to adjust for all differences and this may lead to under or over-estimation of the effects of the intervention (190,191).

Non-randomised comparison studies use a variety of methods to assign participants to study groups. Psuedo- or quasi-randomisation involves techniques such as allocating every other participant, for example, to the treatment group, or assigning one hospital ward as 'intervention' and one as 'control'. Whilst being logistically easier than employing a full randomisation process, the predictability of these methods permit the investigator to tamper with the recruitment process by manipulating the sequence or eligibility of participants, which will introduce bias (190).

Some studies assign participants to groups according to certain criteria; for example, in this study, less mobile patients could be assigned to the control group to remove the problem of attending the pharmacy for a medication review. This would likely increase participant numbers by allowing broader inclusion criteria or

reducing perceived burden of partaking in the study for patients with poor mobility. However this type of technique may lead to unevenly matched groups – for example sicker or less motivated patients are likely to end up in the control group, which may artificially inflate the apparent effectiveness of the intervention (189).

A number of studies reviewed in Chapter 4 used a comparison group of patients who would have been eligible for the intervention but did not receive it due to finite capacity to deliver the service (141,142,147,149). This has the potential to increase sample sizes and simplify the recruitment process, however again it increases the chance the two groups will be different at baseline and reduces confidence in the results produced.

Time-series/before and after design

This design involves evaluating the effects of an intervention by comparing the outcomes of study participants before the intervention with those measured afterwards. The participants investigated before and after the intervention would be from the same sites or centres, and may be the same people or different samples (192). For example in this study, a group of patients discharged before the introduction of the dMUR referral service could be compared to a group discharged from the same hospital after the introduction of the service. However in this scenario, the study groups may not be comparable in their characteristics, introducing bias (192).

In a 'within group' before and after design, measurements are made before and after each participant receives the intervention; with each participant serving as their own control to evaluate the effect of the intervention (189). This design has the advantage that innate differences between groups are eliminated as confounding variables. However, this design will not be used for this research because it is already anticipated that recruitment might be challenging, and administering questionnaires to elderly patients in hospital in addition to the informed consent process may be unduly burdensome and reduce willingness to participate in the study (129,133,176).

The major disadvantages of before and after studies are the lack of a concurrent control group, and, in this study in particular, the chance that factors other than the

intervention may affect outcomes (189). For example, quality of life measurements taken at baseline (whilst patients are in hospital) may expected to be lower than those taken later when they are back at home. Measurements such as medication adherence may be difficult to assess in a hospitalised patient as responsibility for medication administration in hospital is generally taken over by nursing staff, and even if patients are asked regarding adherence behaviour prior to admission the reliability and validity of such measurements is likely to be affected by recall bias. Subsequent measurements may be affected by the complexity of changes to the medication regimen made in hospital, rather than the effects of the intervention. Comparing readmissions in the follow-up period to those in the same time period leading up to the baseline admission may also be possible but again the subsequent readmission may be affected by various factors other than the intervention. For these reasons, this design is not viewed as suitable for this study.

<u>Cross-over design</u>

This design involves half the participants receiving the intervention initially and the other half serving as control, then after a designated time period the initial control group receive the intervention and the original intervention group switch to control (189). This design would obviously not be feasible for a study such as this, where the intervention is time-limited (i.e. referral for dMUR within 4 weeks of discharge).

5.3.3: Chosen Design: Randomised Controlled Feasibility Study

The design chosen for this feasibility study is a randomised controlled design. This was selected due to the already stated advantages of RCTs in relation to the other designs considered. To explore the feasibility of a future full RCT, the willingness of potential participants to consent to randomisation is viewed as an important part of this research. A non-blinded design was chosen due to the methodological difficulties with blinding in this study as explained above.

It was decided to use a post-test only design, whereby outcome measures are only collected at follow-up and not at baseline. As discussed, administering a battery of questionnaires to an elderly patient in hospital, in addition to the informed consent process, may be viewed as unduly burdensome by potential participants and

thereby reduce recruitment. This view was supported by the PPI group who felt that even the participant information leaflet for the study was off-putting in its length (see Section 5.6.2). It was also felt that randomisation of participants would reduce the need for baseline measurement of outcome variables as these would be expected to be the same in each group. Therefore any effect of the intervention should be demonstrated by differences in outcome measures between the groups at follow-up.

5.3.4: Sample Size

It is proposed that between 60 and 100 patients will be recruited (randomised between intervention and control groups). This number is deemed appropriate as:

- The sample size selected needs to provide adequate representation of parameters of interest for this feasibility study, such as participant recruitment and attrition rates.
  - o Recruitment rate: The lowest recruitment rate among the studies in the literature review was Vuong's 2008 RCT of a community liaison pharmacist service, which recruited 27% of patients referred (129). From exploratory work carried out as part of this study on the emergency admissions unit (EAU) at SONT between 3rd and 14th June 2013 it was estimated that 23% of newly admitted medical patients would be eligible for referral to the researcher (Appendix 3). Analysing the number of discharge prescriptions processed by pharmacy on the first weekday of each month between July 2012 and June 2013 showed a mean of 23 discharges from medical wards per day (Appendix 3). This indicates that a minimum of 5 patients should be referred by ward pharmacists per working day for full eligibility screen and consent. Over 12 weeks this should result in 300 patients referred to the researcher. A sample of 300 patients would allow a recruitment rate of 30% (ie effect size of 0.3) to be detected with 85% power (see Figure A4.1 in Appendix 4)
  - o Attrition rate: Experimental/quasi-experimental studies of transfer of care interventions involving older patients have reported attrition rates of up to

64% (143). In a service evaluation of telephone referral from hospital to community pharmacy for stroke patients to receive the NMS, 67% of patients did not receive the service within 4 weeks. A sample size of 60 participants in this study would allow us to detect an attrition rate of 70% with 85% power (see Figure A4.2 in Appendix 4).

- One of the objectives of the study is to investigate if emergency readmissions in this patient group can be characterised in terms of their causality and the contribution and preventability of medication related problems. A baseline six-month readmission rate of approximately 20% (based on readmission data for patients aged $\geq$65 to SONT Nov 2011-Oct 2012) is expected. Therefore a sample size of 60-100 patients should generate between 12 and 20 readmissions to study. This should be adequate to pilot the application of the criteria chosen.

- A published audit of sample sizes for pilot and feasibility trials registered in the UK Clinical Research Network database found that the median sample size for ongoing feasibility studies was 36 participants per arm (range 10-300) (193). The sample size of 60-100 proposed for this study therefore sits comfortably within the range used by other researchers.

5.3.5: Follow-up Periods

Patients will be followed up at two time points; 4 weeks and 6months post discharge. Four weeks was chosen for two reasons. Firstly, the service specification for dMURs states that they should normally take place within that time period. Secondly, data on emergency readmissions (those that occur within one month of discharge) are included in the NHS Outcomes Framework as an indicator of quality care in the NHS (95).

A six-month follow-up will be included to determine any lasting effect from the intervention. Six months was chosen as Cochrane reviews of interventions to improve adherence to long term medications include only studies that are six months or longer in duration. Between November 2011 and October 2012, data from SONT showed a one-month readmission rate of 9%, rising to 19% at six months and 24% at 12 months. It can therefore be seen that almost 80% of one-

year readmissions to SONT occur within the first six months. This suggests that a period of six months from discharge to final follow-up is appropriate for this study.

5.3.6: Outcome Measures

One of the objectives of this feasibility study is to determine appropriate outcome measures to be used to assess the effect of the dMUR referral service. As discussed in the previous chapter, research into transitional care involving pharmacists has been hampered by the use of outcomes that were too broad or only proxy measures of improved health or quality of life. For example, measuring the difference in all-cause emergency readmissions between groups may underestimate the positive effect of a pharmaceutical intervention on preventable, medication related readmissions, or adverse events that do not ultimately lead to readmission (108,131,132). Drug knowledge and adherence are only really meaningful if they can be transferred into improved quality of life, feeling of empowerment, or a reduction in ADEs or health service usage.

Therefore this study will measure patient orientated outcomes including:

- Hospital readmission rates with particular focus on medication related readmissions and their preventability

- A&E attendance rates

- GP consultation rates

- Health related quality of life (HR-QoL)

- Patient satisfaction with service (or related measure)

Readmissions

Reports in the literature estimate that between 20 and 64% of hospital readmissions may be related to problems with medication, the majority of them preventable, with the associated burden for patients and the healthcare system (104-106,194,195). It would therefore be desirable to determine whether referral for a dMUR is associated with a reduced risk of non-elective readmission to

hospital. Additionally, reduced likelihood of readmission was viewed to be the most desirable outcome of dMUR referral by the study's PPI group (Appendix 2).

Some studies of hospital initiated pharmacy interventions have used length of stay on readmission as an additional outcome (116,117,126,128,141,142). It is conceivable that by managing their medication and medical conditions more appropriately as a result of their dMUR, intervention group participants will recognise signs of clinical deterioration or adverse effects of medication before they become too severe, and therefore require fewer days in hospital on readmission, even if the readmission itself is not prevented. Improved knowledge of their medication regimen and sources of support after discharge may reduce time spent on medicines reconciliation and initiation of appropriate medicines management on admission and the complexity of the discharge process, providing another potential means of shortening a readmission. Therefore length of stay on readmission will be used as an outcome measure for this study.

A&E Attendances

Sometimes patients may attend the hospital's A&E department, and, following assessment and any necessary tests and treatments, be discharged from there rather than being admitted to a ward. As many as 1 in 3 A&E visits may be medication related, with over two-thirds of these being preventable (196-198). Therefore not measuring A&E attendance as a separate outcome could result in effects of the intervention going unidentified (196,197). As well as adverse drug reactions, other medication related causes of A&E attendance include non-adherence, and even having run out of medicines (196-199).   Such problems could potentially be reduced by dMUR interventions. Therefore a comparison of the number of A&E visits between intervention and control groups was identified as a potentially important outcome to measure. This is in keeping with several previous studies of hospital pharmacy initiated interventions that have reported the effect on A&E visits as well as actual readmissions (133,200-203).

GP Consultation Rates

GP visits were a recurring theme during PPI group sessions for this study (Appendix 2). Participants described examples of GP consultations regarding

medicines they had made following discharge and also expressed frustration at the difficulty of arranging such appointments. This raised the question of whether, with proper promotion and targeting, there is a role for dMURs in freeing up GP appointments by answering questions patients have re medicines post discharge.

A number of the studies reviewed in chapter 3 used the number GP visits made by participants as an outcome, with fewer visits indicating a positive effect of the intervention (119,122,126,127,134). With the current pressures on GP services, any intervention that reduced the demand for appointments would indeed be hailed as a success. It is therefore planned to compare number of GP visits in each group as an outcome measure in this study.

Medication Review other than dMUR

It would be desirable for dMUR with the community pharmacist to reduce the need for medication reviews by other HCP. It must be remembered that the dMUR is primarily focussed on increasing patient understanding and appropriate use of their medication, rather than being a clinical review, and so will not remove the need for additional review (for example with the GP or practice pharmacist) altogether. However, as discussed in the preceding section, GP appointments are currently being taken up with medication related queries post-discharge. It could be that the number of additional medication reviews would be a more sensitive measure to detect the benefit of dMURs on healthcare usage than GP visits overall (which may be for a variety of reasons other than medication).

HR-QoL

Pharmaceutical care encompasses pharmacist involvement in designing, implementing and monitoring therapeutic plans in collaboration with other healthcare professionals, which can be integrated with other aspects of healthcare, e.g. medical and nursing care (204). As such, the dMUR referral service embraces the central tenets of pharmaceutical care and one way to demonstrate the added value of the service would be through detecting improvements in outcomes such as quality of life, or more specifically, HR-QoL. HR-QoL has been defined as "*The value assigned to the duration of life as modified by the impairments, functional states, perceptions and social opportunities that are influenced by disease, injury,*

treatment or policy" (205). It is a multidimensional construct that generally includes assessments of physical, mental, and social functioning (206). As such it seems important to attempt to capture any effect of dMUR on HR-QoL.

Many factors contribute to and affect a person's HR-QoL, of which the use of medication is only one. Generic HR-QoL instruments assess a range of issues, and some of their content may be of little relevance to individuals in a particular context (207). For this reason, measures may lack sensitivity to small but significant changes in a particular area of an individual's life (such as the better understanding and use of medication). Pharmaceutical care–based activities may influence patient knowledge, medication adherence, and drug therapy effects via an avoidance of drug-related problems, but it is unclear how each intermediate outcome influences HR-QoL (206).

Previous research has shown inconsistent effects of pharmaceutical care interventions on HR-QoL in the elderly (204,206). It has been suggested that this could be due to the greater disease burden in this patient population, meaning that the appropriate use of medication may only have a small effect on overall QoL, which may not be detectable unless sample sizes are large (204,206). Furthermore, the potential impact of medicines optimisation on HR-QoL in patients with chronic disease may take longer to develop than the follow-up period of this study (206). Therefore, although potentially important in demonstrating the value of pharmaceutical care activities, it has been recommended that HR-QoL measurement should be complemented with other indicators to measure the influence of pharmacist interventions (206). HR-QoL will be used as an outcome in this study but will be supplemented by another measure that may be more sensitive to patients' perception of health gain following a dMUR, as discussed in the next section.

<u>Patient Enablement</u>

Whilst patient satisfaction questionnaires generally attempt to measure patients' perceptions of outcome, their structure often appears to measure the extent to which expectations relating to the process of the delivery of care has been met, rather than whether there has been achievement of a specific health gain (208).

Howie et al therefore developed a series of questions about patients' experience of consultations, which identified a concept complementary to, but different from, satisfaction, which related to the themes of patient centeredness and empowerment. They termed this concept 'enablement' and defined it as the patient's '*perception of their ability to understand and cope with their health problem'* immediately following the consultation (208,209). The Patient Enablement Index (PEI) will therefore be used to supplement HR-QoL as an outcome measure in this study.

Furthermore, *'feeling more able to live a normal life'* as a result of better medication management was identified as the most worthwhile outcome of this study by one of the PPI group members (Appendix 2). Self-efficacy (belief in one's own ability to successfully perform an action) is a concept closely related to enablement. Measuring enablement is therefore viewed as a valuable addition to the outcome measures to be studied in this piece of research.

Medication Adherence

Medication adherence will be measured as, despite only being a proxy measure for clinical outcomes, health benefits from more appropriate medication adherence may only manifest months or years later and therefore a six-month follow-up may underestimate these (210). In addition, improving adherence is a key aim of the MUR service (168). Therefore difference in adherence between intervention and control groups is an important outcome measure for this study.

Process Measures

As discussed in the literature review, even among the most comprehensive transfer of care intervention strategies reported, there was little evidence of active engagement of primary care providers in the transitional care planning process, or of measurement of the effectiveness of communication between hospital and community (108,153). One of the key objectives of this study is to identify barriers and facilitators to transfer of information between hospital and community pharmacy on discharge. A mix of qualitative and quantitative techniques will be used to evaluate the effectiveness and efficiency of the dMUR referral process, including questionnaire surveys of both hospital and community pharmacists and

maintenance of a record of time taken to make referrals and any communication problems that occur.

Other process measures to be evaluated as part of this study include:

- Rate of referral by ward pharmacists of potentially eligible patients. If referrals are lower than expected (see Section 5.3.4 above) reasons will be explored. Ways of doing this are discussed in Section 5.4 below. An understanding of these issues will mean that they can be addressed where possible and the implications for the feasibility of the service and any future RCT assessed.

- Recruitment rate and reasons for non-eligibility and refusal to participate. Older people are often excluded from clinical trials, and building a trial with this population in mind may require consideration of more and different factors compared to a trial involving younger people (176,177). Older people, particularly those who have recently been acutely ill or in hospital, may be reluctant to participate in research (176). Therefore there is potential for recruitment to be lower or take longer than expected.

- Drop-outs with reasons if possible. This will help to refine sample size calculation for any future RCT and develop participant retention strategies (e.g. adjusting the way follow up data is collected or recommending changes to the way the service is delivered).

- Percentage delivery of dMURs by community pharmacists, timescale to complete dMURs and manner of delivery (e.g. in-pharmacy, telephone, home visit).

- Return rate of dMUR action plans to researcher. This will help to predict the volume of data generated at this stage for a given number of dMURs performed, and the likely increased workload for the researcher in following up those dMURs where action plans were not returned.

- Return rate of postal questionnaires/participant diaries. Previous studies have shown a wide range of response rates so clarification of likely rate in this patient group would help finalise sample size for a future RCT.

In addition, the number and type of interventions made by community pharmacists will be collated and their potential clinical significance evaluated. As with adherence, the actual significance of these interventions may be difficult to translate directly into patient or economic benefit; therefore a form of objective prospective estimate is required (Section 5.6.6).

5.4: HOSPITAL PHARMACIST FOCUS GROUP

Very few potential study participants were referred to the researcher by ward pharmacists during the early weeks of recruitment. Focus group methodology was chosen to explore the reasons behind this because it allows interaction between participants to develop themes and issues raised. (211). Participants can question each other and comment on each other's experiences and views in a social context. Another advantage of focus group methodology is that participants can provide checks and balances on each other, and extreme opinions tend to be challenged by other participants, thereby providing a natural quality control on the data gathered. They may also feel able to voice opinions and criticisms that would not be captured by a 1:1 interview or questionnaire, thereby allowing the facilitator to discover what people really think about the topic and why. The facilitator plays an important role in clarifying ambiguity as part of the discussion. The most important issues tend to be focussed on and group consensus, if present, is easy to gauge. Less inhibited participants may encourage contribution from quieter ones, who may have been reluctant to be interviewed on their own or felt they had nothing to say.

In addition, a focus group provides a way of gaining the opinions and ideas of several individuals at once, and therefore can be an economical way of gathering a relatively large amount of qualitative data when time is short. This was important as solutions to the poor recruitment rate needed to be identified and put into practice as soon as possible, without taking too much time out of the recruitment process itself, which was ongoing at this time.

5.5: COMMUNITY PHARMACIST QUESTIONNAIRE

A questionnaire will be used in preference to a focus group or 1:1 interviews, as opinion from as many community pharmacists as possible are wanted and it would not be practical, with the resources available, to interview all those involved. Questions are adapted from the questionnaire previously used with hospital pharmacists at SONT and from the recent evaluation of the Wales DMR service (20).

5.6: STUDY OPERATION

5.6.1: Participant Eligibility Criteria

As discussed in Section 4.3.2, one difficulty in the interpretation of previous transfer of care research is the heterogeneous participant selection criteria used, which may affect participants' likelihood of benefitting from the interventions studied (11,108,152). Given the increasing elderly population and the scant resources with which to fund interventions, it makes sense to offer these interventions to those most likely to benefit. In turn, therefore, there is a need to target eligibility criteria for studies of these interventions toward those patients who, based on the literature (as presented in Chapters 3 and 4), we think will benefit the most. This should help to provide a realistic picture of the actual effect of an intervention on its target population.

Risk of Post-discharge DRPs

A reduction in DRPs following pharmacist intervention has been associated with patients aged 65 or over, taking six or more medicines, certain clinical conditions (e.g. heart failure or respiratory disease) and being prescribed a 'problem medication' (such as anticoagulants, insulin, combination antiplatelets, digoxin or narcotics) (117,147,148). Based on these previous works, in an attempt to target patients who could benefit from dMUR referral, it was decided to recruit patients aged $\geq$65 who were either:

- Prescribed ≥5 regular medicines, as taking ≥5 medicines has been identified as an independent risk factor for readmission in several studies (40,103,212) or
- Had changes to their medicines whilst in hospital, since changes to medication regimens are often poorly communicated and lead to readmission (104).

It was decided not to include factors relating to co-morbidities or specific 'high-risk' medicines because this will make the screening process more involved, and the view was taken that there was likely to be significant overlap between these factors and the ones already included. For example patients having three or more clinical conditions are likely to also be taking five or more regular medications.

<u>Medical Index Admission</u>

It was decided to recruit only patients admitted under the care of the medical directorate, as although surgical patients often do have medical problems, they would be less likely to experience changes in long-term medicines during their admission and would be less likely to obtain benefit from the dMUR process. This is supported by the fact that surgical readmission rates tend to be lower than those for medical patients (94).

<u>Independent with Medications at Home</u>

MURs with carers are not allowed under the current arrangements for the provision of MURs as an NHS service by community pharmacists.   MURs are currently only available to the patient themselves and require significant engagement from the patient. It is felt, therefore, that patients whose carers took overall responsibility for their medication would not be suitable participants in this particular study, and will be excluded.

Independence with medication is also considered not to apply to patients who receive all their medication in a multidose compliance aid (MCA) made up in a community pharmacy. Therefore this is set as an exclusion criterion. Patients with MCAs who also have to take medications that cannot be included in their MCA (e.g. inhalers, warfarin, weekly bisphosphonates, 'when required' drugs) must be

independent in taking this medication, and therefore they can be included in the study.

Nomination of Regular Community Pharmacy

The national service specification for MURs states that a patient must have been using a particular community pharmacy for at least three months to be eligible to obtain an MUR from them (168). However, 'prescription intervention' MURs (where the need for an MUR is highlighted by a significant problem on the patient's prescription that reveals the need for a more detailed examination of the patient's medication regimen) are not subject to this criterion. It is felt that dMURs could be seen to fit this category; therefore for the purposes of this study patients can participate as long as they are able to nominate a pharmacy they will start to visit regularly to obtain their prescriptions post-discharge.

Ability to Access Community Pharmacy for MUR

It is recognised that a significant number of elderly, recently discharged patients may have poor mobility and be unable to attend their community pharmacy without extreme difficulty. Unless they are able to have (and will accept) a domiciliary or telephone MUR, these patients will be excluded. The numbers of potential participants excluded on this criterion will be recorded and any impact considered during interpretation of the study results.

Patients who are deemed unable to give informed consent

Due to the age demographic involved with this study and associated prevalence of cognitive impairment it is anticipated that this will be an issue. Potential participants will be given written and verbal information about the study and given time to discuss participation with the chief researcher, relatives and carers as needed. No effort will be made to coerce individuals to take part and any concern over the advice will be sought from a patient's medical or nursing team if there is any doubt over their ability to give consent.

Patients already enrolled on to the study

It is possible that a patient may have been recruited to the study but then re-admitted. These patients will be excluded.

5.6.2 First Approach to Potential Participants

Ideally, the first approach to a potential participant regarding the study would be made by a member of the medical or nursing team responsible for their care, as these professionals are more likely to be familiar to patients and this is likely to help with recruitment. All PPI group members agreed that they would be most likely to participate if they were approached by their hospital doctor or nurse, rather than a pharmacist or researcher. However, the time needed to engage and train all physician and nursing teams at SONT makes this unfeasible. Instead, ward based pharmacists and technicians (who should also be familiar to their patients) will be utilised in the role of making the first approach to potentially eligible patients, as described in Figure 6.1 and Section 6.5.3. This compromise also avoids the ethical issues associated with access to the patient's notes by the researcher before the patient is aware of the study.

<u>Participant Information</u>

Some PPI group members felt that the initial participant information leaflet (PIL) for the study was too long and that this might be off-putting. Following discussion, it was decided to split the PIL into two leaflets. The first will give a general overview of the study and the dMUR service and is designed to be left with potentially interested participants. The researcher will then approach these people with the second leaflet to discuss participation in more depth.

5.6.3 Design of dMUR Referral Form

The RPS has produced a recommended core content of records for when patients transfer between care providers (110). This information is similar to that which has been reported as desirable to receive on transfer of care by community pharmacists (121,130,213). The referral form for this study was developed with reference to the RPS core content alongside the hospital to community pharmacist referral form published by NHS Employers and the PSNC (214).

5.6.4 Measurement of Outcomes

Readmissions

Readmissions to SONT will be measured using the hospital patient administration system (PAS). Obviously, the PAS will not identify readmissions to other hospitals. Initially an application was made to the HSCIC for an extract of hospital episode statistics (HES) data. This would have provided dates of hospital admission and discharge for each participant, the provider responsible for their care during these admissions, and their destination on discharge. However, this type of patient tracking was not feasible to organise within the time and financial constraints of this study.

Additionally, the likelihood of the patient group under study being admitted to another Trust is predicted to be low, as the population under study is not a mobile one and the geographical locality from which they are to be recruited is largely served by SONT. Participants will also be asked to keep a diary of readmissions, to be returned with their follow-up questionnaire. The topic of readmissions will also be addressed during face-to-face interviews with a sample of participants (see later in this section and Section 6.5.4). These methods will provide a means of capturing information regarding admission to other Trusts.

If a readmission has occurred, the patient's notes will be reviewed by a consultant geriatrician and the researcher, using published criteria to identify medication related adverse events and assess to what extent these could have contributed to re-admission and whether they could have been prevented (61,62,215).

A&E Visits

As with readmissions, it is easy to collect data on A&E visits to SONT via the PAS; data on A&E visits to other Trusts will not be captured.

GP Visits

Initially it was planned that participants' GPs would be contacted by telephone to obtain information. However this idea was discarded, partly because of the time it would take to obtain the information, and also because of potential difficulties in surgeries allowing this information to be released. Instead, participants will be

asked to record the number of times they saw their GP in the same diary they will be given to record hospital attendances.

Medication Review other than dMUR

This will be assessed by a mixture of closed and brief free text questions on the participant questionnaire. This will allow more specific information to be collected (i.e. identity of the reviewer, whether the review was HCP or patient initiated) than attempting to gather this data via the participant diary.

Adherence

Methods of measuring adherence can be classified as direct or indirect. Direct methods include directly observed therapy and measurement of concentrations of a drug or its metabolite in blood or urine. Direct methods are obviously impractical for this study due to the time required and lack of access to the necessary equipment and/or personnel. Also their intrusive nature is unlikely to be accepted by potential participants. Questioning the patient (either via interview, questionnaire or medication diary), assessing clinical response or physiologic markers, performing pill counts, ascertaining rates of refilling prescriptions and using electronic medication monitors are all indirect methods of assessing adherence; with a combination of methods being the most accurate way of assessing adherence (67).

However given the time and resource limitations of this study, a questionnaire is the sole method chosen. A number of validated adherence scales have been described in the literature, with the first published and most commonly used being Morisky's Medication Adherence Questionnaire (MAQ) (216,217). The original four item MAQ has since been supplemented with additional items to better capture barriers surrounding adherence behaviour, to form the 8-item Morisky Medication Adherence Scale (MMAS) (218,219). The MMAS score can range from 0 to 8, with high adherence being defined as score 8, medium adherence as 6-7, and low adherence as <6 (218).

Additionally, the MMAS has been successfully triangulated with medication possession ratios (days of supply issued divided by number of days patient is expected to have consumed the medicine) and clinical values from GP computer

records (220). It has also been shown to have high concordance with antihypertensive medication pharmacy fill rates in older patients in two separate studies (221,222). A significant association between low adherence as identified by the MMAS and uncontrolled blood pressure in an older population has also been demonstrated (221). The MMAS has also been used to measure adherence in the context of post-discharge pharmacist medication review in a previous study (129).

A disadvantage of the MAQ/MMAS is that they do not assess patient self-efficacy (belief in ability to successfully perform an action required to give a desired outcome), which has been found to be an important predictor of medication adherence (223). Other scales exist that do address this concept, for example the Self-efficacy for Appropriate Medication Use Scale (SEAMS) and the Brief Medication Questionnaire (BMQ) (223,224). However these scales are not as quick or as easy to complete or score as the MAQ/MMAS (216). As the measurement of adherence is only one of the aspects to be covered in the follow-up questionnaire administered to participants in this study, minimising length and therefore participant burden was viewed as key to maximising return rates. Reducing participant burden was particularly relevant for the current study involving elderly participants, who may be suffering from multiple medical conditions, frailty and/or mild cognitive impairment and therefore be more likely to suffer measurement fatigue with more lengthy assessments.

Taking all the above factors into account, the decision was made to use the 8-item MMAS for the measurement of adherence in this study. Modifications were made to the original MMAS to remove specific references to high blood pressure medication (for which the original tool was developed). Slight changes were also made to some of the wording following input from the PPI group.

There is however no guarantee that even if adherence can be measured accurately, that it will translate into improved health. Health related quality of life was therefore identified as an additional outcome that is meaningful to the patient and might be obtained following more appropriate use of medicines.

Health Related Quality of Life (HR-QoL)

The measurement of HR-QoL can be approached using general or disease-specific instruments. General (or 'generic') instruments provide an overall summary of HR-QoL and can be used to compare patients across different conditions, while specific instruments focus on a particular disease, patient group, or area of function (206,207). HR-QoL instruments have the potential to provide clinicians and researchers with measures of the effectiveness of interventions by capturing HR-QoL changes in a patient population over time and comparing information on patients assigned to different treatment groups (206).

As the participants in this study are anticipated to have a range of medical conditions, it appears most appropriate to use a general instrument to assess differences in HR-QoL between intervention and control groups. Ideally, a tool designed specifically for use with older people would be utilised, as many HR-QoL questionnaire items tend to be phrased predominantly in relation to the person's physical functioning and may thus inadvertently discriminate against older persons, whose physical function is likely to be not as good as that of younger people (207). However no valid measure specifically designed to assess HR-QoL in the elderly could be found in the literature. Although generic QoL measures, such as the Older People's Quality of Life Questionnaire (OPQOL), Control, Autonomy, Satisfaction, Pleasure - 19 items (CASP-19) and World Health Organisation Quality of Life questionnaire - version for older people (WHOQOL-OLD) have been developed for use with the elderly, these do not measure HR-QoL as such and therefore are unlikely to be sensitive to changes in QoL as a result of a dMUR (207,225).

The most widely used generic health status questionnaires in healthcare evaluation, both in studies of pharmacist interventions and in the elderly population as a whole are the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) and its variations, including the shorter SF-12 (206,207). As with the adherence scale, the HR-QoL assessment is only a part of the follow-up survey participants will be asked to fill in, and therefore brevity is viewed as important to increase response rate.

However, the importance of not sacrificing too much in terms of the quality of the measure by reducing its length is also recognised. The SF-12, currently in version 2 (SF-12v2), takes two minutes to complete and consists of 12 questions which yield an eight-scale profile of functional health and wellbeing, as well as two physical and mental health based summary measures (226). The SF-12 reproduces the physical component summary (PCS) and mental component summary (MCS) measures from the SF-36 with at least 90% accuracy (226). Scores from the SF-12v2 can also be adjusted for age, by comparing with age-group 'norms' (226). In this study, relevant age groups are 65-74 and 75 and over. This will allow comparison of the HR-QoL of the study population with the age-group population norms, which may assist in interpretation of other outcomes. The SF-12v2 was therefore chosen as the HR-QoL measure for this study.

Patient Enablement

The PEI was developed in the UK in the 1990s as a measure of quality in general practice doctor-patient consultations (208,209). The tool was developed in response to a lack of suitable outcome measures to assess quality of care in situations where consultations are for multidimensional problems with physical, psychological and social elements as well as the need for health promotion intermingled in a complex way (208,209). Enablement has been linked to health outcomes such as self-management and quality of life in patients with asthma and inflammatory bowel disease (227,228). Since its development, the PEI has been translated into Polish, Croatian, Chinese, French, Portuguese and Swedish, generally exhibiting high internal reliability (229-235). As well as GP consultations, it has been used following nurse practitioner, acupuncture and homeopathy consultations, and has generally shown consistent results across the different professions (236-238), although to date it has not been used by community pharmacists.

The PEI consists of 6 questions with multiple choice responses of "much better," "better," and "same or less" or "not applicable", which are scored 2, 1, and 0 respectively, giving a score range of 0-12. It has since been suggested that a PEI score of ≥6 is required for clinically meaningful enablement (227,239).

Three of the 6 PEI items are now included in the General Practice Assessment Questionnaire (GPAQ), which is used for annual GP practice patient surveys and GP revalidation in the UK (240). This indicates that the concept of enablement and the PEI itself have gained recognition as routine measures of consultation quality in the NHS, demonstrating formal recognition of the value of the PEI and supporting its use in this study.

The PEI will be used at 4-week follow-up with the intervention group only, as it is designed to measure enablement in the immediate period following a consultation. Therefore it will not be relevant to the control group at all, and is unlikely to be relevant to the intervention group by 6 months. The wording of the original tool was changed slightly in order to make it more relevant to the evaluation of an MUR rather than a GP consultation.

Use Of Postal Questionnaire Follow-up

The MMAS, SF-12v2 and PEI use closed questioning techniques, lending themselves to inclusion in to a questionnaire to allow for efficient, uniform and inexpensive data collection (189). Initially, telephone administration was considered as a way of maximising response rate, but following PPI discussion, a postal questionnaire was decided upon as this was their preferred method. Postal questionnaires also reduce the chance of interviewer bias and may allow participants to answer sensitive questions more honestly (241). Postal follow-up has been used successfully in previous trials involving older patients (242).

The biggest problem with postal questionnaires is non-response, which reduces sample size and can introduce bias if non-responders differ from responders. A number of ways of increasing response rate have been trialled and reviewed (241,243,244). The methods felt to be most suitable for this study by the PPI group were:

- A follow-up contact by post with a second copy of the questionnaire. Two weeks after the first questionnaire had been sent was felt to be a suitable time period for this, and only one follow-up was felt to be appropriate. The group suggested encouraging participants by way of a covering letter to contact the researcher if they were having difficulty completing the questionnaire.

- Having the hospital's logo or frank on the envelope and wording the covering letter as coming from the hospital (as opposed to the University as suggested by the Cochrane review)
- Personalised covering letter using mail merge.
- Including a stamped (not franked) addressed envelope in which to return the questionnaire.

Semi-structured Interviews

Questionnaires, however, are less suited to the exploration of the views, perceptions and experiences of participants (for example how they felt about the support they were given to manage their medicines on transfer of care), or to gaining a knowledge of why individuals behave in a certain way (for example why an intervention group participant may decline to attend their dMUR) (245). Qualitative interviews can help to gain insight into participants' situational experience not detectable by the use of a questionnaire (246). They can also collect the answers to open questions that require explanation or guidance, and interviewers can prompt participants to answer questions more fully to provide more in-depth information (189).

As dMUR referral is new, and the dMUR itself is relatively new and little used, it is important to understand how patients feel about such an initiative and their own perceptions of the benefits or lack thereof. It is also valuable to compare these perceptions and experiences with those of participants who did not have a dMUR, in terms of problems experienced with medication and other sources of support used or required by patients.

Qualitative interviews can also be used to contextualise the quantitative data gained from the postal questionnaire (246). For example the PEI could be supplemented with examples of how participants felt more able to understand and cope with their medication following the dMUR, or why they did not.

There are three main types of qualitative interview: structured, semi-structured and in depth (247). Structured interviews usually consist of the interviewer administering a questionnaire in a standardised manner, whilst semi-structured interviews consist of open ended questions defining the area to be explored, from

which the interviewer or interviewee may diverge in order to pursue an idea in more detail. In-depth interviews cover one or two issues in great detail. After introducing these issues, further questions from the interviewer are based on what the interviewee says and consist mostly of clarification and probing for details (247). For this study, it was decided that a semi-structured technique with a fixed topic guide which could be adapted to the views and experiences of each participant would be the most suitable.

It will not be feasible to interview all participants; therefore a purposive sampling technique will be used to identify a maximum variation sample of participants based on baseline characteristics.

Recall has been identified as a limiting factor in collecting data directly from participants in this type of study. However, a copy of the dMUR 'action plan' provided by the community pharmacist for intervention group patients should be held by the researcher at the time of interview, and participants asked to have their own copy to hand as a reference during the interview. Although participants may not be able to recall all aspects of their dMUR, this in itself will be important to explore, as advice which has been forgotten is unlikely to be followed, limiting the usefulness of the dMUR. All intervention and control group participants can refer to their participant diary, discharge summary and other sources of medication support they use during the interview to prompt and clarify answers if necessary.

During PPI group sessions, it was queried whether interviewed participants would also be expected to complete the questionnaire at the same time as this would add to participant burden. The PPI group suggested leaving the questionnaires with interviewed participants along with a pre-paid envelope in which to return them. However, it was finally decided that the researcher will request interviewees to fill out their questionnaire before the interview to avoid the interview content biasing their questionnaire answers. Having the questionnaire affect interview content is more acceptable as this would be more easily accounted for during analysis and might indeed provide a basis for interesting narrative from participants during interview. Additionally, leaving questionnaires with participants might result in some not being returned, whereas this would not be a factor if the questionnaire was completed and taken away with the researcher.

5.6.5 Analysis of Quantitative Data

It is acknowledged that during this study the small number of participants to be recruited means that the study will be under-powered to detect statistically significant differences in quantitative outcomes between groups. For example, previous research has demonstrated that around 20% of all one-month readmissions in the elderly may be caused by preventable DRPs (104,105). Local one-month readmission rates for patients aged $\geq$65 years are in keeping with national figures at around 10%. If 20% of these (i.e. all the preventable drug related readmissions) could be prevented by a dMUR, this rate would be reduced to 8%. To detect this 2% absolute reduction with 80% certainty (power) at a significance level of p=0.05, a sample size of 3,231 participants in each group would be needed. This was calculated using the formula:

$n = P1(1-P1) + P2(1-P2) / (P1-P2)^2 \times f(\alpha,\beta)$

where n= number of participants per group

      P1 = proportion of control group readmitted

      P2 = proportion of intervention group readmitted

      α = significance level (2 tailed)

      1 - β = power of test

      f = value calculated from α and β (248)

$n = 0.1(1 - 0.1) + 0.08(1 - 0.08) / (0.1 - 0.08)^2 \times 7.9$

$n = (0.1636 / 0.0004) \times 7.9$

$n = 409 \times 7.9$

$n = 3231$

This is far beyond the capacity of this PhD project.

However for methodological rigour, and in preparation for any future RCT, the most appropriate test for each outcome (readmissions, A&E visits, adherence, HR-QoL) will be applied (Section 6.6.1). Any differences between groups that do appear significant could be used to identify outcomes worthy of further investigation.

Obviously results from the PEI will only be available for intervention group patients so there will be no way of applying a statistical test. Previous studies have reported the mean PEI with a 95% confidence interval.

Statistical tests will also be used to compare baseline characteristics for control and intervention groups, to check for homogeneity.

Independent samples t-tests

T-tests are used to compare the mean value of a continuous outcome between two groups. The t-test assumes normal distribution and similar variance between groups (249).

Mann-Whitney U-test

The Mann-Whitney U test compares the distribution of a given variable between groups. Mann-Whitney is a non-parametric alternative to the independent samples t-test, used when data are ordinal or requirement for normality is not met (249). There is no standard way for Mann-Whitney to handle tied ranks; therefore if a number of values in each group are identical, accuracy will be reduced.

Chi-squared test

Chi squared compares two or more proportions from independent groups. Chi-squared can also be used to test for an association between two nominal variables or between a nominal and an ordinal variable. It assumes 80% of expected frequencies are greater than 5 and all expected frequencies are greater than 1 (249).

If these assumptions are not met, Fisher's exact test can be used (249).

5.6.6 Analysis of Qualitative Data

Qualitative analysis aims to capture, portray and explain the social worlds of the people under study (250). It has, in the past, attracted criticism for a lack of transparency surrounding how findings are derived; with limited detail of data analysis procedures in many reports of qualitative research from which to interpret its context and meaning (251). In this respect, it is helpful to adhere to the 'analytical hierarchy', the process through which qualitative 'findings' are built from the original raw data (250).

The hierarchy is a form of conceptual scaffolding within which the structure of the analysis is formed (250). It involves three forms of activity: data management, in which the raw data are reviewed, labelled, sorted and synthesised; descriptive accounts, in which the analyst makes use of the ordered data to identify key dimensions, map the range and diversity of each phenomenon and develop classifications; and explanatory accounts, in which the analyst builds explanations about why the data take the forms that are found and presented (250).

Participant Interviews

For this study, the technique of framework analysis (FA) will be used to identify emergent themes and allocate codes to different issues raised relating to these themes during interviews. Unlike entirely inductive and iterative qualitative approaches such as grounded theory, FA may be shaped by existing ideas and is less focused on producing a new theory. It was developed for addressing specific questions and in that sense can be seen as an applied research approach that is useful for informing both policy and practice (251). These attributes make FA an attractive choice for the current study, where semi-structured interviews will be conducted using a pre-defined topic guide based on questions relating to NHS patients' experiences of post-discharge support with medication.

FA is a matrix based method which facilitates rigorous and transparent data management such that all the stages involved in the analytical hierarchy can be systematically conducted. It also allows the analyst to move back and forth between different levels of abstraction without losing sight of the 'raw' data (250,251). The 'thematic framework', which is the core of FA, is used to classify

and organise data according to key themes, concepts and emergent categories. The thematic framework for a particular study comprises a series of main themes, subdivided by a succession of related subtopics. Each main theme is then displayed or 'charted' in its own matrix, where every participant (or 'case') is allocated a row and each column denotes a separate subtopic. Data from each case is then synthesised within the appropriate part(s) of the thematic framework (250).

Most spreadsheet 'worksheets' can be easily adapted to accommodate a thematic chart. Extra worksheets can be created within a spreadsheet file to store additional thematic charts, so that one file can host synthesised data for an entire study (250). The use of charting in FA assists transparency and enables investigators with competing responsibilities, e.g. a part time PhD student, to stop the analysis and return later to continue where they left off. FA can also be useful for those new to qualitative research because it provides a clear track of how data moved from interview transcripts to themes, with summaries in charts enabling researchers to discuss ideas (251). These advantages all support FA as the approach of choice for the analysis of the qualitative data from this study.

Analysis of Community Pharmacy Interventions

Feedback from community pharmacists on the content of dMURs will be analysed to describe, and if possible assign a monetary value to, the potential significance of the interventions made. This was not an original objective of this research but was viewed as a valuable extension following observation of the level of detail provided in the dMUR action plans returned by community pharmacists.

Significance may be considered in terms of improving the efficacy of the patient's medication regimen or improving the standard of care in some other way, avoiding harm or preventing a hospital admission. This will go some way towards characterising the quality of the MURs carried out, a concern raised in previous research (252-256).

Any action taken or piece of advice given to the patient during the dMUR, as reported by the community pharmacists who undertook the dMURs, will be classified as an intervention for the purposes of this analysis.

In order to select the most appropriate tool for assessing the community pharmacists' interventions, the literature was reviewed for previously applied methodologies for evaluating the significance of pharmacists' interventions. Each was considered in terms of what the researcher considered to be the characteristics of the 'ideal' model for the proposed analysis:

- Sensitive to the type of interventions typical of a community pharmacy MUR. Although dMURs may have the potential to reduce hospital admissions, their primary focus is to increase patients' knowledge of and adherence to their medicines. Therefore an impact on admissions may not be apparent immediately or easily definable, whereas other benefits to patient care may be (for example reduction in medicines related anxiety or side effects, or improvement in medicines efficacy without impact on the risk of admission within the time scope of the study).
- Considers interventions in terms of both harm avoided and efficacy/benefit gained.
- Allows for grading of outcomes in terms of importance and probability of occurrence.
- Allows allocation of a monetary value to the interventions considered.
- Considers the timescale over which the outcome of the intervention will be apparent.
- Differentiates between interventions that were actioned and those that were not (ie recommendations not accepted by the prescriber), where this information is available.
- Simple and quick for assessors to apply during peer review.
- Includes examples of interventions in each category, to guide reviewers.

Possible methodologies are described below and summarised in terms of the above characteristics in Table 5.4, page 143.

RiO Score

This tool is adapted from The Hospital Avoidance Scale within the RiO healthcare management system (257). Each intervention is assigned to one of three categories, whereby each level 3 intervention and every 10 level 2 interventions

equates to one avoided admission. A cost avoidance figure is attributed to each potentially saved hospital admission (based on the average length of stay for an older person).

This method has been used previously to assess the value of a number of pharmacist services, including clinical medication reviews for care home residents or otherwise 'high risk' elderly patients, as well as for domiciliary MURs (258-260).

This method is, however unlikely to be sensitive to interventions which may improve patient care without impacting on hospital admissions. Therefore this tool is unlikely to be the most effective for analysing dMUR interventions and will not be used in this study.

Eadon Criteria / School of Health and Related (ScHARR) model

The Eadon criteria were first reported in 1992, when the quality of interventions made by ward pharmacists over a 12-month period were measured using a six point scoring system, shown in Table 5.1 (261).

Table 5.1: Eadon Scoring System for Pharmacist Interventions

Intervention type	Score
Intervention which is detrimental to the patients well-being	1
Intervention is of no significance to patient care	2
Intervention is significant but does not lead to an improvement in patient care	3
Intervention is significant and results in an improvement in the standard of care	4
Intervention is very significant and prevents a major organ failure or adverse reaction of similar importance	5
Intervention is potentially life-saving	6

More recently, the ScHARR model (developed by the School of Health and Related Research at the University of Sheffield) has been used to apply a monetary cost to the patient's outcome had the intervention not taken place, as illustrated in Table 5.2 (262).

Table 5.2: ScHARR Model for Assigning Economic Value to Pharmacist Interventions

Significance of Error	Eadon Score	ScHARR Cost Avoidance(£)
Potentially lethal	6	1085-2120
Potentially serious	5	713-1484
Potentially significant	4	65-150
Minor	1-3	0-6

The detailed economic modelling used by ScHARR considers the incidence of an outcome and the likely impact of the intervention, as well as the costs associated with the interventions, the treatment of preventable ADEs and the value of the health lost as a result of an ADE.

The Eadon score has the advantage of considering interventions which contribute proactively to patient care, rather than focussing on reactive interventions to prevent harm. This is demonstrated by the results in the original report of the Eadon score and a recent consultant pharmacist case management study, where 53% and 84% of interventions respectively were judged to have improved patient care (261,263). This compares to 31% in a previous study which considered only interventions which were made to prevent harm in response to prescribing errors (261).

The tool has previously been applied to interventions made by pharmacy staff working in a variety of settings (secondary, intermediate and primary care) (260,261,263). No previous reports of its application to community pharmacy interventions could be found, which would be a caution in interpreting the results of an analysis using this method. However, its strengths (sensitivity to 'lower impact' and 'proactive' interventions, ability to assign a monetary value to the interventions made, previous use in a variety of care settings) make this model seem an appropriate choice for use in this study.

NPSA Matrix

The NPSA matrix is a risk-scoring methodology from the National Patient Safety Agency, which asks assessors to think about the worst possible consequence of the identified issue(s) going unresolved and assign scores from 1 to 5 for the

likelihood and consequence of patient harm. These two scores are then used to assign an overall risk score using Table 5.3 (264).

Table 5.3: NPSA Risk Scoring Matrix

	→ Likelihood score				
↓ Consequence score	1 - Rare	2 - Unlikely	3 - Possible	4 - Likely	5 – Almost certain
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

The risk is then reassessed after the intervention is made to establish if the intervention helped. Finally, a saving of £2000 (based on the cost of an unplanned hospital admission) is assigned if the first risk score was red (15 or more) AND the second risk score (after the intervention) downgraded the risk to another colour (<15).

The NPSA risk matrix has the advantage of being a recognised tool used to assess risks of harm in a variety of contexts (265,266). However only those interventions judged to have prevented a hospital admission can be assigned a monetary value according to this system. In addition, it leads the scorer to consider an intervention only in terms of harm avoided, rather than benefit gained. No examples of its application to the community pharmacy sector could be found. In view of these disadvantages, this tool will not be used in this study.

Hawksworth's Method (Reported 1999) (267)

In this methodology, interventions are awarded a score between 0 (definitely not) to 10 (100% confident), to the nearest whole number, for each of the following criteria:

- Detrimental to the management of the patient
- Improved the efficacy of the patient's therapeutic management

- Prevented harm to the patient

- Prevented a hospital admission

This method has the benefit of allowing the same intervention to be graded on more than one dimension (for example, the same intervention may be awarded a score for both improved efficacy of treatment and prevention of harm, and then a further score for the likelihood of a hospital admission having been prevented). The range of scores available increase its flexibility, however this may also make application and interpretation more complicated. In addition, no monetary value can be assigned to interventions scored using this method. No recent work applying this tool could be located to inform its use in this study. Considering these drawbacks, this method will not be used in this study.

Buurma's Method (Reported 2004) (268)

In this method, the following algorithm is applied to each intervention:

```
                    ┌──────────────────┐
                    │ What is the      │
                    │ contribution of  │
                    │ this             │
                    │ intervention to  │
                    │ pharmacotherapy  │
                    │ of this patient? │
                    └──────────────────┘
        ┌───────────────┬──────────────┬───────────────┐
   ┌─────────┐     ┌─────────┐    ┌──────────┐
   │ None    │     │ Positive:│    │ Negative │
   │ (stop)  │     └─────────┘    │ (stop)   │
   └─────────┘                    └──────────┘
                  ┌──────────────┐
                  │ What is the  │
                  │ outcome of   │
                  │ the          │
                  │ intervention?│
                  └──────────────┘
```

| Improvement of effectiveness | Both improvement of effectiveness and prevention of ADR | Prevention of ADR | Other eg prevention of discomfort, cost saving etc (stop) |

| Probability: 1-5 Importance: 1-5 | Probability: 1-5 Seriousness: 1-5 |

Figure 5.2: Buurma's Algorithm for Analysing Community Pharmacist Prescription Interventions

This tool was developed for the analysis of community pharmacy prescription interventions, made in response to 'errors' detected; so although it has been previously used in the community sector, it is not certain how easily MUR activities would map onto the algorithm.

The structured process involved in this model may improve the validity of scores, but may be more cumbersome for reviewers to apply than some of the other methods described above. Additionally, no monetary value has been assigned to interventions using this tool. No recent work, or work conducted in England, that

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applied this methodology could be found. In view of these factors this tool will not be used in this study.

Westerlund's Method (Reported 2009) (269)

This method splits community pharmacist interventions into those which could prevent an adverse drug effect and those which could lead to improved therapeutic effect. Interventions are categorised as preventing or initiating a primary care contact, or preventing a hospital admission; with the costs of these outcomes then applied to the interventions to produce an economic assessment.

This method recognises that some pharmacist interventions may initially increase societal cost (e.g. by initiating a GP visit). However, these costs may be recouped in terms of improved health in the future, a factor which, although acknowledged in the report, was not factored into the economic assessment. Those interventions which did not initiate or prevent a primary care contact or hospital admission were not included in the economic analysis. This reinforces the benefit of resources such as ScHARR, which include a detailed modelling of the expected net benefit of interventions. No reports of the application of this method in England could be found. These disadvantages led to the discounting of this method for use in this study.

SMART methodology (Reported 2008) (210)

This methodology was employed to evaluate recommendations made by pharmacists conducting medication review clinics in primary care in Canada. Each recommendation was assessed in terms of expected strength of impact on patient's health, and expected time to this impact.

The researchers found that a moderate or marked impact on patient health within the 5-month follow-up period would have been expected for only 15.5% of all recommendations. The authors argue that this may help to explain why there was no significant difference in patient outcomes between control and intervention groups at the end of their study. Timescale of expected benefit is an important factor to remember in the analysis of pharmacist interventions, particularly those associated with adherence, as the clinical effect may not be apparent for some time. The fact that this model takes this into account is a strength. However the

fact that there is no way of assigning a monetary value to the interventions and the fact that this model has only been applied to clinical medication reviews in primary care in Canada, (so it's applicability to the community pharmacy setting in England is unknown) are disadvantages and this method will not be used in this study.

Ibanez-Garcia's Method (reported 2015) (270)

This method was employed to analyse prescribing errors intercepted by pharmacists working at a tertiary care hospital in Spain. Interventions involving errors in the most serious 4 subcategories (associated with one or more of hospitalisation, permanent harm or risk of death), were then assigned a value according to the probability of this outcome. These scores were then multiplied by the estimated cost of treating an adverse drug event (€6857), and the return on investment based on a pharmacist's salary was calculated.

Considering both the likelihood and severity of the outcome in question is a strength of this model, however a weakness is that, in common with some of the other methods discussed, it considers interventions only in terms of harm avoided, rather than benefit gained. It has additionally never been used in a community pharmacy setting. Furthermore, it only assigns a monetary value to the most severe cases, and therefore would be unlikely to be useful in the economic assessment of MUR interventions. These pitfalls lead to it being ruled out as the method of choice for this study.

Table 5.4: Summary of Advantages and Drawbacks of Scoring Tools for Pharmacist Interventions

	RiO Score	Eadon-ScHARR	NPSA matrix	Hawksworth method	Buurma method	Westerlund method	SMART method	Ibanez-Garcia method
Sensitive to MUR type interventions	No	Yes	No	Not when considering monetary value	Yes	Unclear	Yes	Yes
Considers both harms avoided and benefits gained	No	Yes	No	Yes	Yes	Yes	Yes	No
Grades outcomes in terms of probability and importance of outcome	No	Yes	Yes	Yes	Yes	No	Yes	Yes
Assigns monetary value to interventions	Yes for admission avoided	Yes	Yes for admission avoided	No	No	Yes (primary care contacts and hospital admission)	No	Yes for admission avoided
Considers if intervention was actioned	No	Yes	No	No	No	No	Yes	No
Simple/ quick for assessors to apply	Yes	Yes	Yes	Uncertain	No	Uncertain	Uncertain	No
Includes examples of interventions	Yes	No	No	No	No	No	Yes	No

Conclusion: Choice of Scoring Tool

Considering the advantages and drawback of each tool as above, the Eadon-ScHARR model was selected as the most suitable for application in this study.

Application of Scoring Methodology

Various ways of applying the scoring tools exist, including self-application by the pharmacists performing the interventions, and peer review by other pharmacists or different classes of healthcare professionals (210,258-261,263,265-270). Peer review using a consensus methodology will provide more objectivity and allow each intervention to be graded by more than one assessor. In addition, the added burden of scoring their own interventions may discourage community pharmacists

from taking part in the study. For these reasons, a qualitative consensus methodology using the Eadon scoring system will be employed for this research.

Two consensus methods commonly adopted in medical, nursing, and health services research are the Delphi process and the nominal group technique, also known as the expert panel (271).   The Delphi technique involves expert contributors individually responding to survey questions and submitting the results to a central coordinator. The coordinator processes the contributions, looking for central and extreme tendencies, and their rationales. The results are then fed back to the respondents. The respondents are then asked to resubmit their views, assisted by the input provided by the coordinator. This process continues until the coordinator sees that a consensus has formed. In the Delphi technique, the experts do not know who the others experts are during the process (272). The nominal group technique uses a highly structured meeting to gather information from relevant experts about a given issue. It consists of two rounds in which panellists rate, discuss, and then rerate a series of items or questions (271).

The Delphi process has the advantage of not being limited by physical distance between participants, where time and cost make group meetings unfeasible. It can bring together the views of experts who do not traditionally communicate and who represent diverse backgrounds with respect to experience or expertise. The separation of participants reduces interaction bias, for example domination by quantity or strength of personality of participants with a particular opinion (273). However, this has the drawback that participants are not able to discuss issues, as would be possible with the nominal group technique. This may lead to misinterpretation, and 'discouraged dissenters' dropping out, forcing an artificial consensus (274). Although this drawback will be kept in mind, it was decided that organising a physical meeting between members of the peer review panel would be too logistically difficult, and therefore the Delphi process was selected for use in this research.

In previous peer reviews of scoring tools for pharmacist interventions (not necessarily via a Delphi process), many studies showed that reliability of scores was not affected by the profession of the rater (275). However others found differences in scores assigned between pharmacists and physicians. Wright et al.

demonstrated that community pharmacists, hospital pharmacists, GPs and specialist physicians attribute significantly different values when undertaking these assessments (276). Selecting reviewers familiar with the types of events being reviewed should improve consistency of scores (275). For this reason reviewers invited to participate in the Delphi process for this study will be from different sectors and professional backgrounds (hospital, community and general practice pharmacists, hospital physicians and GPs) but familiar with the types of medication related issued faced by older patients on transfer of care and their consequences.

Delphi studies usually use panels of at least 15 members (272). However this may not be feasible for this small study. From a pragmatic point of view a panel of eight members seems reasonable (four pharmacists and four doctors, with representation from both primary and secondary care to reflect the range of professionals who may award different values to the same intervention). The use of a smaller panel than might be expected must be acknowledged in the interpretation of results.

5.7 ETHICAL CONSIDERATIONS

5.7.1 Risks, Burdens and Benefits to Participants

Participants will be expected to visit their community pharmacy, which may be difficult for frailer/elderly patients. Any patient who envisages significant difficulty accessing their community pharmacy, and whose pharmacy does not offer domiciliary or telephone MURs, will be excluded from the study, as the distress involved in trying to attend may outweigh the benefits arising from the dMUR. However, these frailer patients may be those that would benefit the most from support with their medication. For this reason, a record of the number of patients who would otherwise be eligible for the study, but are excluded because of a high probability of difficulty in leaving home during the first few weeks post discharge, will be kept. Participants who are recruited but then unable to attend for an MUR will be asked about this experience at follow-up. This group of patients may then form a target for the basis of future research.

Participants may not wish to be interviewed in depth, or may be concerned about their identity being known. They will be reassured of the confidential nature of data handling during the study and reminded that they are free to withdraw at any time without giving reason. Training (formal and informal) will be accessed to ensure the researcher has the necessary skills for conducting semi structured interviews. It is hoped this will make the interviewing process as positive as possible for the participants.

Any medication related problem that becomes apparent during the normal clinical care of the patient during admission will be dealt with in the usual way. No aspect of routine clinical care will be withheld from study participants.

MURs are available to all patients who fit the criteria laid down by the PSNC service specifications (168). Whilst the control group will not be actively referred for a MUR during the study, they will not be denied an MUR should they self-refer to their community pharmacy. This will mimic 'usual care'.

When considering the burdens and benefits to participants in this study, it must be noted that there is little evidence that the MUR service is cost effective and that no research currently exists that shows a measurable benefit of MURs on clinical outcomes (277). Results from this research should add to the knowledge pool to help ensure only evidence based services are funded by the NHS.

5.7.2 Older People as a Vulnerable Group

Although older people may be viewed as a vulnerable group, this vulnerability may make them particularly likely to benefit from medication adherence support. However, an individual who is unable to understand what participation in this study means and therefore unable to give informed consent is unlikely to be able to engage in the MUR process.

Potential participants will be given written and verbal information about the study and given time to discuss participation with the chief researcher, relatives, carers etc as needed. No effort will be made to coerce individuals to take part and any concern over the capacity of the patient to consent will be discussed with the patient's medical or nursing team.

5.7.3 Confidentiality

In order to initially screen patients for eligibility, access to a patient's hospital prescription chart will be required, and patients themselves will be required to answer questions about how they currently manage their medication. Screening will be done by the patient's own ward pharmacist or technician as part of their normal clinical service.

Each participant will be allocated a 3-digit participant identification number (PIN) according to their order of entry into the study. Only this number will be used in any table or report generated as part of the study. A list of study PINs and corresponding hospital identification (ID) numbers will be kept in order to identify participants during follow-up. This and all data containing person identifiable information will be held on an electronic NHS 'sharepoint' to which only the investigator and those approved by the investigator will have access.

Once a participant has been consented, baseline demographic data will be collected from their medical notes. This will be entered into a database on the sharepoint, which will identify the participant only by their PIN. Only NHS encrypted portable devices will be used if necessary to transfer data.

In order to send referrals for dMURs to community pharmacists, secure faxes (i.e. in areas inaccessible to persons outside the clinical care team) will be used. Telephone calls will be made to these pharmacies by hospital pharmacy support staff to alert them a fax is being sent and acknowledgement of receipt by return fax or telephone call will be requested.

The community pharmacist will send a copy of each dMUR action plan / outcome back to the hospital pharmacy using NHS or encrypted email or the secure fax procedure outlined above.

Copies of referrals and faxed MUR action plans will be scanned onto the sharepoint and the originals destroyed.

Interview transcripts will be anonymised and transferred into electronic format as soon as possible after the interview has taken place.

If it is necessary to recall patient notes as part of the follow-up process these will be kept locked away in the pharmacy department and used only for the purpose of the study and only by the investigator and the consultant geriatrician involved in their analysis.

Communication with GP surgeries will be done via a secure fax or NHS.net email with the patient's consent. A copy of the original consent form will also be faxed to the GP surgery as proof that the patient has agreed to take part. A covering letter and GP information sheet will also be sent (Appendix 5).

Once the study is complete, any remaining paperwork and electronic files containing patient identifiable information will be destroyed, apart from an electronic list of patient hospital ID numbers and corresponding PIN to allow contact to be maintained, for example to allow feedback of results to participants.

Feedback regarding issues identified during a dMUR or other part of the study will not be given to any person other than the researcher and the patients GP, unless there is a serious risk of harm to the participant or others. In such cases, it may be necessary to provide a participant's relative / carer or other relevant person with details of issues identified during the course of the study. If this is required, the participant will be informed of the line of action being taken. This would be according to normal ethical practice within the NHS.

5.7.4 Conflicts Of Interest

As the investigator works in SONT as a clinical pharmacist, it is likely they will be involved in the routine care of some of the potential participants. As there are no other members of the research team it will not be possible for anyone else to inform and consent potential participants. However care will be taken by the researcher not to exert any influence over a patient's decision to participate.

There may also be a conflict of interests in the motivation of community pharmacists to agree to accept referrals as part of the study. Community pharmacists are remunerated for providing MURs, so it is feasible that some may be motivated to take part for financial gain (or pressure from their managers in the case of pharmacists who work for chains of pharmacies) rather than the desire to

provide a clinical service (173). This may affect the quality of the MURs received by some participants, and therefore the outcomes experienced by these participants. However as long as there is a wide geographical spread throughout the catchment area in the community pharmacies who sign up for the study, it can be assumed that this effect, if present, will be neutralised overall.

If medication related issues become apparent during follow-up, the participant will be referred back to their community pharmacist or GP as appropriate, whether or not this will affect the results of the study. Such incidences will be anonymised and addressed during data analysis.

CHAPTER 6: MEDICINES SUPPORT REFERRAL SERVICE: MATERIALS AND METHODS

This chapter describes the methods used during the randomised controlled feasibility study of a referral service from hospital to a community pharmacy for a dMUR. An overview of the study is followed by a description of the engagement of hospital and community pharmacy staff. Then participant eligibility, recruitment and randomisation procedures are covered, before data collection and analysis methods used are described.

6.1 PATIENT AND PUBLIC INVOLVEMENT

In order to support PPI in this research, a successful application was made to the NIHR's PPI bursary scheme for £270, to cover refreshments and travel expenses for meetings, which were to be held at SONT.

Patient group and public representatives were recruited by placing flyers (Appendix 6) in outpatient departments and the outpatient pharmacy at SONT, via an advertisement in the Foundation Trust Members Newsletter (Appendix 7), and directly by the researcher from the Trust's cardiac rehab programme, warfarin clinic and care of the elderly ward.

Recruitment of the PPI group took place during February and March 2013. Following an initial contact by telephone, fourteen members were invited via post to the first group meeting. Of these, seven attended and came to form the core PPI group.

A total of 6 PPI group meetings took place between April 2013 and January 2014. Sessions were audio-recorded with the group members' permission so the researcher could concentrate on facilitating the session. Specific questions addressed and detailed notes from the sessions can be found in Appendix 2.

6.2: STUDY OVERVIEW

During standard care at SONT, patients are discharged with at least seven days' supply of medicines and a summary of care record sent to the patient's GP. The patient also receives a printed copy of the discharge summary. In this study, patients who intend to self-medicate once back at home are screened for suitability for a dMUR. Suitable patients are offered a dMUR with their nominated community pharmacist. On discharge, a referral form (Appendix 8, (214)) is completed and faxed or emailed to the community pharmacy along with copy of their discharge medication and participant consent form (Appendix 9). The patient then has a dMUR at their chosen community pharmacy within 4 weeks of discharge.

The new service and how it compares with standard hospital discharge care, along with an indication of the research elements of this study up to the point of dMUR, is shown diagrammatically in Figure 6.1.   Participant follow-up for both groups is illustrated in Figure 6.2.

Green = Standard Care   **Yellow** = New service   **Purple** = Research procedure

Patient aged 65 or older admitted to Southport & Ormskirk NHS Trust under medical directorate

Pharmacy medicines reconciliation

Patient intends to self-medicate at home *and* able to nominate community pharmacy?

Unable to ascertain

No

Yes

Potentially eligible for dMUR

Not eligible for dMUR

Attempt to clarify on next pharmacist ward round

Provide brief verbal overview of study/dMUR service. Patient interested?

No

Yes

Leave Participant information part 1 with patient and notify researcher

Exclude and discharge with standard information

No

Check remaining eligibility criteria. Is patient eligible? (NB if patient housebound community pharmacy and patient must both agree to domiciliary or telephone dMUR)

Yes

No

Researcher informs patient fully about study. Patient consent to take part?

Yes

Enter into randomisation

Randomised to intervention

Randomised to control

Tell patient to expect telephone call from community pharmacy following discharge to arrange dMUR

Inform GP of patient's participation

Discharge with standard information

Fill in MUR referral form. Fax referral, discharge medication list and consent form to community pharmacist within 24 hours of discharge. Telephone community pharmacist to check referral received

Follow-up at four weeks and six months post discharge (see other flowchart)

Community pharmacist contacts patient to arrange MUR

Patient receives MUR within 4 weeks of discharge

Figure 6.1: Flowchart Showing Participant Recruitment and Randomisation

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                                  ┌──────────────────┐
                                  │  Randomisation   │
                                  └──────────────────┘
                    ┌──────────────────────────┴──────────────────────────┐
                    ▼                                                        ▼
            ┌──────────────┐                                        ┌──────────────┐
            │ Standard care│                                        │ Intervention │
            └──────────────┘                                        └──────────────┘
                    │                                                        ▼
                    ▼                                                ┌──────────────┐
            ┌──────────────┐                                        │ Receive dMUR │
            │4-week follow-up│                                      └──────────────┘
            └──────────────┘                                                ▼
                    │                              ┌──────────────────────────────────────────┐
                    ▼                              │ dMUR feedback received from pharmacy.      │
    ┌─────────────────────────────────┐           │ (Contact pharmacy if no feedback received  │
    │ o  Check for readmission via     │           │ by 4-week follow-up)                       │
    │    Patient Administration System.│          └──────────────────────────────────────────┘
    │ o  Case note analysis to identify│                           ▼
    │    medicines related readmissions│                   ┌──────────────┐
    └─────────────────────────────────┘                   │4-week follow-up│
```

- Check for readmission via Patient Administration System.
- Case note analysis to identify medicines related readmissions

Standard care branch

Postal follow-up:
Adherence questionnaire
SF-12 v2
Diary

Home visit (purposive sample):
In-depth interview
Diary
Adherence questionnaire
SF-12 v2

Postal prompts after 2 weeks if questionnaire not returned

6-month follow-up – procedure as for 4-week follow-up minus in-depth interview

Intervention branch

- Check for readmission via Patient Administration System.
- Case note analysis to identify medicines related readmissions

Postal followup:
Adherence questionnaire
SF-12 v2
Enablement index
Diary

Home visit (purposive sample):
In-depth interview
Adherence questionnaire
SF-12 v2
Enablement index

Postal prompts after 2 weeks if questionnaire not returned

6-month follow-up – procedure as for 4-week follow-up minus in-depth interview

Figure 6.2: Chart Showing Flow of Participants through Remainder of Study

A briefing session for medical consultants was held to inform them of the study and ensure they were happy for their patients to be approached regarding participation. Nursing staff looking after patients identified as potentially eligible for recruitment were consulted on an individual basis by the researcher to inform them their patient was being approached.

6.3: HOSPITAL PHARMACY STAFF TRAINING

A training session was conducted for hospital pharmacy staff (ward based pharmacists and technicians) on the study procedures, including:

- Identification of potentially eligible patients (see Figure 6.1)

- Making the 'first approach' to potential participants to introduce the study and leave part 1 of the participant information leaflet with any patients that show an interest

- Notification of potentially eligible patients to the researcher (verbally, by written communication or by email)

- Annotations required on medication charts by ward pharmacists when medicines change (to allow accurate completion of the MUR referral form by the researcher)

6.4: COMMUNITY PHARMACIST RECRUITMENT

A covering letter and information sheet about the study were distributed via email to all community pharmacists (n=77) by the Local Pharmaceutical Committee in the two NHS England Areas served by the hospital (Appendix 10). Those wishing to take part were asked to complete and return a consent form (Appendix 11) to the researcher by post, fax or email. The consent form also requested that the community pharmacist provide their contact details, including a safe-haven fax number through which to receive referrals, and indicate whether they felt able to provide domiciliary or telephone MURs.   Forms were circulated twice, after which pharmacies who had not returned sign-up forms were contacted by telephone to check they had received them and to answer any questions. Those who requested it were sent the details of the study again.

6.5: PARTICIPANT RECRUITMENT

6.5.1: Inclusion Criteria

- Patient under care of medical directorate

- Patient aged 65 years or older

- Patient *either* prescribed five or more regular long term medications *or* has had one or more changes to medications during hospital stay.

- Intention by the patient to be independently self-medicating once back at home

- Patient *either* using the same community pharmacy regularly for at least three months prior to admission (as per national eligibility criteria for MURs) *or* able to nominate a community pharmacy they will use regularly on discharge

- Patient's community pharmacy signed up to receive referrals from the hospital

6.5.2: Exclusion Criteria

- Patient will have a relative or carer managing their medication once they are back at home

- Patient unable to name a regular community pharmacy

- Patient unable to visit the community pharmacy for a dMUR (unless the community pharmacy offers telephone/domiciliary MURs)

- Patient's community pharmacy is not signed up to receive referrals as part of study

- Patient lacks capacity to give consent to participate in study

- Patient has already been enrolled in the study during a previous admission

6.5.3: Consent and Randomisation

The first approach to a potential participant was to be made by a ward pharmacist or technician. The procedure used to gain informed consent was:

1) Ward pharmacists identified potentially eligible patients and gave a brief verbal overview of the study.
2) If the patient agreed, an 'Initial contact slip' (Appendix 12) and 'participant information part 1' (Appendix 13) were left with the patient.
3) The researcher was notified.
4) A sticker (Appendix 14) was inserted in the patient's case notes to inform the ward team that the patient had been identified as potentially eligible for the study.
5) The researcher visited the patient to check eligibility.
6) If the patient was eligible, the researcher discussed the study in more detail, including 'participant information part 2' (Appendix 15) and consent form (Appendix 9), answering any questions as necessary.
7) If required, a period of 24 hours was allowed for the patient to decide whether or not to participate.
8) The researcher re-visited the patient to confirm if the patient was willing to participate and, if so, obtain informed consent.
9) Sticker (Appendix 16) and copy of consent form was inserted in patient's case notes to inform the ward team that the patient had been recruited to the study. Copies of the consent form were also left with the patient and faxed to their GP on discharge. The original consent form was kept in the study file.

Following consent, participants were randomised to either receive a dMUR with their nominated community pharmacy or standard hospital discharge care as outlined above. Intervention group participants were informed prior to discharge to expect their community pharmacist to contact them to arrange a dMUR. Control group patients were not approached again.

Data regarding baseline characteristics of participants were collected in terms of general demographics and factors that could affect their risk of DRP or

readmission. A copy of the data capture form is included in Appendix 17. These characteristics were compared between groups using Chi-squared (for categorical data) or the independent samples T-test (for continuous data).

<u>Randomisation Technique</u>

Before recruitment commenced, a randomisation tool (http://www.webcalculator.co.uk/statistics/rpermute3.htm) was used by research technicians at the University of Wolverhampton (independent of the study) to generate a random permutation of 100 digits, assigning them to one of two groups (control and intervention). Sealed envelopes containing the assignments were created and numbered according to the random sequence. These were delivered to SONT, where they were stored in the research department and opened by SONT research staff in sequence as participants were consented.

For those participants recruited in to the intervention arm, a dMUR would then take place within 4 weeks of hospital discharge (as per national criteria) (168). Matters identified by the community pharmacist and actions taken were, together with the participant's consent, returned to the investigator for use in data analysis.

A period of 3-6 months was initially allowed in order to recruit the required number of participants. This was later extended to 9 months due to slow recruitment.

6.6: DATA COLLECTION POINTS

Participants were followed up at four weeks and six months. The data collected at each point is described below.

6.6.1: Identification of Readmission

At each follow-up point, the participant's hospital ID number was entered into the hospital's electronic PAS. This allowed identification of any hospital attendances since discharge, and also allowed for the possibility that a participant was actually an inpatient at the time of follow-up.   If a re-admission had occurred, the patient's notes were reviewed to evaluate contributing medication problems (Section 6.6.2).

6.6.2: Participant Diaries

On enrolment into the study, participants were initially given a diary to keep of readmissions and GP visits, to be returned with their four-week follow-up questionnaire (Appendix 18). A second diary was to be posted to each participant with the four-week follow-up questionnaire, which was to be returned with their six month follow-up questionnaire.

6.6.3: Postal Questionnaire

All participants were posted a questionnaire at each follow-up point, unless they had been selected to receive a face-to-face interview, in which case the researcher took this with them at the time of the interview. Different versions of the questionnaire were created for control and intervention participants at 4-week follow-up as only intervention participants were being asked questions related to dMURs (including the PEI). A further version for all participants was created for 6-month follow-up with slightly different wording to reflect the time frame being covered by the questionnaire (since the last contact by the researcher rather than since discharge). No participants were asked to complete the PEI at 6-month follow-up. Copies of all three questionnaires are included in Appendices 19-21.

A personalised covering letter was created and sent with all questionnaires (Appendices 22 and 23). The covering letter briefly reminded participants about the study and encouraged them to complete and return the questionnaires. A stamped addressed envelope was included in which to return the questionnaires.

If a participant did not return their questionnaire after two weeks, a reminder note (Appendices 24 and 25) was sent with a further questionnaire. If a response was not received after another four weeks, the participant was not contacted again. Patients who did not return questionnaires at 4-week follow-up were still contacted at the 6 months follow-up point using the same procedure.

6.6.4: Semi-structured Interviews

A sample of participants from both control and intervention groups were visited at home and interviewed in depth at the four-week follow-up point, regarding their experiences of medication support during and following their hospital stay (see appendices 26 and 27 for copies of interview schedules). Interviewees were selected purposively in an attempt to represent the maximum variation of participant characteristics.

Interviews were audio recorded to ensure accurate data capture. The interviews aimed to explore:

- The participant's perception of the medicines information they were given during their original admission.

- For participants who received a dMUR, the information provided by the community pharmacists and what the outcome of the dMUR was from the patient's perspective.

- Any form of medication review the patient had that was not part of the study, the reasons for and outcomes of this.

- If an intervention group participant had not had their dMUR, the reasons for this.

- If a participant had had a hospital or GP visit since discharge, whether this was linked to problems with medication adherence.

6.6.5: Hospital Pharmacist Focus Group

Due to slow participant recruitment during the early weeks of the study all ward based pharmacists and technicians working at SONT were invited to take part in a focus group, aiming to identify possible reasons for the slow recruitment rate and discuss solutions. The researcher acted as the facilitator for the focus group, which was audio-recorded with the participants' permission. An information leaflet (Appendix 28) and consent form (Appendix 29) were circulated before the session, which took place in the pharmacy department at SONT.

A complete topic guide for the focus group is included in Appendix 30. Due to the low referral rate of potential participants for the study, it was desirable to start the session on more general ground to stimulate discussion and ensure the focus group participants did not feel threatened or as if the session had been designed to interrogate them about why they had not been referring more patients into the study.

6.6.6: Hospital Pharmacist Questionnaire

In order to see if the issues identified during the focus group affected the pharmacy department more widely, and the extent to which the solutions posed were felt to be useful, the qualitative data from the focus group was used to develop a quantitative questionnaire to be circulated to all pharmacists at SONT.

The final questionnaire consisted of a mix of open, closed and Likert (5-point agreement scale) questions. It was piloted on one pre-registration pharmacist, one band 6, one band 7 and two band 8a pharmacists working for the Trust, who were aware of the project but had not been actively involved in the recruitment phase of the study. These members of staff were asked to record how long the questionnaire took to complete, and to assess all questions for comprehension. All staff reported the questionnaire took 10-15 minutes to complete. Following their feedback, minor amendments were made to two questions.

After piloting, the questionnaire was circulated (via email and on paper) to all 22 pharmacists who had been working at SONT during the feasibility study. Email reminders were sent 2 and 4 weeks later. A copy of the questionnaire is included in Appendix 31.

6.6.7: Community Pharmacist Feedback

dMUR 'Action Plans'

A copy of the actions taken and/or advice given during each dMUR conducted as part of the study was to be returned to the researcher by the participant's community pharmacist by fax, post or email. If dMUR feedback had not been

received by four-week follow-up, the community pharmacist was contacted by telephone to ascertain if the dMUR had taken place. If it had not taken place, reasons for this were explored and the participant re-referred for a dMUR if necessary. If the dMUR had taken place a copy of the MUR feedback was re-requested.

<u>Community Pharmacist Questionnaire</u>

Following referral of the last participant for dMUR, community pharmacists who had participants referred to them during the study were sent a self-completed questionnaire. The questions specifically addressed the quality of referrals sent by the hospital and the community pharmacists' opinion of the service. A copy of this questionnaire is included in Appendix 32.

Prior to survey distribution, all pharmacies who had a dMUR referral from the hospital were contacted by phone to confirm that the pharmacist who had received the referral was still working from those premises. If the original pharmacist was no longer working at that pharmacy, a forwarding telephone number was requested and an attempt made to contact the pharmacist at their new working premises. Following verbal consent, surveys were sent by fax or email. Surveys could be returned by fax, email or post. Follow-up phone calls to non-responders were made at 2 and 4 weeks to prompt return of the survey.

6.7: METHODS OF DATA ANALYSIS

6.7.1: Statistical Analysis of Quantitative Data

This study aims to find out as much as possible about which outcomes may be worth investigating further with regards to the effectiveness of dMUR referrals. Therefore, it would be desirable to ensure any effects of the intervention are not missed because of the relatively large proportion of participants in the intervention group (nearly one-third) who did not go on to receive their dMUR. For this reason, results were analysed according to both an intention to treat (ITT) and a per-

protocol (PP) approach (described below); however the PP analysis will be interpreted with due caution due to the potential for bias.

All statistical tests performed on the data collected during the study were conducted using the electronic Graphpad software (available via https://www.graphpad.com/)

Intention to treat

In this approach, all participants are included in the analysis according to their randomised group, irrespective of whether they received the intervention (ie had a dMUR) or not (189). This was the primary analysis approach as it avoids the problem of bias that may be introduced if participants who do not adhere or drop out of the study are different in some way to those who adhere to the study protocol. However, ITT analyses may underestimate the full effect of the treatment, as participants who did not receive a dMUR will be included in the analysis of the effects of dMURs.

Per protocol

In this approach, only participants who adhere to the study protocol are included in the analysis (189). In this study, a PP analysis would exclude intervention group patients who did not have a dMUR within 4 weeks of discharge. Per protocol analysis also excludes participants who did not return a completed follow-up questionnaire and therefore did not provide a full set of data on the outcome measures.

Recruitment Rate

The total number of participants recruited was analysed in relation to:

- The total number of medical patients discharged from SONT during the recruitment period
- The number of potentially eligible patients identified by ward pharmacists but not recruited, along with the reasons for failure to recruit
- The variation in recruitment rate during different periods in the recruitment phase was also analysed in relation to factors which could affect this

Baseline Characteristics

Demographic characteristics of both the control and intervention groups were compared using Chi-squared (for dichotomous data) and the independent samples t-test (for continuous data) to check for homogeneity between groups. This included calculation of the Medication Regimen Complexity Index (MCI) of each participant, to rule out existing differences in the complexity of their medication regimen as a cause of any differences in outcomes (particularly adherence) between groups (278).

Dropout Rate and Loss to Follow-Up

Overall loss to follow-up was calculated using the percentage of the total number of original participants for whom follow-up data was available.

Delivery of dMURs

The delivery of dMURs as per study protocol (within 4 weeks of discharge) and overall were calculated as a percentage of all patients referred. Reasons for non-delivery were collated in order to make recommendations for increasing uptake, if appropriate.

Readmission

The proportion of participants in each group having one or more readmission during the follow-up period (dichotomous data) was compared using Chi-squared at both 4-week and 6-month follow-up. When the conditions for Chi-squared were not met, Fisher's exact test was used instead.

The relative risk of readmission in the intervention group at each time-point was also calculated, along with 95% confidence intervals (CI).

In addition, the total number of readmissions in each group (ordered discrete data) was compared at 4-week and 6-month follow-up using the Mann-Whitney U-test.

The mean length of readmission episodes in each group was also compared using the Mann-Whitney U Test.

A&E Attendances

The proportion of participants in each group having one or more A&E visit (but being discharged from here rather than admitted to a hospital ward) was compared using Chi-squared at both follow-up points. The relative risk of an A&E visit in the intervention group at each time-point was also calculated, along with 95% CI.

In addition, the total number of A&E visits in each group was compared at 4-week and 6-month follow-up using the Mann-Whitney U-test.

HR-QoL and Adherence Scores

SF12-v2 and MMAS scores were treated as continuous numerical data and compared between groups using an unpaired t-test at both follow-up points.

Enablement

Previous studies have reported the mean PEI with a 95% CI. Therefore the same practice was employed here for intervention group participants who received a dMUR and returned a scorable questionnaire.

6.7.2: Qualitative Data Analysis

Readmission Data

The hospital notes of each readmitted participant were examined by a consultant geriatrician and specialist care of the elderly pharmacist (the researcher). Any ADEs identified on readmission were assessed for causality and contribution to admission and consideration was given to whether these could have been prevented by the dMUR. Previous work on identifying medication related hospital admissions was used as a guide during these sessions (see Appendix 33) (61,62,215). The consultant was blinded to the study group of the participants.

dMUR 'Action Plans' / Feedback

Each piece of advice given to a participant or recommendation made to their GP as a result of the dMUR was classed as an intervention for the purposes of this study. Interventions were grouped by type to identify any recurrent issues. Contents of

individual action plans were also used to inform discussion during semi-structured interviews with participants at 4 week follow-up.

To assess the potential clinical impact of interventions made, an expert panel was convened and Delphi methodology used to arrive at consensus. The term "expert" in this context has been described as "clinicians practicing in the field under consideration" (271). Therefore the expert panel for this study comprised 5 pharmacists, 2 medical practitioners based in academia and 2 family doctors.

Consensus was defined as 75% agreement between reviewers' scores as advocated by Diamond et al (279). In addition, consensus can also be achieved when stability of the distribution of scores occurs (272,273). If variation between rounds is less than 15%, a state of stability is said to exist (273,279). It was decided to use 75% agreement as the primary target, but also to consider the variance in scores if the 75% threshold was not reached.

All recorded interventions were collated and reviewers were instructed to award each intervention a value according to the Eadon scoring criteria (Table 5.1, page 137). Space for free text comments was provided after each statement, allowing reviewers to provide a rationale for their positions. The resulting questionnaire was piloted by a hospital pharmacist who had not been involved with the study to ensure clarity and that enough detail was provided to allow reviewers to answer. The pilot identified that clear instructions needed to be available to reviewers on when the different scores should be applied (particularly the score of 3).

The questionnaire was then sent to Delphi panel members via email to score independently. A copy of the 'Round One' questionnaire, including instructions to reviewers, is reproduced in Appendix 34.

Reviewers were asked to return their scores within two weeks. Reminder emails were sent at 2 and 4 weeks if no reply had been received. If no response was obtained by week 6, that participant was viewed as having left the process.

Following the return of 'Round One' Delphi questionnaires, all scores and free-text comments were collated. Each reviewer then received a personalised 'Round Two' survey, with box plots showing their score along with median and upper and lower

quartiles for group scores. These personalised surveys were then circulated to reviewers, returned and analysed using the same process as for 'Round One'.

Once consensus was achieved, the ScHARR model, used to apply an 'opportunity cost' saving to medication errors and adverse drug events avoided, was mapped onto the Eadon score to determine the economic impact of pharmacist interventions (262,263). These values were totalled to give an overall cost avoidance (expressed as a minimum-maximum range in line with the ScHARR reference figures) for the interventions reviewed. These figures were then divided by the number of interventions reviewed to estimate a mean cost avoidance per intervention. Finally, this was multiplied by the mean number of interventions made per dMUR to estimate a cost avoidance per dMUR carried out during the study (again expressed as a range).

<u>Semi-structured interview data</u>

Interviews with participants were audio-recorded with the participants' verbal consent and transcribed verbatim. Transcripts were then analysed using FA. During the process of FA, transcripts were reviewed and recurring or important themes identified. These were of both a substantive nature, such as attitudes, behaviours, motivations or views, or more methodological, such as the general atmosphere of an interview or the ease or difficulty of exploring particular subjects. A conceptual framework was then devised by grouping themes and subthemes hierarchically. A copy of this conceptual framework can be found in Appendix 35.

The framework was then applied to the raw data, so that each interview transcript was indexed in according to which parts of the conceptual framework applied. The data were then sorted using Microsoft Excel to construct a set of thematic charts. Brief notes summarising the key points were then made in each chart's cell where a particular subtheme had appeared in a particular participant's interview, along with a quote from the transcript to illustrate this. Where one passage was relevant to more than one theme or sub-theme, this was cross referenced in each cell to which the passage applied. Interpretative comments were added to the charts where applicable.

Each theme was then examined across all interviews and the range of perceptions, views, experiences or behaviours demonstrated by the participants studied. Key dimensions within each phenomenon were noted in order to compare and contrast different manifestations of the data. Links or connections between two or more phenomena were also looked for.

Explanations of phenomena within the data were then considered, based on explicit reasons given by participants themselves, or implicit reasons inferred by the researcher. Both the behaviour and intentions of the participants and contextual factors were considered in this analysis of the data. When developing implicit accounts of phenomena, the researcher searched for underlying 'logic' in what participants had (or had not) said during the interviews, drew on patterns identified within the data and looked for the interweaving of apparently unconnected themes which nevertheless occurred in close proximity within the interviews. Findings were also compared with existing knowledge or theory when developing these implicit accounts.

Hospital Pharmacist Feedback

Following the hospital pharmacist focus group, the recording of the session was transcribed and emailed to all participants for comment. A printout was then made and read through in its entirety, with notes being made of themes that were either recurrent or important enough to stimulate discussion within the group. A coding index was created identifying different issues occurring within these themes, which allowed the data to be labelled according to the code applicable to particular sections of the transcript.

Quantitative data from the hospital pharmacist questionnaire survey was analysed descriptively using Excel and responses to open-ended questions themed.

Community Pharmacist Questionnaire

Data from the community pharmacist questionnaire survey were analysed as for the hospital pharmacist questionnaire.

6.8: ETHICAL APPROVAL

Ethics approval for this study was obtained from the Northwest Research Ethics Committee (Ref 13/NW/0779).

6.9: LOGISTICAL PROBLEMS WITH OPERATIONALISING STUDY DESIGN

6.9.1: Initial Approach to Potential Participants

As described in Section 6.5.3, this was to be made by ward pharmacy teams, who were to give initial study information to the patient and notify the medical team via the patients' case notes. However it appeared that this was only done in a minority of cases and most of the time the researcher ended up making the initial approach to the patient following identification by the ward pharmacist.

6.9.2: Involvement of Pharmacy Technicians in Recruitment

Initially it was envisaged that pharmacy technicians would assist ward based pharmacists with identifying and making the initial approach to potential participants, and notifying the researcher when a potential participant was identified. However due to a shortage of ward based technicians and other demands on their time, this was not possible.

6.9.3: Participant Diary

Following confusion from early participants about how to complete the diary, and a number of diaries being returned incomplete or not at all, it was decided to discard the diary as a means of data collection (and therefore GP visits as an outcome) during this study.

CHAPTER 7: RESULTS

This chapter presents the data collected during this PhD research project. Firstly, results pertaining to the barriers and facilitators to transitional care of older patients utilising community pharmacy via the dMUR referral service will be considered. These include data relating to the engagement of both community and hospital pharmacists with the service and the impact on of this on participant recruitment. Participant recruitment data are then presented along with reasons encountered for exclusion and refusal. Next is a description of participant attrition during the course of the study and how this affected the calculation of participant outcome data. This is followed by presentation of quantitative participant outcome data according to both intention to treat and per protocol analyses. Following this are the results of the analysis of the case-notes of participants who were readmitted to hospital during the study's follow-up period. The results of the framework analysis of semi-structured participant interviews are then laid out. Data relating the dMURs themselves are then presented, in terms of completion rate, the type of interventions made by the community pharmacists conducting these reviews and the clinical significance of these interventions as assessed by peer review. The chapter closes with data relating to community pharmacists' perceptions of delivering the dMURs referred to them by the hospital.

7.1: MEDICINES SUPPORT REFERRAL SERVICE: BARRIERS AND FACILITATORS

7.1.1: Community Pharmacist Recruitment

Seventy-three out of the 77 pharmacies (95%) in SONT's catchment area agreed to participate in the study. Thirty-two (44%) stated they could provide telephone dMURs with a further ten (14%) who might be able to do this. Regarding domiciliary visits, ten (14%) could offer dMURs in this format, with a further 5 (7%) responding that they 'possibly' could. Where a potential participant required a telephone or domiciliary dMUR and their nominated pharmacy only expressed this as possible, the pharmacist was contacted and asked specifically whether they would provide the

service to that patient. If the response was negative, that patient was excluded from the study.

7.1.2: Impact of Community Pharmacy Accessibility on Participant Recruitment

Inability to access a dMUR from their regular community pharmacy was the second most common reason for excluding patients from the study (n=22, 10% of patients screened, 24.2% of exclusions, see Table 7.2). These patients, who all used pharmacies that did not provide domiciliary visits, felt they would be unable to attend the pharmacy for a dMUR. Additionally, they were unable to have a telephone dMUR, either because of cognitive or hearing difficulty, or because their community pharmacy did not offer telephone MURs. Three patients who could not attend their community pharmacy but would have been able to have a telephone MUR refused to take part because they did not like the idea of discussing their medication over the telephone. Two patients used community pharmacies within the study catchment area, but which were not signed up to receive referrals during the study. One patient was excluded because she did not use any one particular community pharmacy.

7.1.3: Hospital Pharmacist Focus Group

This focus group aimed to identify possible reasons for the slow participant recruitment rate during the early weeks of the study and discuss possible solutions. Five hospital pharmacists attended the entire focus group, with two more entering part way through. Each pharmacist was assigned a number according to the order in which they first spoke during the session. The pharmacists are therefore referred to as P1 to P7 throughout the transcript. Two participants were NHS Agenda for Change (AfC) Band 6 (basic grade, rotational, ward based pharmacists), four were Band 7 (specialist, ward based pharmacists), and one was Band 8a (specialist pharmacist, with ward/clinic based roles as well as managerial and service development roles).

Five major themes were identified. These were:

1. Problems with current procedure for transfer of medicines related care

2. Attitudes (largely positive) to the referral service and post discharge medicines use review (dMUR)s as a whole

3. Barriers to dMUR referral service

4. Solutions for dMUR referral service

5. Priority/target groups for referral for DMUR

A full reproduction of the coding index developed from the focus group transcript, including themes and subthemes can be found in Appendix 36.

<u>Problems with current procedure for transfer of medicines related care</u>

At the start of the focus group, participants were asked to give examples of problems they had experienced with transfer of medicines related care from the hospital back into the community. This was aimed at providing background to the study and context for the rest of the discussion. Two main issues were identified by participants: the quality of communication of medication changes on discharge and the timeliness of information transfer from secondary to primary care.

Poor communication of medication changes that occur in hospital can lead to uncertainty on the part of patients, carers and primary care health professionals over what these changes are. The process used in SONT around discharge and medicines was highlighted as an issue, specifically the communication of discontinued medicines:

P2: I get [queries from primary care] like: 'has this stopped?'
P1: Yeah [agreeing with P1]
P2: And it's not documented on the [electronic discharge summary]

This issue is discussed further in Section 8.3.1.

The timeliness of information transfer from secondary to primary care, and the subsequent integration of this information into primary care records were also raised as concerns. Examples were cited of cases where patients had been re-admitted on medication regimes that had been altered during a previous admission, which may or may not have contributed to the re-admission:

P3: …the GP hadn't had the information. And it was about two or three weeks. So they'd come back in on drugs that were stopped. Quite a few.

P5: You definitely get prescribing errors where the patient's come in with a GP letter, and maybe they've been really recently admitted…and the doctors clerk them off the information they've got there at the time, and it's not until the pharmacist checks the second source … or until the old notes appear, or whatever, that we realise that there have been changes

<u>Attitudes to the referral service and dMURs in general</u>

The role of dMURs in preventing prescribing errors following discharge was alluded to when P3, who had spent time working in community pharmacy, described an example of an opportunistic dMUR she had done, where a patient had erroneously been taking both an antiplatelet and anticoagulant, both of which are classed as high risk medicines for hospital admission (45):

P3: we automatically try and pick up MURs on anything new, particularly high risk medicines, and she was on apixaban and aspirin, and the GP hadn't had the information to stop the aspirin, so they were both there. So I did an MUR with her, and we got to the bottom of it, and contacted the GP and managed to get it stopped. And she was a good one….

Although not a planned dMUR, the positive attitude engendered by this examples such as this could act as a facilitator to the referral service.

Indeed, the concept of the dMUR referral service was met with broadly positive comments from the group:

P4: It's probably a very necessary thing really
P2 / P5: Mmm[agreeing]

The most widely expressed potential benefit of dMURs was the reinforcement of advice regarding changes to a medication regimen that had been provided for the first time in hospital. Pharmacist number 5 explained the reasoning behind this view:

P5: I think also, as well, at the point of discharge, and during hospital admission, for these patients, there's quite a lot going on, and maybe, you know, they're just coming to terms with the fact that they've suddenly got to take this many medicines and maybe at that point they're not going to take it in, and maybe they need to be followed up when things are slightly calmer, and they've got used to the idea
P2: Yeah
P6: Even the warfarin, sometimes, with the warfarin counselling on the ward, its probably better a couple of days later isn't it, back in community?

P2 / P5: Mmm

P3: Which is ideally placed, because they've got the new medicines service, and MUR…

This acknowledges that, although patients may be 'counselled' on medicine changes during hospital admission, this is not necessarily enough for adherence to the new regimen. The dMUR therefore could be viewed as a resource to back up or build on discussions started in hospital:

P3: [Hospital pharmacists] can counsel [patients], and then refer them

P3 was able to identify a number of benefits for patients receiving dMURs that she had identified during her own personal experience, including identifying side effects, particularly with cardiac patients, and promoting adherence in medicine taking:

They [dMURS] help people understand the importance of taking their medicines.

[One patient] had a reaction to statins, and [her husband] was started on statins and he stopped him taking them, and he's had a few heart attacks! And it's that kind of thing. You just need to talk to [patients], don't you?

I've picked up on people with side effects, particularly post cardiac issues

Barriers to the dMUR Referral Service

Lack of familiarity with community pharmacy processes was considered a barrier to the dMUR referral service, since at least one pharmacist attending the focus group was not familiar with community pharmacy services:

P4 (in response to question from facilitator to group about their opinions on dMURs): I haven't worked in retail for years.

Despite being in support of the referral service and dMURs in general, P3 had doubts over the motivation of community pharmacists to conduct post-discharge medicines reconciliation and solve problems identified as a result:

P3: …So I think pro-active chemists… but it probably won't work with all.   Because some of them are lax about it.

The focus group highlighted a number of barriers to the effective running of the dMUR referral service. The most frequently recurring theme was that of the limited

time available on the wards, which made them less able to spend time identifying and referring patients into the service:

P4: It's just a time problem isn't it; you just haven't got the time

P1: [Talking about increasing involvement of ward pharmacists beyond marking potential patients on the ward bedplan] It's not going to happen…
P4: It's too much time isn't it?
P1: It's just too much

P3: …it's really difficult to think about at the moment, because we're all inundated, with no time

P3: …from a time constraint issue, here, it's difficult, isn't it?

The issue of funding was also raised, with one participant alluding to the fact that community pharmacies get paid to provide dMURs, whilst hospitals get nothing for referring patients to the service**:**

P3: We're lacking the funding, aren't we, to be sitting down with every patient that's started on new drugs…..we would almost need a payment….if you get paid for that referral, cos in the community pharmacy contract there's room for those kind of things... It's actually worthwhile the community pharmacists doing it.

Identifying suitable patients and engaging them with the idea of post-discharge follow-up with their community pharmacy was also a recurrent theme within the focus group:

P6: there's lots of elderly people, isn't there, who might not be suitable
P3: Mmm
P1: Yeah, and the nursing homes and dementia and all that business

P5: I think also, as well, at the point of discharge, and during hospital admission, for these patients, there's quite a lot going on, and maybe, you know, they're just coming to terms with the fact that they've suddenly got to take this many medicines and maybe at that point they're not going to take it in, and maybe they need to be followed up when things are slightly calmer, and they've got used to the idea

P2: Not all of them will have a regular chemist anyway

Related to this was the perceived difficulty in establishing who a patient's community pharmacist was, which would make the referral more time consuming:

P2: Sometimes it is hard though, because they're just like, I don't know "Oh it's on [name of street]"
P3: Or "it's near the shops"
P2: And then you're having to ask them, "what is it? A Rowlands or a Lloyds or what?"

Although in the initial feasibility study recruitment process, it was intended that ward pharmacists would establish whether a patient had a regular community pharmacy, and if so, who that was, before referring them to the researcher, comments made during the focus group indicated that this was not in fact being done:

F: So, do you find it easy to identify who the chemist is?
Pause
P1: I don't [identify the chemist]! You do that! I just put [researcher's name on the bed plan] and you do it!

This lack of integration of the activities needed for referral to community pharmacy with the routine work of the hospital pharmacy team recurred in other parts of the focus group, as a barrier to selecting patients who might benefit from post discharge follow-up:

P1: …It just won't enter their [ward pharmacists'] heads. Either because of time constraints, or because it's not normal practice

This situation may be exacerbated by the high patient turnover on particular wards, which was raised as a contributing factor to difficulties in pharmacists retaining the information required about the patient in order to refer them on:

P1: …when you've got 10 [new admissions], you do one and forget, you do one and forget… and it's hard then, you know, and it's like that every day on the short stay unit

When discussing potential ways of continuing the service once the researcher was no longer managing all referrals, the extra effort that would be required to make referrals using the current discharge system was viewed as a barrier:

P1: …If you ask us to free-type the chemist [on to the discharge summary] it won't happen

The suggestion by participants that this could be mitigated by introducing 'drop-down' lists on the electronic discharge system was then tempered by concern that increasing the number of steps in the process might lead to errors, if referrals were to be made this way:

P1: You know, the more steps you have though, the more chance there is of something going wrong, you know, ticking the wrong box
P4: Yeah, sometimes [the e-discharge system] does make it easier to make an error. Especially when you're rushing

A further barrier raised was the issue of information governance and patient confidentiality when transferring information about altered medication to community pharmacies:

P2: There's probably information on [the discharge summary] that the community pharmacist doesn't need…
Noises of agreement from group

P2: And that might be where the consent issue comes in because, I don't think information governance would allow it would they, because they're getting information they don't need

However it was acknowledged that the community pharmacist would need some background information in order to support the patient with an altered medication regimen:

P3: Maybe just the medicines, we could find a way of just transferring…
P6: But then the community pharmacist still wouldn't know what had changed and why

Solutions for the dMUR referral service
Solutions to the low referral rate were identified, with the commonest theme being improvements to the e-discharge system to make good quality referrals easier to make:

P1: …what if we could have something on the [e-discharge system], where you could click a button and they would get it?

P1: It needs to be computerised, and then once you've done it you can forget about it.
P1: It wouldn't be too onerous on the [e-discharge system]

P2: Mmm

P1: You know, drop-down list of chemists, find all the suitable patients, tick yes and that would be it

P4: May be we need a box… on [the e-discharge] that says new, increased, decreased, or something like that, just to highlight changes to the drugs

Integrating promotion of dMURs and the dMUR referral process into established activities of hospital pharmacy, having been identified as a barrier currently, was identified as an area that could be improved with relatively little effort:

P1: …you could [get patient consent] when you were talking to them about their medicines
P2: Yeah
P1: It's not too… if it's already part of the process you do
P2: Yeah
P1: It's built in, isn't it, at the end of each conversation, "oh, by the way, when you go home I'm just going to set up for you to have a chat with your chemist" – you can just put it like that, can't you? And they'll probably say "yeah, ok".

<u>Target groups for dMUR referral</u>

Priority or 'target' patient groups for post discharge referral was a recurring theme throughout the focus group. This theme arose early in the session from discussion of past experiences between participants. From this, it could be deduced that groups of patients who might be priorities for referral included cardiac patients, patients prescribed new medication during admission and patients using high risk medications such as anticoagulants:

P3: [Talking about experience of working in community pharmacy] …we automatically try and pick up MURs on anything new, particularly high risk medicines, and she was on apixaban and aspirin

P1: What if they're on new meds? What if they didn't come in on anything and they go home on six?
P2: Yeah
P3: Yeah, that's even more important

P3: I've picked up on people with side effects, particularly post cardiac issues

In response to these comments, and coupled with the low referral rate of potential participants, it was desirable to find out if the pharmacists were prioritising

particular patients to refer, and if so whether this was helping or hindering the process. Therefore the facilitator asked directly:

F: …do you think we should be referring all patients, or do you think we should try and identify patients that would be able to engage and benefit from it?

Arguments both for and against targeting were made:

P1: If you're being selective, you're relying on individual pharmacists to do that. And not all will do that.

In fact, a role for community pharmacists in targeting patients who would benefit from dMUR so that hospital pharmacists did not have to be selective over which patients they referred was identified:

P4: Maybe, if [we referred] all [patients], then the chemists…
P1: Could decide [which to contact to arrange an MUR]
P4: ...would know the patients better than we would and they would know which patients might need counselling more than others

However, this was quickly countered:

P2: I think they might get a bit inundated though
(Laughter)
P2: I mean if it was, like, every hospital

A final consensus was that an effort did need to be made to be selective when referring patients:

P3: I think it probably does need to be targeted, thinking about it
P1: Targetted?
P2: Mmm [agreeing]
P6: Yeah, because as well, in this hospital, there's lots of elderly people, isn't there, who might not be suitable
P3: Mmm [agreeing]
P6: So then the community chemist is going to get too overwhelmed with going through loads
P1: Yeah and the nursing homes and dementia and all that business
Noises of agreement
P3: So I think you probably need to think, if it's someone going home, managing their own medicines without any help from anyone…

Actions Following Focus Group

Analysis of hospital pharmacy focus group data led to modification of the participant recruitment process for the study. Firstly, criteria for referral to the researcher were simplified, to reduce the burden on the ward pharmacists. Pharmacists were asked to refer any medical patient over the age of 65 who in their professional judgement would benefit from a dMUR. Secondly, referral to the researcher could be made simply by noting the patient's hospital number on a special communications board by the back exit to the dispensary.

Additionally, an effort was made to encourage ward pharmacists to integrate the possibility of dMUR referral into their routine ward visits, by sending regular email reminders about the study and the types of patients that were appropriate.

<u>Outcomes Following Changes to Recruitment Procedure Based on Focus Group Findings</u>

The number of potential participants identified by ward pharmacists did increase after the focus group. One hundred and ten potential participants were identified over the 12 weeks following the focus group, a mean of 9 per week, compared to 67, or 6 per week, during the 12 weeks prior to it, a 50% increase. The recruitment rate also increased by a similar amount; 11 participants were recruited in the 12 weeks before the focus group (mean 1 per week) and 18 in the 12 weeks after (1.5 per week, 50% increase). However, the number of patients referred to the researcher was still small compared to the number of patients discharged from the Trust each week (mean 219 discharges per week for medical patients aged 65 or older during the study period according to internal data).

7.1.4: Hospital Pharmacist Questionnaire

It was acknowledged that the opinions expressed during the focus group were not necessarily representative of the majority of pharmacists working at the hospital. In particular, only one senior clinical pharmacist and no senior managers had attended the focus group. In order to see if the issues identified during the focus group affected the pharmacy department more widely, and the extent to which the solutions posted were felt to be useful, qualitative data from the focus group was used to develop a quantitative questionnaire (Appendix 31).

Nineteen of the 22 questionnaires (86%) were returned. The profile of respondents by NHS AfC banding and patient facing role was representative of the profile of the department as a whole (apart from those in a managerial role who were proportionately over-represented in the questionnaire responses) and is presented in Table 7.1.

Table 7.1: Profile of Hospital Pharmacists Returning Questionnaire

AfC Band (Patient facing role)	Number of Respondents (% of all respondents)
6 (Non-specialist)	6 (31.6)
7 (Specialist)	5 (26.3)
8a (Specialist)	5 (26.3)
8b or above (Managerial)	3 (15.8)

General views toward the service were broadly positive. The majority of respondents (n=16, 84.2%) agreed with the statement that the service would foster better working relationships with community pharmacists. All but one (n=18, 94.7%) agreed that dMURs would allow adherence problems and medication errors, following hospital discharge, to be identified and resolved sooner than they otherwise would be. Further, 16 (84.2%) felt dMUR referrals would help patients manage their medicines better after being in hospital.

However, as identified in the focus group, 18 (94.7%) respondents agreed that referring patients for dMUR is not yet ingrained in the daily work of a ward pharmacist.

From the choices provided on the questionnaire, the most common reason for pharmacists referring patients to the service was that new medication had been started in hospital. This was cited by 13 (68.4%) of the respondents. This was followed by the concern that a patient was at risk of poor adherence (n=6, 36.8%) and that changes to doses of medicines had been made during admission (n=5, 26.3%). Other reasons selected included that patients were taking 'high-risk' drugs (n=4, 21.1%), had asked for more information regarding medicines, had medicines stopped in hospital (n=3, 15.8% each), lacked understanding of their medication or were experiencing polypharmacy (n=1, 5.3% each).

Barriers to Referral

Ten (52.6%) respondents agreed with the statement that time spent on dMUR referrals takes hospital pharmacists away from other patients, whilst 11 (57.9%) agreed that the patient's priority is to get home from hospital, so it is hard to engage them with the concept of the dMUR service.

Fourteen (73.7%) respondents reported identifying fewer than five patients per month for referral during the recruitment period. Reasons given from the options provided by the questionnaire are shown in Figure 7.1. Time pressure was the most commonly cited barrier (n=13, 68.4% identified this as a 'major' or 'always' a barrier). This was followed by forgetting to look for patients, and patient length of stay being too short to engage them with the service (n=7, 36.8% each). Six (31.6%) respondents had difficulty in identifying suitable patients. Having to complete a referral form was only viewed as a major/always barrier by two respondents; however this was likely due to the fact that during the feasibility study the referral form was filled in by the researcher. Nursing home residents, dementia sufferers and patients in poor clinical condition were identified via free text as commonly encountered patients who respondents felt were unsuitable. Two respondents (AfC grade 8b or above) cited via free-text their managerial role as the reason for identifying few/no patients, whilst pharmacists covering surgical, admissions, palliative care and frail elderly specialities identified the type of ward they worked on as yielding few suitable patients.
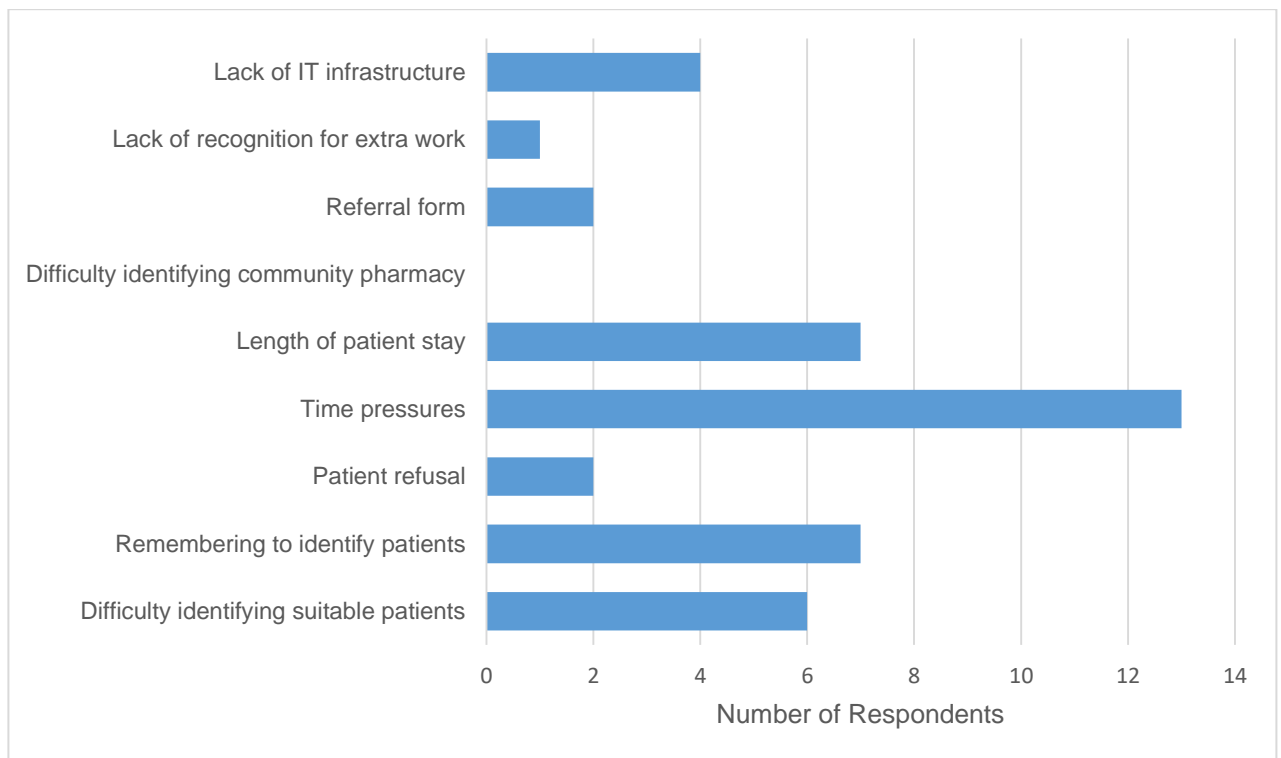
Figure 7.1: Barriers to dMUR Referral Identified by Hospital Pharmacists

Identifying a patient's regular community pharmacy was not viewed as a major barrier by any of the respondents, in contrast to concerns raised during the focus group. Again, this could have been due to the fact that to maximise recruitment during the feasibility study, the researcher had ascertained which pharmacy participants wished to use.

<u>Potential Solutions to Improve the Service</u>

Of the potential solutions offered in the questionnaire (Figure 7.2), investing in hospital pharmacy staff time and sending referrals electronically to community pharmacy were identified as the most likely to make a 'substantial' or 'major' improvement to the service (n=17, 89.5% respondents each). Additionally, 16 (84.2%) respondents identified that better documentation of medication changes on discharge summaries would result in improvement. Greater promotion of dMURs to patients, both in hospital and in the community, was identified by 12 (63.2%) of respondents as a potential solution for the service, as was targeting specific patient groups.
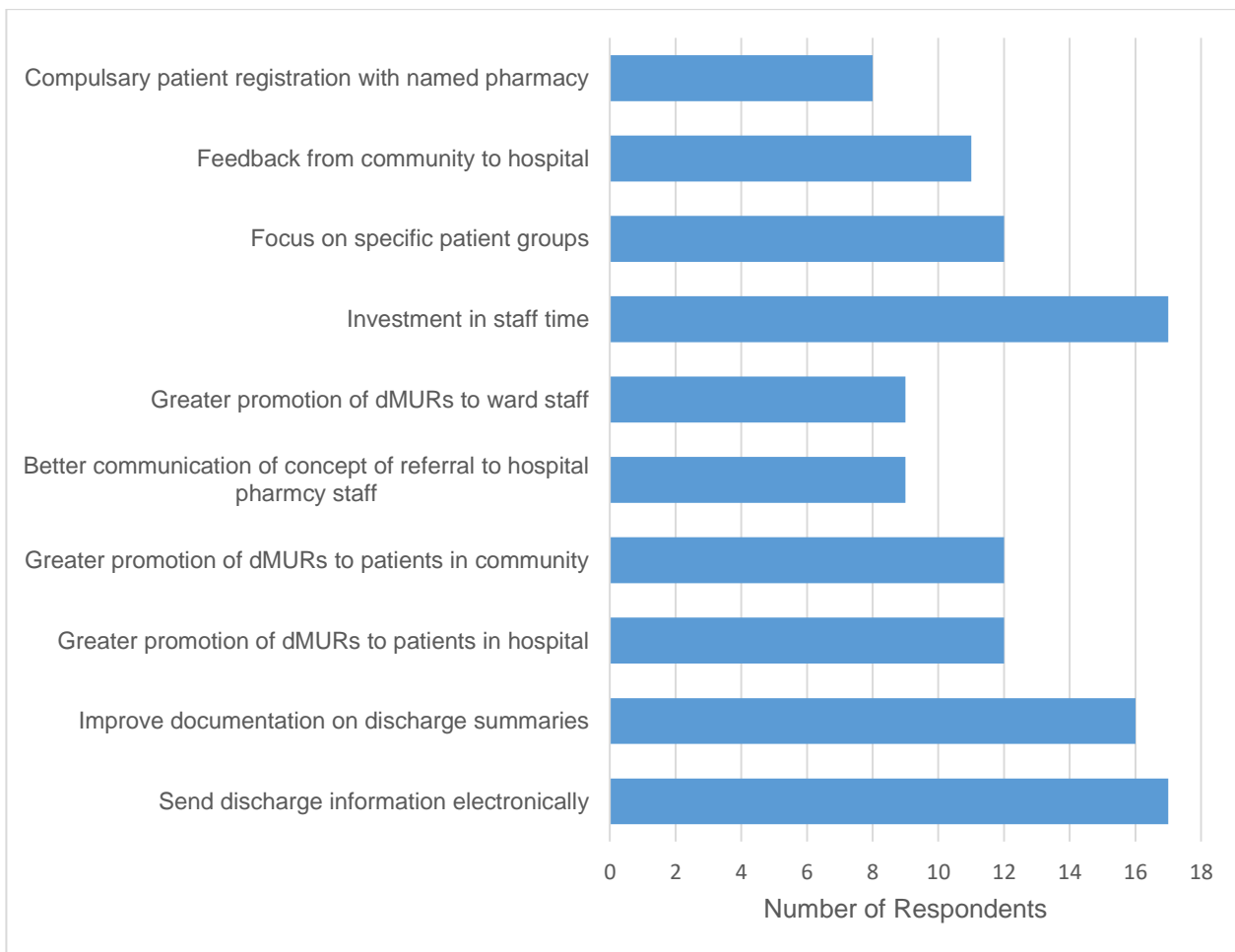
Figure 7.2: Potential Improvements to dMUR Referral Service Identified by Hospital Pharmacists

7.2 PARTICIPANT RECRUITMENT

Recruitment took place between 7th April 2014 and 6th January 2015. Over the 9-month period 337 potential participants were identified by ward pharmacists, which ultimately resulted in 60 patients recruited (Figure 7.3).
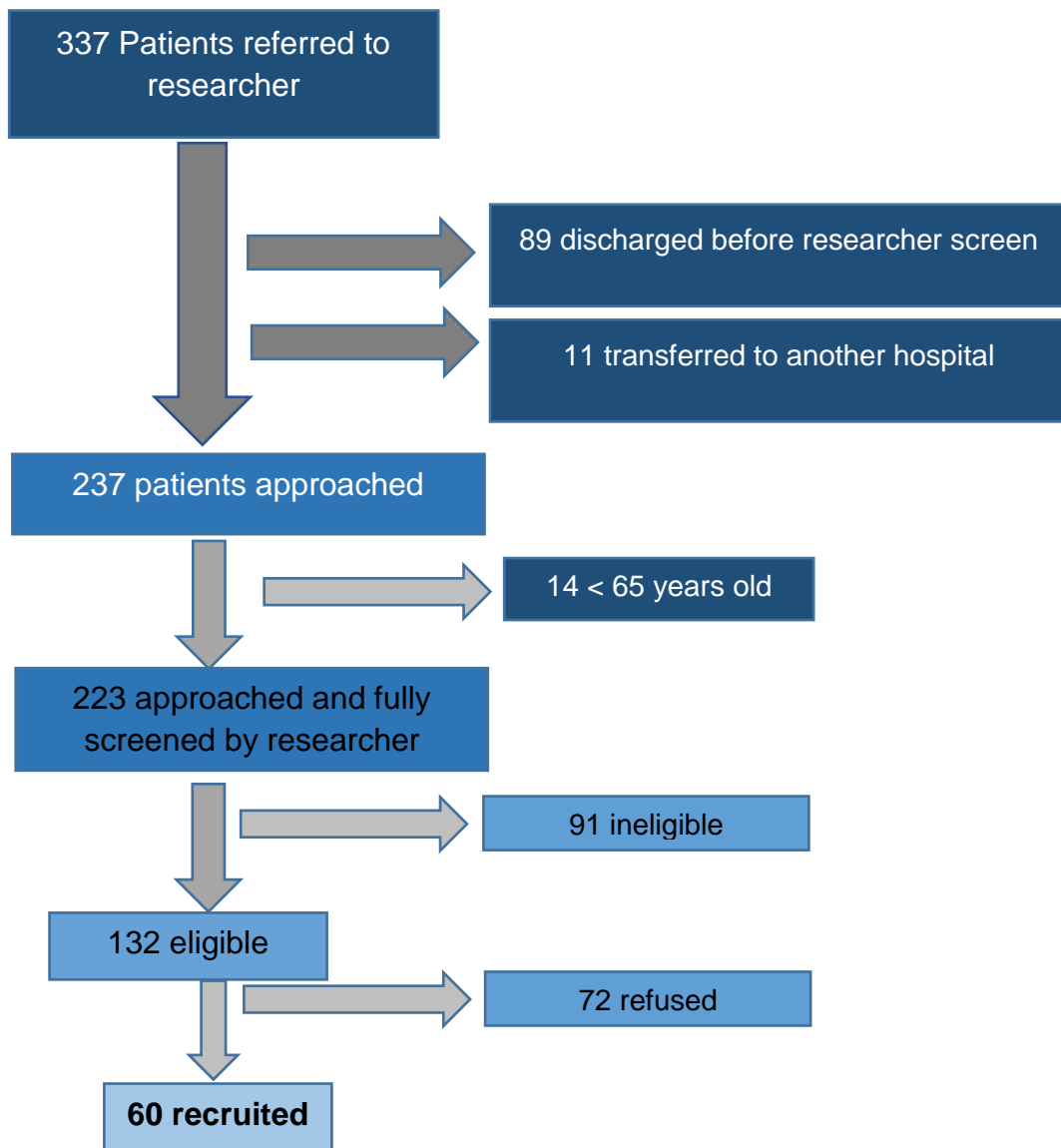
Figure 7.3: Summary of Participant Recruitment

This represents a recruitment rate of 17.8% of patients referred by ward pharmacists, or 45.5% of eligible patients. Reasons for exclusion and refusal are shown in Table 7.2.

Table 7.2: Reasons for Ineligibility (n=91) and Refusal (n=72)

Ineligibility	Number (%)
Protocol exclusions	
Patient not self-medicating at home	28 (30.8%)
Unable to access dMUR from chosen pharmacy	22 (24.2%)
Being discharged out of study area	11 (12.1%)
Participants community pharmacy not taking part in the study	2 (2.2%)
Patient does not use a regular pharmacy	1 (1.1%)
Patient exclusions	
Lack of capacity to consent	11 (12.1%)
Too unwell to approach	9 (9.9%)
MUR not needed	7 (7.7%)
Reason for Refusal*	**Number (%)**
Patient sees no benefit to MUR	20 (27.7%)
Patient already has good links with community pharmacy	15 (20.8%)
Unwilling to engage with research	14 (19.4%)
Health reasons	11 (15.3%)
Time constraints	11 (15.3%)
Would rather see GP	6 (4.5%)
Hospital counselling adequate	4 (3%)
Patient does not want telephone MUR (home visit not available and patient cannot attend pharmacy)	3 (2.3%)
Patient does not agree with changes to medicines	2 (1.5%)
"Too old"	2 (1.5%)
Belief that medicines information will automatically be transferred to community pharmacy	1 (0.8%)

*The number of reasons for refusal is greater than the number of patients refusing, as some patients gave more than one reason.

No significant differences existed in age or gender between patients who refused to participate and the study participants. However, refusing patients tended towards being older (p=0.0831, two tailed independent samples t-test). There was also a trend towards more females being among the refusers, although this was not statistically significant (p=0.0657, chi-squared test).

There were no significant differences detected in baseline characteristics between participants in control and intervention groups (Table 7.3). However, the intervention group tended towards being more likely to live alone (43% vs 21%, p=0.0628).

Table 7.3: Participant Baseline Characteristics

Baseline characteristics	Overall (n=59)	Intervention (n=30)	Control (n=29)	P value (2-tailed)	Test used
Female (%)	33 (56)	16 (53)	17 (59)	0.6826	Chi-squared
Mean Age in years (Range)	78 (65-92)	79 (68-92)	77 (6-89)	0.1142	T-test
Living alone (%)	19 (32)	13 (43)	6 (21)	0.0628	Chi-squared
Mean number meds (Range)	9 (2-19)	9 (3-16)	9 (2-19)	NA	NA
Mean MCI (Range)	20 (5 - 41.5)	21 (7.5–41.5)	19 (5-40.5)	0.3476	T-Test
Cognitive impairment (%)	11 (19)	7 (23)	4 (14)	0.3469	Chi-squared
Mean number co-morbidities (Range)	4 (2-8)	4 (2-8)	4 (2-8)	NA	NA
Admission in last 30 days (%)	11 (19)	8 (27)	3 (10)	0.108	Chi-squared
Admission in last 12 months (%)	29 (47)	15 (53)	13 (45)	0.6908	Chi-squared
Mean length baseline admission in days (Range)	7 (1-27)	6 (2-19)	7 (1-27)	0.7730	T-test

There were a total of 7 participants (3 intervention and 4 control) who used a community pharmacy dispensed MCA for some of their medication but had extra medications (e.g. inhalers, warfarin) with which they had to independently self-medicate. The MCI for these participants was adjusted so that all solid medicines in one compartment of the MCA (i.e. morning, lunch, tea or night) were classed as one medicine for the purposes of the calculation.

7.3 PARTICIPANT DROPOUT AND LOSS TO FOLLOW-UP

Of the 60 patients originally recruited, 10 were lost to the study because they either died (n=2), were admitted to a care home (n=4) or were no longer self-medicating at follow-up (n=4). The overall return rate of usable questionnaires was 74.6% at four-week follow-up and 59.3% at six-month follow-up. Eleven participants who

were inpatients or did not return a usable questionnaire at four weeks were included in the six-month follow-up as per the study protocol. Overall, 24 participants were lost to the study by six-month follow-up. These losses and the points at which they occurred are shown in Figure 7.4.

60 participants randomised

1 discharged to care home (excluded from follow-up)

59 four week follow-up questionnaires distributed

15 did not complete four-week follow-up

2 admitted to care home (C) (excluded from further follow-up)
2 readmitted at time of follow-up (1xI, 1xC) (included in 6 month ITT follow-up)
1 RIP (I) (excluded from further follow-up)
1 no longer self-medicating (C) (excluded from further follow-up)
1 x incomplete questionnaire returned (I) (included in 6 month ITT follow-up)
8 unknown (3xI, 5xC) (included in 6 month ITT follow-up)

55 six-month follow-up questionnaires distributed

19 did not complete six-month follow-up

1 admitted to care home (I, unknown at 4/52)
2 readmitted (I)
1 RIP (C, readmitted at 4/52)
3 no longer self-medicating (1 x I, readmitted at 4/52, 2 x C)
2 x incomplete questionnaire returned (I, 1 also returned incomplete questionnaire at 4/52)
10 unknown (3xI, 7xC)

36 completed six month follow-up questionnaires received

C=control group participants
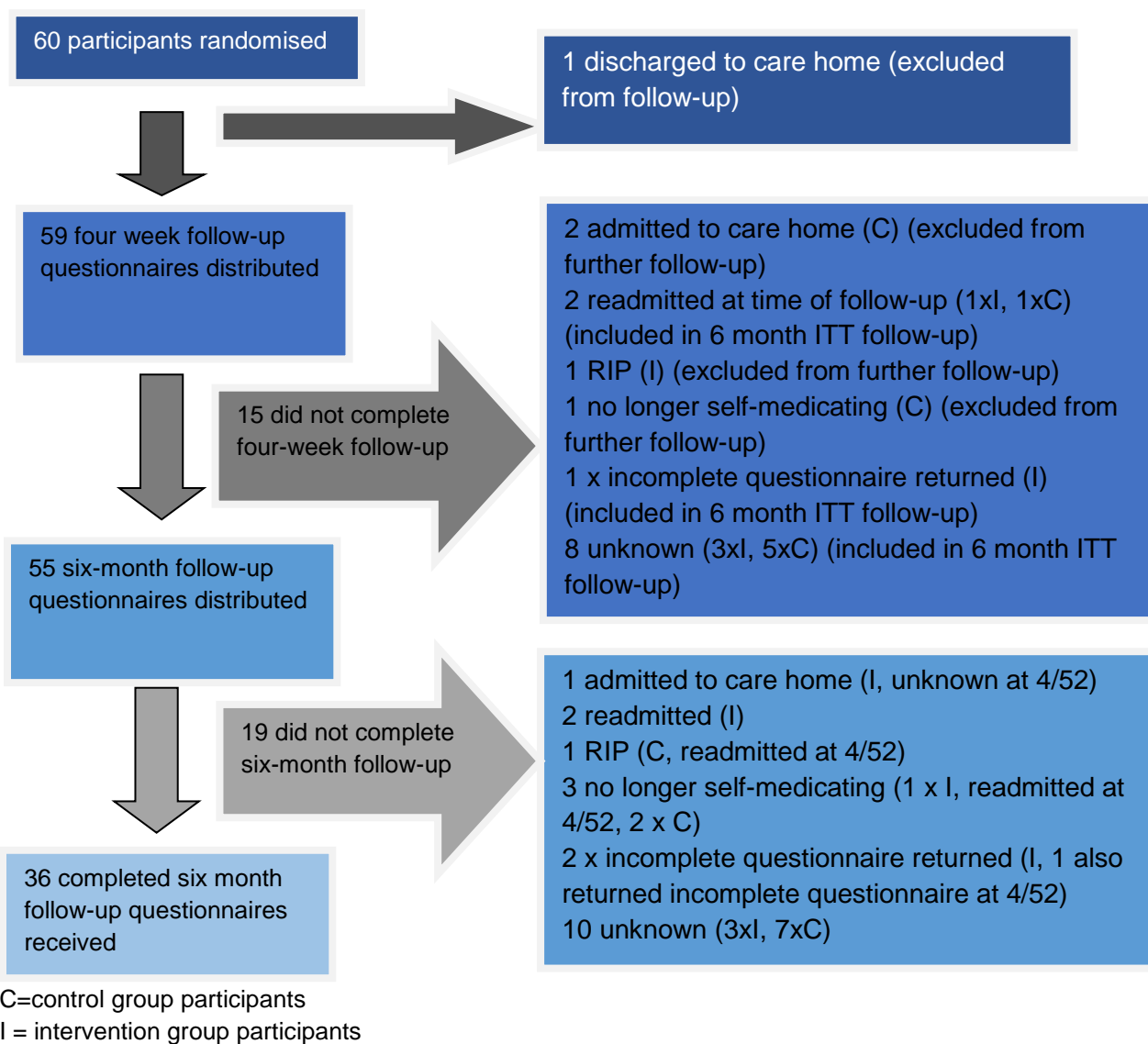I = intervention group participants

Figure 7.4: Summary of Participant Dropout and Loss to Follow-up

In addition to these losses, a further 14 participants were excluded from the PP analysis as they either did not take part in their dMUR (intervention group, n=7), had their dMUR after the 4-week window specified in the study protocol

(intervention group, n=6) or requested a dMUR when one was not planned (control group, n=1).

The 4-week PP analysis therefore included 30 participants (19 control and 11 intervention group). This represents attrition of 49% of randomised participants between discharge and 4-week follow-up (34% of control and 63% of intervention group participants had deviated from the study protocol by this stage).

The 6-month PP analysis included 24 participants (15 control and 9 intervention). This represents attrition of 59% of randomised participants between discharge and 6-month follow-up (48% of control and 70% of intervention group participants had deviated from the study protocol by this stage).

7.4: PARTICIPANT OUTCOME DATA

Results showed no significant differences in any of the outcomes studied between the intervention and control groups, in either the ITT or PP analysis at 4 week or 6-month follow-up (Tables 7.4-7.7).

Table 7.4: Intention to treat analysis: 4-week follow-up

Outcome	Intervention (n=30)	Control (n=29)	p-value (2 tailed)	Test Used
Patients having $\geq$ 1 non-elective readmission	6 (20%)	5 (17.2%)	0.7377	Chi-squared
Relative Risk of Readmission in intervention group = 1.2 (95% confidence interval = 0.41 - 3.50)				
Total number of non-elective readmissions	8	6	0.8026	Mann-Whitney
Mean Length of Readmissions (days)	4.38	7.00	0.1713	Mann-Whitney
Patients having $\geq$ 1 A&E attendance	7 (23.3%)	8(27.6%)	0.7643	Chi-squared
Relative Risk A&E attendance in intervention group = 0.86 (95% confidence interval = 0.33 - 2.24)				
Total number of A&E attendances	9	9	1	NA
Morisky Medication Adherence Score (MMAS)	7.20	7.54	0.3475	T-test
Health related Quality of Life (SF-12v2) Physical	34.77	34.50	0.9174	T-test
Health related Quality of Life (SF-12v2) Mental	44.41	42.68	0.6164	T-test

Table 7.5: Intention to treat analysis: 6-month follow-up

Outcome	Intervention (n=30)	Control (n=29)	p-value (2 tailed)	Test Used
Patients having ≥ 1 non-elective readmission	15 (50%)	16 (55.2%)	0.7924	Chi-squared
Relative Risk of Readmission in intervention group = 0.94 (95% confidence interval = 0.58 – 4.50)				
Total number of non-elective readmissions	26	23	0.9690	Mann-Whitney
Mean Length of Readmissions (days)	5.67	7.04	0.4487	T-test
Time to First Readmission (days)	72.87	57.81	0.4315	T-test
Patients having ≥ 1 A&E attendance	16 (53.3%)	17 (58.6%)	0.7909	Chi-squared
Relative Risk of A&E attendance in intervention group = 0.94 (95% confidence interval = 0.6–1.47)				
Total number of A&E attendances	36	32	0.9690	Mann-Whitney
Morisky Medication Adherence Score (MMAS)	7.40	7.22	0.5916	T-test
Health related Quality of Life (SF-12v2) Physical	40.80	35.41	0.0983	T-test
Health related Quality of Life (SF-12v2) Mental	43.42	45.34	0.5384	T-test

Table 7.6: Per-protocol Analysis: 4-week follow-up

Outcome	Intervention (n=11)	Control (n=19)	p-value (2 tailed)	Test Used
Patients having ≥ 1 non-elective readmission	2 (18.1%)	3 (15.8 %)	1.0	Fisher's exact test
Relative Risk of Readmission in intervention group = 1.15 (95% confidence interval = 0.2261 to 5.8646)				
Total number of non-elective readmissions	2	3	0.9143	Mann-Whitney
Mean Length of Readmissions (days)	3.5	10	NA	Not tested*
Patients having ≥ 1 A&E attendance	2 (18.1%)	5 (26.3%)	1.0	Fisher's exact test
Relative Risk of A&E attendance in intervention group = 0.69 (95% confidence interval = 0.1601 to 2.9812)				
Total number of A&E attendances	2	5	0.7145	Mann-Whitney
Morisky Medication Adherence Score (MMAS)	7.39	7.66	0.4276	T-test
Health related Quality of Life (SF-12v2) Physical	35.72	34.58	0.6875	T-test
Health related Quality of Life (SF-12v2) Mental	44.24	42.99	0.7451	T-test

*Unable to run Mann-Whitney U Test as fewer than 5 values per group

Table 7.7: Per-protocol Analysis: 6-month follow-up

Outcome	Intervention (n=9)	Control (n=15)	p-value (2 tailed)	Test Used
Patients having > 1 non-elective readmission	3 (33.3%)	6 (40%)	0.6828	Fisher's exact test
Relative Risk of Readmission in intervention group =0.83 (95% confidence interval = 0.2739 to 2.5352)				
Total number of non-elective readmissions	3	6	0.7884	Mann-Whitney
Mean Length of Readmissions (days)	3	11.5	NA	Not tested*
Mean Time to First Readmission (days)	25	58	0.3664	T-test
Patients having > 1 A&E attendance	2 (22.2%)	7 (46.7%)	0.3891	Fisher's exact test
Relative Risk of A&E attendance in intervention group = 0.4762 (95% confidence interval = 0.1251 to 1.8125)				
Total number of A&E attendances	3	10	0.3554	Mann-Whitney
Morisky Medication Adherence Score (MMAS)	7.47	7.25	0.5842	T-test
Health related Quality of Life (SF-12v2) Physical	40.92	35.93	0.1769	T-test
Health related Quality of Life (SF-12v2) Mental	44.74	44.69	0.9905	T-test

*Unable to run Mann-Whitney U Test as fewer than 5 values per group

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7.4.1: Participant Questionnaire Results

Completed questionnaires were returned for 74.6% and 59.3% of participants at 4-week and 6-month follow-up respectively.

The mean enablement score (PEI) for participants who received a dMUR and returned a scorable questionnaire (n=16) was 3.69 (95% CI 1.68 – 5.70). When those who received their dMUR as per protocol (within 4 weeks of discharge, n=10) were analysed separately, their mean PEI was 2.9, whilst for those who received their dMUR after 4 weeks (n=6) the mean PEI was 5. The difference in

enablement between participants who received their dMUR within 4 weeks and those who received it later was not significant (P=0.2965 using an unpaired t-test).

The mean MMAS adherence score across all participants at 4-week follow-up was 7.37, which had dropped to 7.31 by 6 month follow-up (p=0.9408, change not significant using a paired t-test).

The overall mean SF-12v2 for physical aspects of HR-QoL was 34.64 at 4 weeks and 38.11 at 6 months (p=0.1267, change not significant using a paired t-test).

The overall mean SF-12v2 for mental aspects of HR-QoL was 43.55 at 4 weeks and 44.38 at 6 months (p=0.5287, change not significant using a paired t-test).

Adjusted SF-12v2 norms are available for the 65-74 and the 75+ age groups, as presented in Table 7.8 (226). It is apparent from these figures that older people generally perceive their physical health as being worse than their mental health. This was reflected in the results from this study, where physical health scores were consistently lower than mental health scores.

Table 7.8: Age Adjusted SF-12v2 Norms for Older People

Age Group	Health dimension	Population Norm	Age-adjusted norm
65-74	Physical	50	45.17
75+	Physical	50	42.77
65-74	Mental	50	53.83
75+	Mental	50	54.39

Medication Reviews other than dMUR

On the 4-week follow-up questionnaire, 35% (n=7/20) of control group respondents and 44% (n=11/25) intervention group respondents indicated that they had some form of medication review other than the study dMUR, which rose to 71% (n=12/16) of control group respondents and 63% (n=13/22) intervention group at 6 months. Four participants (all control group) reported having a review with more than one HCP. The HCP undertaking the review was usually the GP (51%, n=25/49 reviews), followed by the community pharmacist or the hospital outpatient department (both 16%, n=8/49 reviews). Specialist nurses undertook 6% of the reviews (n=3/49) and practice nurses 4% (n=2/49). In three cases the participants

were unsure of the role of the HCP undertaking the review. The vast majority of reviews were initiated by the HCP; only 20% (n=5/25) of all medication reviews for intervention group participants and 8% (n=2/24) for control group participants were requested by the patient themselves (p=0.2433 using Chi-squared).

Of intervention group participants who completed their dMUR and returned a questionnaire, 44% (n=8/18) had an additional medication review within the month following their discharge, similar to the 37% (n=10/27) of those (intervention and control) who did not receive a dMUR.

Between 4-week and 6 month follow-up, 59% (n=10/17) of respondents having had a dMUR had a further medication review, compared to 71% (n=15/21) of those who had not had a dMUR.

7.4.2: Case-Note Analysis of Readmitted Participants

Overall, 19% of the total study population were readmitted within 4 weeks of their original discharge. This is higher than the baseline 4-week readmission rate (9%) for patients aged ≥65 discharged from SONT and also slightly higher than the latest available national emergency readmission figures (11.5% for all readmissions and 15% for those aged over 75 in the financial year 2011-12) (91,92). At 6-month follow-up, 31 (52.5%) study participants had been readmitted to SONT at least once, giving a total of 49 readmissions. This is also higher than the SONT baseline 6-month readmission rate of 20%.   The mean length of readmission episodes for intervention group participants (ITT analysis) was 2.62 days shorter at 4-week follow-up than for control group patients (p=0.1713: not significant when assessed by t-test). At 6 months the difference in mean readmission length had lessened to 1.37 days (p=0.4487).

Case notes for 48 of the readmissions were located and analysed (Table 7.9). According to the criteria applied (Appendix 33), 12 (25%) of these were at least possibly medication related (Figure 7.5, Causality). In 6 cases (50% of all medication related readmissions), the medication was classed as the dominant cause of the readmission (Figure 7.5, Contribution). Seven (58.3%) of the medication related readmissions were classed as at least possibly preventable,

with 4 (33.3%) assessed as definitely preventable (Figure 7.5, Preventibility). The most common type of medication related readmissions were those associated with patient non-adherence and idiosyncratic events such as ADRs (Figure 7.5, Classification). The medication classes most commonly associated with readmission were loop diuretics (associated with 4/12 medication related readmissions) and antithrombotics (associated with 3/12 medication related readmissions).

Table 7.9: Analysis of medication related readmissions

Pt ID	Reason for Admission	Causality Drug Related?	Classification of Drug Related Admission	Contribution of Drug Related Problem to Admission	Preventable?	Drug involved
3	Abdominal pain – biliary colic	No				
7	Cellulitis	No				
11	Collapse – PAF	No				
12	Dizziness - labyrinthitis	No				
13	Chest pain - angina	No				
13	Chest pain – ACS	No				
13	Chest pain – NSTEMI	No				
16	Exacerbation bronchiectasis	No				
19	Seizure related to alcohol	No				
22	ACS	No				
22	Chest pain - ACS	No				
22	NSTEMI	No				
23	SOB/Chest pain – CCF	No				
23	SOB	Probable	Non-compliance	Dominant	Yes	Furosemide
26	Palpitation – AF	No				
29	SOB/LRTI – Type 1 respiratory failure	No				
30	Hip/thigh/back pain – Osteoarthritis	Possible	Inappropriate prescribing / monitoring	Partly contributing	Possibly	Lack of analgesic titration
34	SOB – Infective exacerbation COPD	No				

36	Nausea and vomiting	Possible	Patient idiosyncrasy	Partly contributing	No	Chemo-therapy
36	Dizziness ?postural hypotension	Possible	Patient idiosyncrasy	Partly contributing	No	Furosemide ISMN
36	CCF	No				
6	Chest pain – angina	No				
10	Rash – drug eruption	Probable	Patient idiosyncrasy	Dominant	No	Perindopril
15	Sepsis	No				
17	Chest pain – uncontrolled AF and acute kidney injury	No				
24	Fall: Twisted R ankle / heamatoma	No				
28	SOB: CCF ?secondary to PAF (not known AF). Started on furosemide	No				
28	SOB: CCF. Discharged from EAU with note 'commenced on furosemide' on discharge summary and furosemide was not on list of discharge meds	Probable	Non-compliance	Dominant	Yes	Furosemide
28	Chest pain: ACS ruled out	Probable	Non-compliance	Dominant	Yes	Furosemide
33	Delirium – steroid induced	Definite	Patient idiosyncrasy	Dominant	No	Prednisolone
38	TIA sec to atrial flutter	No				
38	TIA	No – aspirin added to anticoagulant to reduce risk				
38	Heamatoma L leg	Probable	Patient idiosyncrasy	Dominant	Possibly	Rivaroxaban Aspirin
38	Confusion: ?TIA secondary to rivaroxaban being withheld: however seen by stroke consultant and no further mention of new vascular event so ?failed	Possible	Unable to classify	Less important	No	Rivaroxaban

	discharge from above. NB seen by psychiatry later in admission and ??vascular dementia					
41	Unable to pass urine (clots)	No				
41	Haematuria	No				
41	Haematuria	No				
41	Haematuria	No				
42	Idiopathic pulmonary fibrosis	No				
52	SOB: COPD / Poor diabetic control	Possible	Non-compliance	Partly contributing	Possibly	Metformin, gliclazide, saxagliptin (patient reluctant for injectables)
55	Found on floor	No				
55	Found on floor	No				
55	Weakness/ epigastric pain: gastritis. Lansoprazole increased from 15mg daily to 30mg daily.	Probable	Inappropriate prescribing	Partly contributing	Yes	Clopidogrel Sertraline. NB/ Patient had lansoprazole reduced from 15mg bd to 15mg od on admission 1/3/15 as this is how it had been written on the drug chart by the admitting doctor and the team saw no need to change it back.
55	Fall out of bed: general decrease in coping	No				
57	Dizzy / poor mobility following recent GI bleed (h. pylori)	No				
59	R MCA infarct	No				
62	L foot ulcer	No				

PAF – Paroxysmal atrial fibrillation
NSTEMI – Non-ST elevation myocardial infarction
CCF – Congestive cardiac failure
L – left
MCA – middle cerebral artery

ACS – Acute coronary syndrome
SOB – Shortness of breath
TIA – transient ischaemic attack
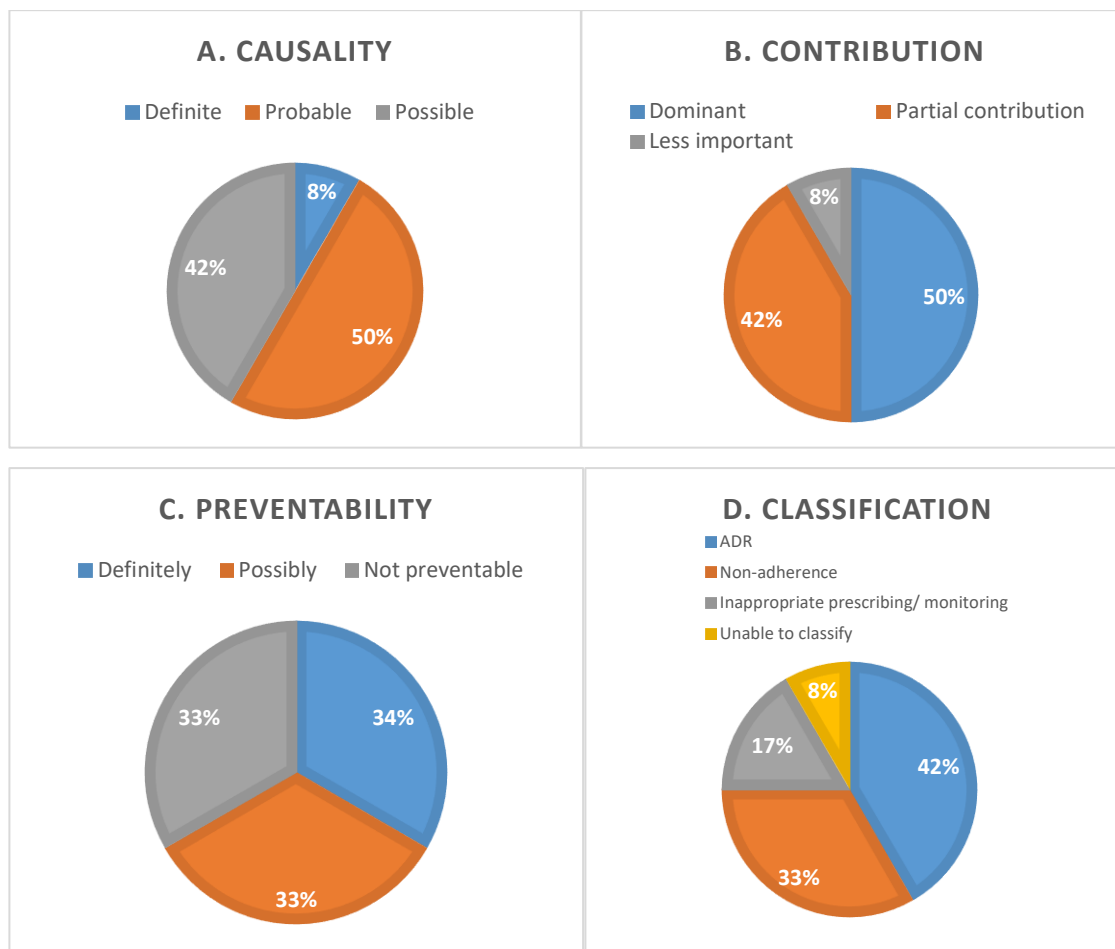R – right
ISMN – isosorbide mononitrate

Figure 7.5: Charts showing: A. Certainty of medication related causality, B. Contribution of medication, C. Degree of preventability and D. Classification of Medication Related Readmissions

7.4.3: Framework Analysis of Semi-Structured Participant Interview Data

Seventeen participants were interviewed in their own homes regarding their experiences of medication support during and following their hospital stay (see Appendices 26 and 27 for copies of interview schedules for control and intervention group participants). The characteristics of interviewed participants are shown in Table 7.10.

Table 7.10: Characteristics of interviewed participants

PIN	Study Group	Gender	Age	Living Alone	Number meds	MCI	Number co-morbidities	Length baseline admission
1	Control	M	89	Y	6	14.0	3	2
2	Intervention	F	74	Y	4	11.5	2	6
3	Intervention	F	77	N	6	16.5	3	11
7	Intervention	F	92	Y	9	17.5	6	11
10	Intervention	M	84	N	16	41.5	6	15
13	Intervention	F	88	N	3	11.0	6	6
16	Intervention	F	70	N	9	22.0	5	19
24	Control	F	87	N	7	19.0	3	5
32	Control	F	68	N	5	7.0	5	9
33	Intervention	F	73	N	9	20.0	4	6
48	Intervention	M	79	Y	9	18.5	4	2
49	Intervention	F	68	N	6	15.0	3	5
52	Intervention	M	73	N	13	29.0	5	2
54	Control	F	79	N	6	10.0	4	27
57	Control	F	85	Y	10	24.5	5	7
62	Control	F	79	N	13	23.0	4	8
63	Control	M	75	N	6	15.5	3	1

Interviewed participants were selected to reflect a range of the entire participant cohort in terms of age (range 68-92 vs 65-92 years), number of medicines taken (range 3 – 16 vs 2 – 19), medicines complexity (MCI range 7 - 41.5 vs 5 – 41.5), number of co-morbidities (range 2 – 6 vs 2 – 8) and length of baseline hospital admission (range 1 -27 days).

As interviews needed to begin before all participants had been recruited, the first three participants to be recruited were interviewed irrespective of their characteristics. This allowed the interviewer to become used to the interview process and make any necessary modifications to the interview schedules based on early themes identified. Thereafter, selection of interviewees continued purposively to achieve maximum variation in the demographic features described above. New themes and subthemes stopped appearing relatively early in the interview process (at the 10[th] interview conducted); however a decision was made to continue interviewing until the full range of participant demographics had been represented in both intervention and control groups.

Interviews lasted a mean of 25 minutes (range 6 – 69 minutes). A full reproduction of the coding framework including subthemes is reproduced in Appendix 35. As

with the hospital pharmacist focus group, some themes were pre-determined by the interview schedule designed by the researcher; others emerged during discussion between the interviewer and interviewees.

Nine main themes were identified and are presented below.

1. Information / Advice regarding medication given in hospital

The general attitude of participants to the information they had received from the hospital about the changes to their medicines was highly variable. Those who described receiving information from several sources, particularly where conversations were backed up with written information, seemed to demonstrate greater confidence in and understanding of their medication. For example:

'I had plenty of information…It was [the ward pharmacist] and I spoke to the doctors a few times. And the nurses giving me the medication…I'd just chat to them' (P1, control).

Although not mentioned as the primary source of information, this patient also placed value on the written copy of her discharge summary:

'*It's all on here* (produces discharge summary)…*[I'll] keep it. It was handy'*

Another participant also displayed confidence in the information about medication given whilst in hospital:

'*I understood it, and why the medication had been changed when I left hospital…The cardiologist came to see me before I left, and he understood, he explained a lot'* (P49, intervention).

The benefit of receiving medication information from different sources, as well as having access to further support following discharge was demonstrated by a participant who had experienced several medication changes whilst in hospital:

'At first it was quite confusing...but I was reassured by the sister on the ward, that if I had a problem to ring back, which I did, erm, because it was about the warfarin and when I was to take it' (P3, intervention).

The importance of family members in obtaining information on behalf of some participants who were less cognitively able during admission was also highlighted:

'Son: the [other] members of the family would get the information off the doctor and the nurse in the afternoon, but we used to get it off the nurse in the night

time…. because I mean my brother, my nephew, my sister, my niece, everyone was around'. (P7, intervention).

Not all participants described such a positive experience. Thirteen participants indicated gaps in the information given at the hospital and four of these could not recall any discussion regarding medicines with a member of hospital staff, or being given any written information to take home; for example:

'I didn't feel I'd had any information about the tablets I was on. I knew I was on metformin for my type 2 diabetes, and… but there were lots of other extra medicines which I had no idea what they were for.' (P54, control).

At least one participant had experienced a hurried discharge at the expense of discussion about medication:

'...it was just a bit airy fairy, the way I came out, you know, from being told that I might be out that day, and then erm, that I was being out. But I had to wait for the pharmacy for the medication. So we waited for the medication and they just brought it, and gave it to me, and we went. That was it. There was no discussion about it' (P13, intervention).

However it was not always clear whether there was a true lack of information about medicines given at the hospital, or whether the information given had since been forgotten:

'*Interviewer: …nobody talked to you when they prescribed you the statins in the hospital?*
Participant: No. Well, at least if they did I can't remember' (P54, control).

This was reiterated by a participant who had had one medicine stopped and a further four started during admission:

'They didn't change my medication while I was in hospital… I can't remember…' (P57, control).

In terms of the type of information participants felt was missing from the hospital, side effects were mentioned by two participants, exemplified by Participant 10:

'I wasn't informed of the likely side effects of the three or four new medications, one of which subsequently proved to be upsetting for my system…' (P10, intervention)

Information regarding reasons for changes and indications for new medicines were also perceived as lacking by six participants or their carers. For example:

'Participant: Well I would like to know whether they were for blood pressure…
(P54, control)

However not all participants expected detailed discussions regarding medicines. Sometimes this was due to the perceived simplicity of the change:

'Well it was only clopidogrel, just take one every day. So I didn't find that difficult at all …' (P2, intervention, no dMUR).

Even participants who had multiple changes to their medicines did not always feel the need to understand the reasoning behind them:

'Interviewer: So, where you aware of why they were making the changes?
Participant: No, they never told me.
Interviewer: Would you like to have been?
Participant: No, not really. I've been taking this medication for years now, and the fact that they altered it a bit didn't bother me…I didn't really need a lot of information' (P62, control).

Two participants felt that they did not require much information from the hospital because they had worked with medications in the past:

I understand my medical conditions, because of my background as a nurse' (P48, intervention)

'...It was fairly standard stuff anyway, which I did know a bit about.' (P32, control, former administrator in GP surgeries).

Some participants presented a stoical, uncomplaining attitude towards a lack of medication information:

'Well I was prepared to take it on the chin so to speak, er I took the medication in the full belief it was going to help me' (P10, intervention).

Here, the apparent lack of communication from the hospital was compounded by a lack of information seeking on the part of the patient, which may stem from the belief that 'the doctor knows best' and shouldn't be questioned too closely. This attitude was demonstrated more clearly by another participant:

'I used to tell them when I was in hospital, if you go and see the doctor, there's no point in going and not doing what he tells you, or what he suggests. You've got to vote with him ' (P48, intervention).

2. Transfer of care issues surrounding medicines

Issues relating to poor communication between healthcare providers on transfer of care were described by two control group participants:

 '*I got the warfarin with this lot [of repeat medication], and I rang [the GP's surgery], and I spoke to the receptionist. Now, whether she knew about the prescription, I don't know. But she said, 'you shouldn't have had the warfarin'. They used an old prescription, with the warfarin on it, and it shouldn't have been on'* (P57).

'*Participant: the warfarin isn't on my prescription, my repeat prescription yet, because I've never actually got it from the doctor's, I've only ever got it from the hospital.
Interviewer: Right [pause]…so has that caused a problem?
Participant: Yeah, when I come to get some. Because what happened was ...They screwed it up anyway, getting the prescription from the pharmacy, and backwards and forwards.'* (P63).

The lack of timely information transfer to this patient's community pharmacy also led to a switch in the brand of his newly prescribed diltiazem:

'*And they [community pharmacy] didn't have that drug, so they had to swap it for another drug*'

3. Contact with healthcare professionals (HCP) since discharge

Participants described numerous contacts with HCP (mean =3 per participant interviewed), many with a primary focus other than medication, in the few weeks following discharge. Examples included seeing phlebotomists for blood tests (2 patients), hospital outpatient appointments for echocardiograms (2 patients), 24 hour electrocardiograms or endoscopies (1 patient each), district nurses changing dressings (1 patient), practice nurses conducting annual diabetes review (2 patients), GP appointments for new symptoms not related to their admission (4 patients) as well as readmissions to hospital (3 patients).   In some of these cases (for example one of the diabetes reviews and two of the readmissions) medicines had been altered.

Eight of the 17 interviewed participants – (five out of 10 intervention group participants and three out of seven controls) had had a medication review other than a dMUR since being discharged. This may have been with their own GP:

'GP told me that I didn't need to continue with the inhalers'. (P10, intervention)

or practice nurse:

'Interviewer: So, you've been to see the nurse as well, you were telling me?
Participant: Yes. She cut some [medicines] out' (P7, intervention).

Others had had their medication reviewed by a specialist nurse, sometimes more than once:

'Interviewer: So the nurse went through your medication with you as well, you said?
Participant: Yes, yes….
Interviewer: And was it [community matron] that went through all the medicines as well?
Participant: Yes' (P16, intervention).

Another participant described having medication reviewed by both the GP and specialist nurse, with an associated feeling of frustration at the number of appointments she had:

'Interviewer: So that [titration of heart failure medicines]'s been managed by the GP initially and then…
Participant: No, by the cardiac nurse. Well, they're both doing it. This is another debate. Interviewer: Right?
Participant: There's too many fingers in too many pies. There really is' (P32, control).

Some participants described appointments with the anticoagulation monitoring service where they had been able to obtain advice regarding a specific medicine:

'Participant: Well I understand it [warfarin] thins the blood.... Pause... I also understand if the reading gets too high it can lead to difficulty with bleeding, if I cut myself while shaving or if I happen to cut myself doing odd jobs about the house I'd have to be careful. I'm told that wherever I go I need to have this [anticoagulant record book] with me, or at least advise people that I'm on warfarin.
Interviewer: And did that advice come from the warfarin clinic?
Participant: Yes' (P10, intervention).

4. <u>Medication support (other than dMUR) since discharge</u>

Some participants took it upon themselves to seek medication support they felt was lacking from the hospital, and the community pharmacy was the first port of call for two of these:

*'Interviewer: did that [lack of information] make it more difficult for you going home?
Participant: No not really, because I went to see the pharmacist' 'I took it [new
medication] down to [community pharmacist] the next day, and she talked me
through them'* (P13, intervention).

*'I've got an old BNF, and I checked it, and I picked out what I thought it
[unidentified medication given during admission] was, and I took it to [community
pharmacist] and asked what he thought it was'* (P48, intervention).

Other participants used the internet or the manufacturer's information to answer
unresolved questions:

'The questions are either in the leaflet or in the other leaflet you can get online'
(P32, control).

Family members played a key role in supporting some patients to manage the
changes made to medication in hospital:

*'As soon as we got out of hospital, I bought that container and said, right, we're
going to do it this way. I'll pop them out and you [participant] just get them out [of
the dosette box]'* (P7, intervention).

*'Interviewer: So, how did you find out about the changes in medication?
Participant: Oh, my son told me!'* (P24, control).

However, this raises the question of who has supported the family member:

*'Interviewer: Has anybody sat down with you and gone through the tablets?
Son: No.'*

Other participants had been the recipient of support from outside agencies
regarding their medication. One participant described how the reception staff at
her GP surgery had helped resolve unanswered questions regarding her altered
medication regimen*:*

*'She says anything different, erm, I'm worried about, to phone her, because she
erm, sorts my medicines out as well, erm, she said that she rang the hospital to
see why they'd taken some of my medicines off me. So she was very good'* (P3,
intervention).

5. <u>Barriers to medication adherence</u>

In the COM-B model of adherence (Section 3.1.1) barriers to adherence may concern a patient's capability (mental or physical) of taking the medicine, them having the opportunity to take it, and their motivation to take it (60). Interviewed participants demonstrated all three types of barrier, as exemplified below.

Capability

Memory was the most frequently discussed barrier to adherence, alluded to in varying degrees in six of the 17 interviews. For some participants this manifested as a fear (real or perceived) of forgetting doses, which had motivated them to instigate preventative solutions:

'It's as well to keep a note, because otherwise I'd forget ' (P13, intervention).

One participant described how he was in the routine of taking all his medication in the morning, and was struggling to remember the second daily dose of the new oral anticoagulant prescribed by the hospital*:*

'But for the second [dose], you know, I'll forget' (P52, intervention, no dMUR).

For other participants, a greater degree of cognitive impairment was compounded by other issues:

'Participant: I'm so forgetful, and I don't always hear. I know I've got a hearing aid, but I don't always hear' ... 'and I depend on [my family] listening ' (P7, intervention).

This participant also struggled with her manual dexterity:

'*Participant: I just can't do things with my hands any more'
Son: my mum was really struggling with some of the tablets, trying to pop them out of the packs, you know out of the actual foil packs'.*

Another physical barrier to adherence was eyesight*:*

'I can't really see them properly, so, it's a job!' (P24, control).

Opportunity

One participant felt that the complexity of her medication regimen was *'daunting',* and was in the process of having her solid medicines put into MCAs by her

community pharmacist, so that they would be *'all together, and at hand'* (P33, intervention).

Another participant was unaware of the technique for using his new inhaler:

'*I put that in my mouth, press it, and go 'it's not doing anything*
Wife: He doesn't take it properly you know. I don't think anybody's shown him how to actually use it!' (P52, intervention, no dMUR).

Motivation

Barriers to adherence concerning the opportunity to take medicines as agreed (such as a complex regimen) may also be compounded by motivational barriers. One participant in particular made several statements which may have reflected a lack of engagement in adhering to his complicated medication regimen, possibly stemming from a pre-existing belief that regarded 'pills' as 'taboo':

'You've got to understand that for 60 years, I would never take a pill. I wouldn't take a painkiller or nothing. Pills were taboo. I would never allow them in the house, until this. You know. And now all of a sudden I've got to take 20 pills a day.' (P52, intervention, no dMUR).

This participant also made comments that suggested he might be suffering from information overload from the multiple agencies involved in his care, which may have further reduced his motivation to adhere:

'So many people are telling me, that half the time it goes in one ear and out the other'

6. Medicines management systems at home

This theme was not included in the original interview schedule, which only planned to explore the subject in the context of support systems for any participants who were no longer managing their medication on their own at home:

'Son: I regulate her medicines, I put them all out in…
Participant: In one of those things (indicates 'dosette box' MCA)….
Son: so it's easier for her to remember what she's got to take and when' (P7, intervention).

However, following several participants volunteering details of their own personal solutions to potential adherence barriers, it was decided to explore this in more

detail across the interviews. It was hoped this could provide valuable insight into the barriers to adherence that exist in the older post-discharge population, and the development of solutions, whether through dMUR or another means.

Solutions to adherence barriers presented by participants included handwritten records or 'ticksheets' to record when medication is taken:

'I'll show you my list, of what I do..... I record every day, what I take' (P1, control) *'I'd already made a checklist'* (P49, intervention).

An alternative system, using annotation of the packaging of medicines with complex dosing instructions, was being used by another participant:

'I put the date on the box, when I started taking them, and I then I just take it every second day from there. So I'm not doing too bad on them' (P52, intervention, no dMUR).

In these cases, the participants were using these written records as a reassurance that medication has been taken and to act as a prompt for which medicines need to be taken when, and they formed part of the 'habit' of medication taking.

At least one participant had taken this idea a step further and re-dispensed her own medication into a 'dosette-box' MCA:

'I've got mine in, er, like now, I'll just show you…(fetches dosette box)….' (P3, intervention).

Community pharmacy dispensed MCAs had also been initiated for two participants since discharge. In one of these cases (P33, intervention) this was reportedly to simplify a complex regimen, and in the other (P 54, control) the reason was a lack of manual dexterity.

Some participants also found it valuable to keep a written record of medication changes*:*

It's as well to keep a note, because otherwise I'd forget' (P13, intervention)*.*

7. Discharge Medicines Use Review (dMUR)

Of the 17 participants interviewed, eight had had a dMUR following referral from the hospital. Opinions of the dMUR consultation were generally positive, with

participants using words such as *'helpful', 'useful'* or *'good'* to describe the experience. However others were less enthusiastic:

'Interviewer: *And did you find that it was useful, having that review with the pharmacist? (Pause)… Please be honest!*
Participant: *Er, well shall we say reassuring, I think' 'I'd been taking them [medicines] for quite some time, and they weren't new to me, the majority weren't new to me'* (P10).

'Yeah, it was alright' (P16).

One participant, who had reported being given good information from the hospital prior to discharge, indicated that the dMUR, whilst reassuring her that she was managing her medicines well, was more suited for a different type of patient:

'I did ask him some things, but I'd already made a checklist... but I can imagine that if you were given a load of tablets and didn't really understand them or anything, then yeah, or perhaps someone who was a bit confused, then yeah I think it would be really advantageous to see the pharmacist, yeah' (P49).

In terms of the content of the dMURs, most participants described a process of discussing each of their medicines in turn, with the pharmacist checking understanding of what the medicines were for:

'They went through each of the medications I was taking, asking me if I knew why I was taking the medications. To which I replied that I knew fairly well, why I was taking them' (P10).

'We went through all the tablets and he said, do you understand those things, well I already did' (P3).

However a different approach was taken during at least one of dMURs, whereby the pharmacist had asked questions of the participant and her son to ascertain what they knew already about her medication, then helped them to 'fill the gaps':

'Son: we told her about the aspirin, you know, them stopping the aspirin in the hospital, and putting her on the digoxin, put her on that, and she said, why was that?' (P7).

This consultation had helped the son gain a better understanding of his mother's medication:

'Son: It's better for me (laughs). I understand it a bit more.   I knew what all the medicines were for initially. But it's just understanding why she needs them'.

This dMUR consultation had also helped this participant's son gain an understanding of the more clinical role of the community pharmacist:

'Now it's becoming more involved… they have to be that buffer between the doctor and the patient. Because the patients are getting medicines that, really, why are they getting them? ...they are the people trained on the medicines and if they think a medicine is in conflict with another medicine, they knock it back to the doctor'.

Another participant had also valued the opportunity to ask questions of the pharmacist about their new medicines:

'...I asked him anything I wanted to about the medication. He explained a few things, things I wasn't sure about warfarin….So em, yeah he explained, I did ask him a few things about what you should and shouldn't eat, and he answered me' (P49).

Other topics discussed during dMURs, as reported by the participants, included logistics of obtaining further supplies of medication started by the hospital and the importance of checking interactions between prescribed and over the counter medicines:

'if I was buying anything over the counter, to always come and ask him if it was ok for me to take, that it doesn't interfere with any of my tablets' (P3).

One participant who had been hospitalised with an exacerbation of COPD, reported a discussion re her new inhalers and a check of inhaler technique:

'And he explained the inhalers and how they worked, and why I was changed to the different ones' (P33)*.*

Although most interviewees could describe what had happened during the dMUR, some aspects had been forgotten by the time of the interview, which was typically about 2 weeks later. One participant was still recovering from a subsequent illness which had affected her recall:

'It's very hard for me to remember…I'm very very tired now. I'll just try and think (long pause)...' (P33)*.*

Another requested further reinforcement of which medicine she was no longer to take: *'So that's… just write that name down for me, because….'* (P3)

It emerged during the interviews that one aspect of the dMUR process that varied between community pharmacists was the method of organisation of the dMUR. When describing their dMUR experience, most participants indicated that they had been contacted by telephone to arrange the dMUR, but some had taken place opportunistically when the participant had happened to be in the pharmacy:

'[pharmacist] said, have I got time to do it now, and I said yes we'll go through it' (P3)

'I went in on the Friday, and who was there but [pharmacist]!' (P48).

Difficulty in leaving home, due to ill health or poor mobility, was the most commonly reported barrier to dMUR discussed by interviewed participants:

'You might as well say I'm housebound. I haven't got the confidence to go out. At the moment….I couldn't do it. So I couldn't make it [to the pharmacy]' (P57, control).

'There's no-one to take me, so it's a taxi there and back, which is costly.' (P33, intervention).

Another barrier to dMUR identified through the participant interviews was a lack of perceived need by the patient:

'Interviewer: (Briefly describes dMUR). Is that that something you think you would have benefitted from? (Pause) Or…?
Participant: *No… I er, I think I'm reasonably intelligent…'* (P63, control)*.*

These tended to be the same participants who had felt they did not need much support from the hospital with regard to medication, either through background knowledge or preference for doing their own 'research':

'I could find out. Easily. Erm, and in this particular instance even easier than usual because my brother-in-law's a cardiologist... So erm, I haven't really needed it' (P32, control)

or because their personal desire for information was low:

'I don't think I really need to have a chat about my medication. As I say, I've been taking it for a number of years, and as far as I know it's doing the job. And I wouldn't know how to talk about it, anyhow!' (P62, control).

Patients' other commitments could also be a barrier to dMUR provision. The wife of one participant in the control group indicated that their community pharmacist had been about to offer a dMUR, but they had been unable to stay:

'He said I'm sorry I can't, we're on our way to a funeral! Otherwise, they were going to chat to him about it, yeah' (Participant 63, control).

At least one participant voiced the opinion that medicines should be reviewed by whoever prescribed them, and therefore a dMUR would be superfluous to requirement*:*

'...I expect that whoever's doing the prescribing is doing the reviewing. Or else what's the point?' (P32, control).

However some participants who had not had a dMUR indicated that they would have liked to have had one:

'Interviewer: So do you think that that's something that would have been useful for you to have?
Participant: Yes, yes. Yes it would. I don't know whether [in the hospital] I was mentally fit enough to understand….' (P54, control).

'It's useful to be reminded of these things, and not just take them for granted. I don't know half the things… the doctors say to me, what pills are you taking? and I say, I don't know! I just take them. You know. And that's me, and that's how… they never go through them' 'The pharmacy... we used to go to, she'd ring up and say call in, I want to talk to you about your meds. And she'd bring me in and go through the meds with me, which I thought was a good idea' (P52, intervention, did not have dMUR).

8. <u>General attitudes towards community pharmacy</u>

Conflicting points of view on the value of a dMUR may be influenced by the relationship a particular patient has with their community pharmacist. This was demonstrated by one control group participant, who had recently changed her pharmacy. When asked if she would have liked to receive a dMUR, she replied:

'I don't know really. Because, I used to go to [pharmacy], and they were a menace, they really were. They didn't have it in and you had to wait for it, and they couldn't get it and all this. So I stopped there. And I got this [new pharmacy]… And they're very, very much nicer than [previous pharmacy]. And I shouldn't say this but as regards pharmacists, [previous pharmacy] had different ones all the

time. Every time you go it's somebody different, and they don't know what's going on. But here, they know you. And it's the same ones all the time' (P57, control).

The importance of the relationship between patient and community pharmacist was a recurring theme during the interviews. One participant was in the habit of using her community pharmacy as the first port of call for medicines related information:

'If there's any doubt about anything, we usually go there before we go to the surgery' (P13, intervention).

Previous positive experience was an important factor:

'They're very helpful down there, and very approachable'.

The length of relationship was also important:

'It's always been a good pharmacy, you know, it's continued, erm. A bit different from when he [previous pharmacist] was there but, with the two girls there now, they're, the owner of the, the owner is called [name], he's got three pharmacies.' (P13, intervention).

'The girls in there understand me, I've been going for years. I don't have to wait in a queue now-a-days, I go in on my bike and they go, "Hello Mrs [Name], how're you doing?"!' (P16, intervention).

This long-standing relationship provided an opportunity for the patient to build up trust in the pharmacist and come to see them as a reliable source of support with medicines:

'I've got full confidence in [pharmacist] because I've had him for a number of years now and he's always explained things, and he's been a good deal of help to me' (P33, intervention*).*

'I have confidence in [pharmacist]...We'd talked about medicines long before this happened. I used to talk things over with him. He explained things and that helped.' (P48, intervention).

Another aspect of their interaction with community pharmacy which was valued by participants was the opportunity to have a private consultation:

'He spoke to me in confidence, there was area to speak to him in confidence, so that was good' (P49, intervention).

Most of the positive comments made about community pharmacy came from intervention group participants, whilst control group participants seemed more likely to express ambivalent or negative views of community pharmacy:

*'I have used pharmacies on occasion, but usually the questions are either in the leaflet or in the other leaflet you can get online' (*P32, control).

'Son*: I think, when you go in to the pharmacy, to the pharmacist, it makes you more stressed, doesn't it, when you go to see him?'* (P24, control).

9. Residual information needs surrounding medication

Participants who had not had a dMUR tended to express more unresolved information needs during interview than those who had. These related to duration of treatment, side effects*,* indications for new medicines, how to take medicines, monitoring requirements, interactions of new medicines with over the counter medicines, goals of therapy, obtaining further supplies of medication post-discharge and misunderstanding of previously given advice*.*

Methodological Themes/Limitations of Interview Data

Difficulty in discussing particular topics

Discussing the topic of medicines information (given or required) during hospital admission presented difficulties in some interviews, illustrated by pauses or participants avoiding giving direct answers to questions. Although not representative of all the interviewed participants, this may reflect a reluctance of certain patients to criticise the care they received or a desire to give the answers they thought the researcher wanted.

Vagueness in answers regarding who had discussed medicines with them in the hospital may also reflect that participants had met a lot of different healthcare professionals during their stay and had difficulty remembering who had given which information. This is understandable as being acutely unwell in hospital can be disorientating, particularly for elderly patients, and remembering six weeks later (which is when the interviews tended to be) who had given which information may be considered unimportant. In addition, 13 of the 17 interviewees displayed poor

or partial recall of the actual medicines information given to them in hospital. This suggests that sometimes the information from the hospital was either incomplete, or poorly recalled by the time of interview.

Digression of interviewer into HCP role

Knowing that the interviewer was a pharmacist appears to have led some participants to opportunistically ask questions regarding their medication during their interview, which otherwise may have remained unanswered. In other cases, a clear lack of knowledge or misapprehension regarding their medicines led the researcher to provide information or advice which the participant would otherwise not have received.

In order to analyse the extent and potential effect of this behaviour by the researcher, a further thematic chart was created which collated the trigger or prompt for each digression, the nature of the information provided by the researcher and any likely effect on outcomes for that participant. From this analysis, three control group participants had received advice approaching a full dMUR from the researcher, and therefore effectively 'crossed over' into the intervention group. An intervention group participant who had been unable to attend his dMUR also received this level of information. Potential to influence behaviour was also noted for the other intervention group participant who had not had a dMUR, and for an intervention group patient who had had a dMUR but required reinforcement of discontinued medication and advice on how to interpret her dose of warfarin. All other digressions were viewed as unlikely to affect patient behaviour.

Difficulty of participants with completing questionnaire

Two interviewed participants experienced difficulties in completing the follow-up questionnaire, which was posted to all non-interviewed participants but hand delivered to interviewed participants, who were asked to complete it before the interview commenced. In one case this was due to cognitive impairment, and in the other it was due to visual impairment.

Although not a theme of the interviews as such, this constitutes valuable data in the interpretation of why some questionnaires may have not been returned (or

returned incomplete), and provides a consideration in the planning of future research with this patient population. This is discussed further in Section 8.5.3.

7.5: dMUR DATA

Below are presented data related to the proportion of dMUR referrals which were completed by community pharmacists, reasons for non-completion, the type of interventions made during dMURs and the potential significance of these for patient care.

During the 9-month study, 30 patients were referred to their regular community pharmacist, resulting in 20 dMURs conducted (67% completion rate). Twelve (60%) were completed as per study protocol (defined as dMUR completion within 4 weeks of discharge). The others were completed after 4 weeks, following one or more prompts from the researcher. Table 7.11 shows the type of pharmacies used by those participants who were referred for dMURs during the study, and the completion rate (in total and as per protocol) by each pharmacy type.

Table 7.11: Type of pharmacies used by referred participants and numbers of dMURs completed by each pharmacy type

Type of Pharmacy	Patients Referred (% of all referrals)	dMURs completed (%)	dMURs completed per protocol (%)
Chain	14 (46.7)	10 (71.4)	5 (35.7)
Independent	12 (40)	8 (66.7)	5 (41.6)
Supermarket	4 (13.3)	2 (50)	2 (50)

dMUR completion rates and completion as per protocol between the types of pharmacy were not significantly different (chi-squared p= 0.4227 for the difference between the highest (chain) and lowest (supermarket) completers of dMURs and p= 0.1904 for the difference between the highest (supermarket) and lowest (chain) completers of dMURs as per protocol).

Patients being unable to visit the pharmacy or being non-contactable were the main reasons why dMURs were not completed as per protocol, although some

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pharmacists reported not receiving the original referral or this had been lost by the pharmacy (Table 7.12).

Table 7.12: Reasons given by community pharmacists for not completing a dMUR as per the study protocol

Reason for non-completion/ deviation from protocol	Number of Referrals Affected (% of all referrals)	dMURs remaining incomplete following prompt from researcher (% of all referrals)
Pharmacy had not tried to contact patient	1 (6)	0 (0)
Referral misplaced or not received from hospital	3 (17)	0 (0)
Patient non-contactable	5 (28)	2 (11)
Patient too unwell to attend pharmacy and domiciliary visit not feasible	6 (33)	5 (28)
Patient did not attend dMUR appointment	1 (6)	1 (6)
Regular pharmacist absent	2 (11)	2 (11)
Total	**18 (60)**	**10 (33)**

7.5.1: dMUR 'Action Plans'

The study protocol required that community pharmacists feed back to the researcher the outcome of each dMUR, in terms of advice given to the patient and actions undertaken. In total, feedback was received for 17 of the 20 dMURs conducted.

Thirty-five interventions were reported by community pharmacists. The most common type of intervention (n=14, 40%) was provision of information to improve understanding of why and how they were taking their medicines. Six interventions (17%) involved medicines reconciliation to ensure discrepancies between pre-admission and discharge medications were intentional and understood. Four interventions resulted in the provision or recommendation of a medication compliance aid (such as a monitored dosage system or a spacer device to aid inhaler technique).   Others included referral for monitoring (n=4) of their medication/condition and provision of lifestyle advice (n=3) (see also Table 7.13, page 217).

7.5.2: Impact of Community Pharmacist Intervention

To assess the potential clinical impact of the interventions made by community pharmacists during the dMURs in this study a peer review was conducted using Delphi methodology. Five of the 35 reported interventions were very similar in nature and for the purpose of the Delphi review were considered to be the same intervention. Hence 30 interventions in total were reviewed.

Eight participants (all five pharmacists, both academic clinicians and one of the two family doctors) returned Round One surveys, and seven participants (all five pharmacists, one academic clinician and one family doctor) returned Round Two surveys. Following Round Two, greater than 75% agreement in scores was achieved for 5 of the 30 interventions, although 8 more achieved 71% agreement. A further 8 achieved 57% agreement. When the percentage change in mean scores between Rounds One and Two were calculated, the variation was less than 10% for 28 of the 30 interventions, and less than 15% for all but one. This indicated that participants were not likely to alter their scores very much if a third round was undertaken and at the risk of further drop-outs a further round was not conducted.

None of the interventions made by community pharmacists were found to be detrimental to the patient's wellbeing. Fifteen interventions (50%) were assessed as being significant and leading to an improvement in patient care, whilst one intervention, where a prescription for pre-admission medication was identified and referred back to the doctor by the community pharmacist, was graded as highly significant and preventing major organ failure or adverse reaction of similar importance (Table 7.13). The value of the 'average' dMUR conducted as part of this study is therefore estimated to be between £112.53 and £254.53.

Table 7.13: Clinical significance of 30 interventions made by community pharmacists during dMURs and associated cost avoidance, as estimated using a Delphi process

Intervention	Eadon Score	ScHARR Cost Avoidance (£)
1. Patient discharged after acute coronary syndrome struggling to remember to take medicines as prescribed. Community pharmacist organised blister pack multi-compartment compliance aid (MCA)	4	65-150
2. Patient having difficulty with co-ordination of metered dose inhaler device. Patient not keen on breath actuated device so community pharmacist requested spacer from GP *(Unknown if spacer was actually provided)*	4	65-150
3. Patient discharged with atrial fibrillation newly prescribed antiarrythmics and warfarin. Struggling to remember if she has taken all medication so community pharmacist provided medicine administration record (MAR) sheet *(patient had previously been trying to produce own tick-sheet)*	4	65-150
4. Community pharmacist explained to patient the system for obtaining future prescriptions following discharge after a stroke	3	0-6
5. Patient had been buying antihistamine to help with skin itching. Community pharmacist suggested GP add this to repeat prescription *(Actioned by GP)*	3	0-6
6. Clopidogrel prescribed during admission for acute coronary syndrome for a patient already taking warfarin. Patient unsure of indication, and whether clopidogrel will be long term. Community pharmacist liaised with hospital pharmacy to find answer *(Clopidogrel to be discontinued after 12 months)*	4	65-150
7. Community pharmacist discussed indication for new medication (betahistine) and how to obtain further supplies.	3	0-6
8. Community pharmacist provided information on newly initiated furosemide - indication (heart failure) and how to take to manage side effects, for example can take at lunchtime instead of in morning if need to go out in morning, rather than skipping dose altogether to avoid polyuria (previous poor compliance)	4	65-150
9. Community pharmacist explained indication for new medicine (finasteride 5mg daily)	3	0-6
10. Patient prescribed iron supplements during admission and noticed dark stools following discharge. Community pharmacist reassured patient that darkened stools whilst taking iron supplements is normal	3	0-6
11. Community pharmacist reinforced counselling on apixaban (replacement for warfarin) as patient unsure of reason for switch and why blood tests no longer required	4	65-150
12. Healthy living advice given re diet and physical activity to patient with angina	4	65-150

13. Patient is a current smoker despite diagnosis of COPD. Community pharmacist provided smoking cessation advice *(unknown if acted on)*	4	65-150
14. Patient unsure of how to take some medicines and reasons for taking (patient has angina, diabetes and chronic kidney disease stage 3B). Community pharmacist reinforced times of day to take them and indications	4	65-150
15. Patient taking simvastatin in the morning. Community pharmacist explained rationale for evening dosing and patient changed time of dose	3	0-6
16. Lansoprazole removed from blisterpack MCA following discussion with patient to facilitate administration on empty stomach	3	0-6
17. Dispersible aspirin not being dispersed as placed in blisterpack MCA and patient could not identify it. Removed from blisterpack by community pharmacy to aid identification	2	0-6
18. Patient with osteoporosis not always taking Cacit due to forgetfulness. Community pharmacist discussed with patient and son, who will now help her remember to take it	4	65-150
19. Patient not taking senna regularly but still 'very constipated'. Pharmacist advised to try taking regularly	3	0-6
20. Patient had restarted isosorbide mononitrate which had been stopped during admission due to low blood pressure. This medicine was also still on repeat prescription. Pharmacist liaised with GP and isosorbide was discontinued.	4	65-150
21. Gabapentin still on current record at pharmacy. Community pharmacist ascertained that this had been discontinued and records updated to prevent re-ordering	3	0-6
22. Colecalciferol increased during admission. Community pharmacist updated their records accordingly	3	0-6
23. Bisoprolol stopped in hospital but no indication as to why. Re-issued by GP. Community pharmacist liaised with GP surgery to clarify situation. (Bisoprolol to continue)	3	0-6
24. Patient presented prescription for pre-admission medication which was identified by community pharmacist due to information provided with dMUR referral from hospital pharmacy. Prescription referred back to GP surgery. (Diuretic had been changed from bendroflumethiazide to furosemide, perindopril dose increased and warfarin and bisoprolol started)	5	713-1484
25. Community pharmacist asked GP to consider whether patient appropriate for steroid inhaler due to recent discharge following exacerbation of COPD requiring antibiotics and steroids. (Patient had been on no regular inhalers prior to admission although reported having been on inhaled steroids in the past. She had been discharged on salbutamol and tiotropium)	3	0-6
26. Patient started on warfarin during recent admission. Community pharmacist noticed INR had risen from 1.5	4	65-150

to 2.5 in 7 days with no dose change and patient had later seen blood (small amount) after going to toilet. Pharmacist arranged INR clinic appointment the next day.		
27. Pharmacist advised patient to consult GP if dizziness symptoms return, for review of blood pressure medicines (postural drop in blood pressure had been evident during admission)	3	0-6
28. Blood pressure medicines reduced in hospital. Community pharmacist re-checked blood pressure and it was 80/44mmHg. Pharmacist told patient to see GP.	4	65-150
29. Amlodipine stopped in hospital as perindopril had been started and blood pressure controlled by this. Patient started taking amlodipine again post-discharge as did not realise it had been stopped. Therefore taking both drugs. Pharmacist referred patient to GP.	4	65-150
30. Patient taking metformin and Novomix 30 insulin for diabetes was altering dose of metformin depending on blood sugars. Pharmacist advised this is not the correct way to manage their readings and advised patient to ring diabetes nurse for review.	4	65-150
Total cost avoidance		**£1688 - £3818**
Mean cost avoidance per intervention		**£56.27 - £127.27**
Cost Avoidance per dMUR (mean = 2 interventions per dMUR)		**£112.53 - £254.53**

7.6: COMMUNITY PHARMACIST QUESTIONNAIRE

Following referral of the final participant for dMUR, a self-completed questionnaire was sent to community pharmacists who had patients referred to them for dMUR during the study. A copy of this questionnaire is included in Appendix 32.

In total 21 pharmacists were traced and asked to complete the questionnaire and 19 returned it (90% response rate).

Thirteen pharmacists (68%) thought all participants referred to them were suitable to partake in a dMUR. The main reason for unsuitability (n=4, 21%) was patient inability to attend the pharmacy. In one case the pharmacist had been unable to contact the patient using the details on the referral and one pharmacist reported that they had not received the referral sent by the hospital. In terms of the time taken to conduct a dMUR, 60% (n=9/15 who answered this question) estimated a dMUR to take less than 20 minutes, with the remainder stating it took up to 40 minutes.

There were four instances (21%) where pharmacists felt they had received insufficient information from the hospital to enable them to conduct a dMUR. They

did not elaborate on the reasons for this. However, when asked in general what further information they would have liked to receive (see question 1 in Appendix 32), knowing the reasons for medication changes made in hospital (n=5) and the specific indications for new medicines (n=4) were most commonly reported. Despite most respondents stating referrals were suitable, concerns were raised regarding aspects of dMUR process. Seven pharmacists (37%) felt that it was hard to engage patients in having the dMURs, and spoke of '*patient non-attendance*' or the '*need to get special permission to conduct an MUR at home*', whilst eight (42%) stated that dMURs were '*more complex*' than other types of MUR.

Despite these concerns, community pharmacists agreed that dMURs would help patients to manage their medicines better after being in hospital and that adherence problems (n=19, 100%) and medication errors (n=17, 90%) would be identified and resolved sooner than they otherwise would be. Pharmacists saw value in the service with free text comments such as *'the dMUR referral service was excellent' or 'useful'* and *'not enough patients were referred'* or that they *'would love to have more involvement'.*

Eight pharmacists (42%) had performed dMURs during the study period which were not direct referrals as part of the service. Most (n=7/8, 88%) reported undertaking between one and five, although one pharmacist stated they had done more than 20.

CHAPTER 8: DISCUSSION

This chapter provides an evaluation of the findings of this research in the context of other recent and ongoing research and policy on the role of the pharmacy profession in the transfer of care of older people. Firstly, participant outcome data from this study are discussed, followed by the qualitative findings from participant interviews. Findings from the analysis of the dMURs conducted during the study are then evaluated. Then follows a section exploring the barriers and facilitators to the dMUR referral service, from the viewpoint of the hospital and community pharmacists involved in the feasibility study.

These sections are followed by an overall discussion which highlights the contribution of this research to the current knowledge base in this area and how this may be taken forward in future research and practice. The chapter finishes with a discussion of the limitations of this research and their implications.

8.1: PARTICIPANT OUTCOME DATA

All quantitative outcome data regarding readmissions, A&E visits, HR-QoL and medication adherence showed no significant difference between intervention and control groups at any time point (Tables 7.4-7.7). Whilst this is disappointing it is unsurprising as this was a feasibility study and the research was not designed or powered to detect such differences.   Rather, the suitability of the measures themselves to assess these outcomes during a future, adequately powered RCT was the matter under investigation. However, certain findings do generate hypotheses for further investigation, which are discussed in the sections below.

8.1.1 Readmission and A&E Data

Readmission figures in this study (Section 7.4.2) suggest that both control and intervention group participants in this study were at higher risk of readmission than the general elderly population admitted to hospital. This could be due to the high degree of polypharmacy (mean 9 medicines) and multi-morbidity (mean 4 comorbidities) among participants, which have previously been associated with preventable medication related admissions in older people (38,212,280,281).

These results might indicate that the clinical judgement of ward pharmacists in this study was effective in identifying patients particularly in need of post discharge support.

The trend towards a shorter length of stay on readmission for the intervention group (p=0.1713 in the ITT analysis at 4 weeks) is a key finding from this study. A reduction in the average length of readmission episodes has been observed previously in studies of the effect of an integrated medicines management service, including, but not limited to, copying community pharmacists into discharge medication, and, more recently, with electronic referral from hospital to community pharmacy (18,141,142). The current study therefore adds to the body of evidence that referral from hospital to community pharmacy may have potential to reduce the length of readmissions and a further, adequately powered study focussing on this as a primary outcome is warranted.

Furthermore, intervention group participants who adhered to the study protocol were 52% less likely to have at least one A&E attendance within 6 months of discharge than control group participants. Again, the lack of statistical significance of this result (p=0.3891) could be due to the small participant numbers involved.

There could be several possible ways in which dMUR interventions could lead to a reduced number of A&E visits or a shorter length of stay on readmission to hospital. As suggested during the HOMER study, pharmacist review could potentially help patients to recognise the signs of deterioration earlier so they seek help before their condition becomes too severe, thereby shortening length of admission, or preventing the need to attend A&E (134). However, no interventions of this nature were reported in the dMUR feedback from community pharmacists in this study.

Alternatively, patients' improved knowledge and management of their medication and sources of support after discharge could conceivably shorten a readmission by reducing the length of the medicines reconciliation process on admission and the complexity of the discharge procedure (for example the need to wait until social care packages can be implemented to provide support with medicines). Similarly, better medication adherence and organisation of ordering repeat supplies might

reduce the chance of an A&E attendance due to running out of medication or decompensation of a clinical condition following non-adherence.

Several of the interventions described by community pharmacists conducting dMURs in this study (Table 7.13, page 217) involved patient education on their medication regimen and ordering procedures for repeat supplies, introduction of compliance aids to increase independence with medication, or improved accuracy of GP, community pharmacist and patient held records. All these factors could improve adherence and continuity of treatment, thereby reducing the need to attend A&E with DRPs, or assist with medicines reconciliation and discharge planning if a patient is readmitted (thereby shortening their hospital stay). Conversely, interviewed participants who had not had a dMUR tended to express more unresolved information needs regarding medicines (Section 7.4.3). These included (among others) duration of treatment, side effects, how to take medicines, monitoring requirements, interactions with over the counter medicines and obtaining further supplies of medication post-discharge. DRPs related to any of these factors could precipitate an unplanned hospital attendance.

The National Audit Office recently reported that delayed discharges from hospital of elderly patients who no longer need to receive acute care are costing the NHS £820 million per annum (282). As such, any possible link between improved medicines management prior to (re)admission due to community pharmacy involvement, and the ability to be discharged sooner, is worthy of further investigation.

When interpreting the readmission data for this study, the timing of the readmission in relation to the timing of the dMUR must be considered. Two intervention group participants were readmitted before going on to have their dMUR, one of whom had two readmissions in this time period. Both participants were readmitted within two days of discharge, before the dMUR could reasonably have taken place. One of these participants was then readmitted again 21 days after the original discharge (15 days after the second discharge).

This situation raises the issue that if a patient is readmitted before receiving a dMUR they have been referred for, their medicines may change again. This would

render the medicines list on the original referral incorrect and could lead to confusion and incorrect advice being given unless a new referral is generated. However with good communication between the hospital and community pharmacy, a dMUR conducted under these circumstances could be highly valuable to the patient in clarifying changes and building confidence in their altered medication regimen.

The scenario presented above also highlights the importance of timing of the dMUR intervention. It has been suggested that the risk of medication-related problems is greatest in the 7 to 10 days after discharge from hospital, and that follow-up with a pharmacist should occur within 7 days or sooner for high risk patients (283-285). Examples from the current study included two patients who had had medicines stopped in hospital due to low blood pressure, but had started taking these again erroneously on discharge (Table 7.13). In a patient still recovering from an acute illness, this could quickly lead to adverse effects such as falls, with possible readmission. However early medicines reconciliation with the community pharmacist for patients with significant changes to their medication regimen could prevent this happening.

However, a compromise must be achieved between allowing time for a patient to recover from admission sufficiently to engage in the dMUR process, and making the intervention timely enough to address any medication related problems early enough to prevent them developing further. As described in Appendix 2, the PPI group for this study had mixed feelings about the optimum timing for the dMUR, with opinions ranging from as soon as possible after discharge to 4-6 weeks after.

It could be that early initial contact to answer any urgent queries, with arrangement of the subsequent dMUR intervention for a later mutually convenient date, would be the answer. This initial contact would not necessarily have to be by the pharmacist; it is possible that a suitably trained member of the pharmacy staff (e.g. accredited checking technician) could undertake the task of making contact with the patient, handing over to the pharmacist if any questions of a clinical nature arose.

This two-part intervention is analogous to both the NMS and the Welsh DMR service. In the DMR service, the part one intervention (medicines reconciliation) must be completed within four weeks of discharge, whilst there is no time limit on the part two (adherence review) element (20). As described in Section 4.5, the NMS consists of two consultations 7-14 and 21-35 days after the prescription of a new medicine (167). This is based on the finding that approximately one-third of patients may be non-adherent to new medicines at 10 days, and 25% remain so at 4 weeks. Over this time period, some problems may be resolved, but new ones also emerge (66). Indeed, participants in this PhD study demonstrated a range of medication support needs arising at various points following discharge, as evidenced by both dMUR feedback from community pharmacists (Table 7.13) and semi-structured interview data (Section 7.4.3). These ranged from confusion regarding the discharge medication regimen and/or incorrect resumption of medicines which had be discontinued during admission, which needed addressing immediately, to additional information needs (such as duration of therapy, side effects and interactions), which may only present themselves weeks after discharge.

8.1.2: Participant Questionnaire Data

Medication Reviews other than dMUR

Medication reviews with other HCPs in the month following discharge occurred at a similar rate in both intervention and control groups despite the provision of dMURs in the intervention group. GPs (or their practice nurses) were responsible for the majority of additional medication reviews carried out, although some were also conducted by specialist nurses not attached to the GP surgery. The exact purpose of these additional reviews, what exactly prompted them, and how they were communicated to the other HCP involved in the patients' care is not clear.   The variety of HCP reviewing one or more aspects of a patient's medication may reflect a co-ordinated response to problems.   However it seems likely that in patients having multiple reviews with different HCP there was at least some duplication of effort, reflecting poor continuity of care in a fragmented system. In this case, better

communication of the plan for the dMUR, and its outcome, might reduce the number of unnecessary reviews conducted and free up time for GPs and nurses.

From the pharmacist's point of view, a lack of knowledge of which services a patient is already receiving is compounded by uncertainty as to which aspects of medicines support are being delivered by these professionals. For a patient with several co-morbidities, a specialist cardiac nurse, for example, may not necessarily also check inhaler technique, advise on pain relief or provide a tick sheet for a patient who is having trouble keeping track of their regimen. A respiratory nurse is likely to advise on inhaler technique, but might not check the patient knows how to use their GTN spray. A community pharmacist providing a dMUR could potentially focus on any or all of these aspects as required by the patient. However, not knowing which other support the patient has recently received makes it harder for a community pharmacist to know which areas to target during the dMUR.

One interviewed participant who had been seeing a community psychiatric nurse described how the nurse was organising her a community pharmacy dispensed MCA. Interestingly, this participant had already had her dMUR when this suggestion was made and the community pharmacist had not perceived a need for an MCA. There could be a number of reasons for this, including that the community pharmacist had completed an assessment and decided that blister packs were not necessary or appropriate for this patient. Alternatively (or in addition) the patient's needs could have changed since the dMUR, or the nurse may have perceived something the pharmacist did not. Either way, the pharmacist and nurse being aware of each other's input would enable them to liaise in a timely manner over the best support plan for this particular patient.

The roles of the GP and their team (both HCP such as nurses and practice pharmacists and support staff), community specialist nurses and other services need to be considered when planning post discharge medicines support, so that different practitioners can work together. Any plan for medicines support organised by the pharmacy team should be clearly communicated to the patient's GP, and the hospital pharmacy team should also be aware of other follow-up organised for the patient, and communicate this to the community pharmacy team. Better documentation on discharge summaries of the planned clinical and social care

package for the patient, with contact details where possible, copied to all those involved, would be helpful in achieving this. Ideally, all healthcare professionals in primary and secondary care would have access to the same shared care record to which they could input their contributions to patient care and highlight concerns identified for another more suitable professional to address.

However, in the current study there was little evidence of pharmacists and GPs working collaboratively to get the best out of the dMUR service. Indeed, collaboration between community pharmacists and GPs regarding MURs of any type has historically been lacking (256,286-289). The GPs of all participants were notified that their patient was taking part in this study; however GPs were not told whether their patient was in the intervention or control group. It might be that if GPs were informed by the hospital that their patient had been referred for a dMUR, this would reduce the number of additional medication reviews performed; although this would need further investigation. Community pharmacists reported conducting few dMURs outside of this study, and where these were performed, patients were identified via changes to regular prescriptions or by the patient or their carer informing the pharmacy. Referrals from GPs where not mentioned as a source for initiating dMURs, despite some patients being uncertain or unapproachable regarding the service in hospital, indicating a role for screening and referral post-discharge in primary care.

Community pharmacist feedback did indicate that in some cases, the pharmacist had liaised directly with the GP to address issues arising as a result of the dMUR. However these tended to be where a specific problem with a prescription was identified, such as medicines discontinued by the hospital being restarted by the patient or re-prescribed by the GP. Where a more general issue was identified (such as low blood pressure in a patient who had had antihypertensive medication altered during hospital admission), pharmacists tended to recommend that the patient made an appointment with the GP, rather than contacting the surgery themselves. This approach has been raised as a concern during previous research with MURs, as it may result in problems remaining unresolved if the patient does not follow the pharmacist's advice (288). Comments made by some of the Delphi panel reviewing the dMUR interventions in this study also indicated

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that they would have ranked these interventions more highly if the pharmacist had liaised directly with the GP rather than relying on the patient. However the overall evaluation of dMUR interventions by the Delphi panel (Section 7.5.2) indicated that the majority did improve the quality of care. This highlights that there is an opportunity for GPs and pharmacists to work together to optimise the use of medicines, but as suggested by others, the potential of MURs may not fully be realised until there is progress made to improve GP–pharmacist collaboration (289).

Medicines Adherence Score (MMAS)

The MMAS in both study groups indicated overall medium to high adherence at both follow-up points, which may reflect over-reporting of adherence by participants, or recruitment bias, whereby adherent patients are more likely to agree to participate in the study at the outset. Both are known issues with adherence research (67,126,290).

When the change in adherence score between 4-week and 6 month follow-up was considered, it appeared that the control group experienced an overall deterioration (0.69 points) on the MMAS relative to the intervention group. Previous research has suggested that a change of 2 or more points on the MMAS over time is needed to represent a real change in adherence (291). However, these exploratory findings suggest that dMURs may help to prevent deterioration in medication adherence over time.

It has been suggested by other studies that effects on adherence do take time to develop following a community pharmacy intervention – in the NMS evaluation, significant differences in the MMAS were observed at 10 but not 6 weeks (292). A larger study of sufficient power is required to prove this data in relation to dMURs. The collection of baseline adherence measures would allow investigation of whether the differential change in adherence between groups represents an ongoing trend. However how meaningful baseline adherence measures would be in patients who have just been hospitalised for acute illness is questionable, and as discussed in Sections 5.3.2 and 5.3.3, there are concerns that introduction of

baseline questionnaires into the recruitment process might further limit participation rates.

<u>Health Related Quality of Life (SF-12v2)</u>

One interesting finding from this PhD study was that the mean physical health score at six months for intervention group patients was 5.39 points higher than for control group patients in the ITT analysis. Although not quite statistically significant, (p=0.0983), this could be due to small sample size. However it must be noted that the difference in the PP analysis was less at 2.81 points (p=0.3931). Nevertheless, along with the finding of a trend towards higher medication adherence over time in intervention participants relative to control, the possibility that dMURs could improve patients' self-reported physical health in the months following discharge is worthy of further exploration.

Mean HR-QoL scores for control and intervention groups at both follow-up time points, for both mental and physical health, were lower than the age adjusted population norms (Table 7.8, page 191). The low levels of HR-QoL reported by the participants in this study might impact on their ability to benefit from the dMUR service in its current form and indicate that a more intensive intervention tailored to their needs (for example including home visits) might be needed in order to make a difference.

<u>Enablement (PEI)</u>

The mean enablement score following dMUR in this study (3.69) was similar to the mean enablement score of 3.8 among patients aged $\geq$65 in Howie et al's original cross-sectional study of GPs' consultations (293).   However it has since been suggested that a PEI score of $\geq$6 is required for clinically meaningful enablement (227,239). The dMURs conducted during this study fell short of this mark, which could be due in part to the high levels of medication adherence reported by participants, leaving little capacity for improvement or enablement. Widening the scope of the current dMUR service by facilitating provision to patients of potentially greater need (for example, those who are housebound or receive significant help from carers with their medication) is relevant in this respect. Additionally,

consideration of the reasons for this, as presented below, could help improve the quality of future dMURs.

Howie et al found that enablement increases with the length of the consultation and knowing the doctor well.   Various pressures limit the amount of time pharmacists feel they can spend on an MUR with an individual patient, which may in turn reduce their ability to enable the patient (173,289,294). Previous research evaluating post-discharge medication reviews conducted by pharmacists has reported these to take between 30 minutes and one hour, whilst pharmacists completing a recent survey estimated that a 'standard' MUR lasts for around 10 minutes (20,126,128,134,174,202). In this PhD study, all community pharmacists involved estimated a dMUR to take less than 40 minutes, with nearly two-thirds estimating them to take less than 20 minutes.   Therefore, whilst taking longer than a 'standard' MUR, the majority of dMURs in this study seem to have been completed more quickly than other post-discharge medication reviews.

The importance of an established relationship with the community pharmacist in perceiving benefit from dMUR consultations was an emergent theme from the qualitative interviews conducted with participants in the current study (see Section 8.1.5 for further discussion). The formal association of enablement score with the relationship between pharmacist and patient was not within the scope of this study, but it seems likely that a consultation with a familiar pharmacist would have resulted in greater enablement, as is the case with GP consultations. This could have important consequences for community pharmacies who are staffed frequently by locums, with patients using such pharmacies potentially deriving less benefit from dMUR.

Terminology used to present the MUR service to patients may also be unhelpful in respect of the concept of enablement, with community pharmacy staff in an observational study describing the MUR as a 'quick check' of their medicines and one pharmacist in a qualitative interview study reporting introducing the consultation by asking patients if they had 'a few minutes' (173,294). While this was not the manner in which the service was introduced to participants during recruitment to this study, how they were subsequently approached by community pharmacists to arrange their dMUR may have differed.

Conducting a dMUR under this banner is unlikely to lead to a feeling of significant enablement. If enablement is viewed as a primary objective of the dMUR service (or indeed the MUR service as a whole), then the way they are promoted to patients and conducted may need to change. As the purpose of the MUR service is to improve a patient's understanding and use of medicines, and the definition of enablement is the patient's perception of their ability to understand and cope with their 'health problem' (substituted for 'medication' in this study), one could argue that enablement *is* a desirable outcome measure for the service. Therefore the concept of the dMUR as a patient centred discussion and review of the way they take their medicines, rather than a quick check or chat may need to emerge, and community pharmacists may need support to facilitate this.

The finding that participants who received their dMUR more than 4 weeks after discharge had a higher mean enablement score (although not significantly so) is worthy of further investigation, as the optimum timing of the dMUR remains open to question. Indeed, as discussed in Section 8.1.1, it has been suggested by others that early initial intervention is needed during the first week post-hospitalisation when the risk of medicines misadventure is highest. However data from this PhD study suggest that this may not be the optimum time to fully engage in concordant, 'enabling' discussions around medicines. This provides further support for the adoption of a two-part dMUR service, akin to the NMS.

8.1.3: Case-Note Analysis of Readmitted Participants

The difficulty in demonstrating significant reductions in hospital readmissions following an intervention was illustrated by van Walraven and Forster (295). They suggested that that 23% of all emergency readmissions are actually avoidable, and that in order to achieve a 20% reduction in total hospital readmissions, a 91% reduction in potentially avoidable readmissions would be needed. This analysis demonstrates that finding an intervention that can decrease overall hospital readmissions in a statistically significant manner is a challenge for clinicians and researchers, and may help to explain why no difference between intervention and control groups was found in this study.

The reduction in potentially avoidable medicines related readmissions may therefore be a more appropriate outcome to measure to the benefit of pharmacist interventions than overall readmissions. In the current study, the number of readmissions which were medication related and avoidable was judged using previously published criteria. Using these criteria, one in seven of the readmissions occurring within the 6-month follow-up period were judged as both medicine related and preventable, which is consistent with previous reports (46,102-105).

The finding that no preventable medication related readmissions occurred in patients who had completed a dMUR suggests that dMURs could be effective in preventing such readmissions. However this would need confirming in a larger, adequately powered RCT.

8.1.4 Semi-Structured Interview Data

Opinions of interviewed participants regarding medicines information given before discharge from hospital were influenced by their underlying expectations and perceived need for information. This in turn was determined by their background level of knowledge and experience of taking medication, the complexity of the changes that had occurred and their personal desire and capacity to be involved in and understand the changes. How closely the amount and nature of information given matched these expectations and capabilities then determined how positively participants felt about the advice and support given to them by the hospital about their medicines. Participants who described receiving information from several sources, particularly where conversations were backed up with written information, seemed to demonstrate greater confidence in and understanding of their medication, a finding which supports the work of others (296). Unfortunately, participant numbers were too small to triangulate these findings with more quantitative outcomes such as readmissions or adherence.

Access to further support following discharge could be reassuring, particularly if multiple changes had taken place. This finding highlights a role for dMURs as potentially being particularly beneficial for older patients who have experienced

multiple medication changes in hospital, and targeting of referrals to this patient group is one possibility for making the most of the service.

However, over half the interviewed participants displayed only partial recall of information regarding medicines given to them in hospital, and almost a quarter could not remember any discussion regarding medicines, or being given any written information to take home. It was not clear from the interviews whether information given was inadequate, poorly recalled, or a combination. Problems with processing and retaining information may result from underlying cognitive impairment, participants' acute medical condition, or the various other physical and mental stressors they were exposed to in hospital. These findings are consistent with other research highlighting unmet medicines information needs among discharged (or soon to be discharged) patients (8,83,86-89). Patients often meet a variety of health care professionals in hospital, including pharmacists, but have little time to learn their names or understand their roles. Schedules are often unpredictable, and in patients who are already under stress, information overload may provoke confusion (7). This highlights a role for dMURs in reinforcing or supplementing advice that was (or should have been) given for the first time in hospital. The experiences of participants in this study suggest that there is a large group of people who could benefit from the service.

Poor recall of information by some participants also highlights the need to include relatives and carers in the medication support process where appropriate. For participants with persisting cognitive impairment, a dependence on others to act as a proxy in the receiving, understanding and implementation of information about medicines changes was evident. All participants who enrolled in the study were required to have capacity to understand the implications of being involved and consent to participation, as well as the capacity to partake in the dMUR consultation, as these cannot be conducted solely with carers. As such, patients with moderate to severe cognitive impairment were screened out. However a number of participants with mild cognitive impairment were enrolled with joint agreement from family members. Interviews with two such participants and their family members were carried out and in these cases the perceived need of the participant for information about medicines was replaced by that of their family.

The importance of carers in assisting some participants in this study with their medication is likely to represent only the tip of the ice-burg, because most patients who were not independent with their medication were excluded. The fact that MURs cannot currently be conducted with carers is at odds with various guidelines which advocate their involvement in medicines management at care transitions where appropriate (76,110,297,298).

The absence of discussion regarding medicines as a result of a hurried discharge described by some participants emphasises the importance of, rather than reserving 'medication counselling' for the point of discharge, talking with patients about changes in medicines throughout admission. Despite a general lack of complaint regarding any information deficits that had occurred, most interviewed participants did desire knowledge of medication changes and a lack of information could prove unsettling. Types of information desired, which were perceived as lacking from the hospital, included discussion of the reasons for changes and indications of new medications, as well as potential side effects, which are similar to findings from other research (86,89,296). These aspects could be discussed with patients during a dMUR, as long as the community pharmacist was in receipt of suitable information from the hospital. This highlights the importance of sending information regarding the reasons behind changes and exact indications for new medicines to the community pharmacist, as without this information, the benefit of a dMUR may be limited.

In this PhD study, collaboration and information sharing between pharmacists in hospital and community settings was key and represents a major step forward in improving transfer of care. However, it could be argued that this needs to be done to an even greater extent, to allow tailoring of the dMUR intervention as advocated above. Community pharmacists who received dMUR referrals during this study would have liked more information regarding reasons for medication changes and the indications for new medicines, to facilitate patient centred discussions during dMURs. Although this information was provided on the referral form as far as possible by the researcher this was limited by the space available on the form and the researcher's knowledge of the participants.

Sending community pharmacists the full discharge summary completed by the patient's own ward doctor and pharmacist would be a way of providing more detailed information, as well as removing the requirement for hospital staff to complete a separate referral form. Concerns were voiced by the hospital pharmacist focus group in this study, regarding patients' confidentiality if community pharmacists were to receive the same discharge summary as GPs. However this could be incorporated into the patient consent process for the referral, and does not seem to have been an issue during implementation of the electronic Refer-to-Pharmacy system, which shares the whole discharge letter with the community pharmacist (17,299). Alternatively, the digital platform PharmOutcomes now allows pre-specified fields from the hospital's electronic systems to be pulled through into the community pharmacy referral, to allow targeted sharing of information (300).

Not all participants expected detailed discussions regarding medicine changes, which has also been found by other researchers (296). Even some participants who had experienced quite complex changes, or changes involving high risk medicines, such as NSAIDs or antiplatelets, expressed a low need for medicines information.   Some viewed the routine of the medicines round in the hospital as adequate preparation for taking their altered medication regimen at home and the labels on the medicine boxes and patient information leaflets (PILs) inside them as adequate direction. Others were used to taking multiple medicines, or had worked with medicines in the past and did not feel the need to have everything explained in detail.

These examples demonstrate the need to explore the specific information requirements of the individual patient during consultations about medicines (296). Results of this research therefore indicate that blanket referral of all patients with medication changes may not be necessary or desirable in the eyes of the patient. Targeting referrals using patient desire for support as well as the presence of factors such as age and multiple medication changes may be more productive. Professional judgement is needed in order to explore this further with the patient, or offer referral at a later stage (e.g. by GP practice pharmacists), as patients may have knowledge gaps that they themselves are unaware of, or only realise at a

later stage (66). This was demonstrated by medicines information requests from several participants during interviews in this study, the vast majority of which came from participants who had not had a dMUR.

Interviews revealed that despite all the guidelines that exist regarding transfer of medicines information between providers when patients are discharged from hospital, there are cases where the process still does not run smoothly. Moreover, delays and errors were described regarding high risk medicines such as warfarin. Two of the three participants where such an incident occurred were in the control group. In the third case, transfer of discharge information directly to the community pharmacy in the form of the dMUR referral had alerted the pharmacist to the changes in medication, enabling him to liaise with the GP surgery and ensure the patient's records were updated and a new prescription generated. This prevented an erroneous prescription being dispensed.

Interviewees described numerous barriers to using their medicines as agreed, including cognitive, physical, accessibility and motivational barriers, and in many cases had introduced personal strategies to overcome these. Solutions to adherence initiated by participants themselves included handwritten records or 'tick sheets' to record when medication was taken, annotation of medicine packaging and personally filled MCAs. This type of system is likely to work only if the patient is organised and motivated enough to keep it up to date, and where the main problem is a lack of confidence or low-level 'absent mindedness'. Despite these measures, complex dosing instructions could still cause confusion and repeated follow-up and checking of understanding by community pharmacists following a dMUR could be valuable.

Some participants also found it helpful to keep a written record of medication changes. Again, the importance of backing up verbal discussion with written information seems to be paramount for this patient group. This could be achieved by a dMUR either via a dMUR action plan, or other resources tailored to the individual patient, for example large print PIL or dosing instructions for a new medicine. Other assistance from community pharmacists as a result of dMUR may include medicines administration record (MAR) sheets to help patients keep track of doses taken, suggesting simplification of regimens (e.g. switching to once daily

dosing where possible), assisting with inhaler technique and performing assessments for introduction of MCAs.

At least one interviewee had altered their medication dosing regimen to fit in with their daily life. This participant (a retired nurse) was aware from previous advice or experience that the splitting of his diuretic dose was appropriate. However in a patient without this knowledge the side effect of polyuria may well have reduced adherence. Conversely, altering dosage regimens without prior discussion with a HCP may compromise the benefit of some medicines, or lead to adverse effects. This highlights the importance of concordant discussions to support adherence, which is a primary aim of the dMUR.

Opinions of the dMUR consultation from interviewees who had received one were generally positive. However participants who were used to taking multiple medicines, had support from other HCPs (such as specialist nurses) or who had been motivated to investigate and manage their own changed medication regimen following discharge were less enthusiastic. These responses further reinforce that dMUR referral is not desirable for all older patients, and again highlight the need for co-ordination of services, as well as better patient education as to what a dMUR is and what it can provide.

The concept of an initial contact by the community pharmacist (or suitably qualified support staff) following referral from the hospital has already been broached in Section 8.1.1. This early contact could help to gauge the patient's need for and engagement with the dMUR service, which could lead to a mutual agreement that an MUR is not needed at the present time. Equally, confirming a dMUR appointment with an understanding of what it will entail may avoid the need for some patients to see their GP for the sole reason of discussing discharge medication. If the GP was aware of the potential for a dMUR, they might signpost the patient to their community pharmacist rather than dedicate a valuable surgery slot to the purpose of confirming that the patient is managing their discharge medication. However in order to use dMURs to significantly reduce GP workload in this way will require increased collaboration between pharmacists and GPs, and greater confidence in the MUR service on the part of both patients and GPs, than is currently the case (287-289,301).

In terms of the content of the dMURs, most participants described a process of discussing each of their medicines in turn, with the pharmacist checking understanding of what the medicines were for. Comments made by three of the eight interviewees who had received a dMUR suggest that these participants had not learned anything new regarding their medication by attending, although one of these had found the consultation *'reassuring'*. These results mirror earlier observational research which found that MURs tended to follow a formulaic approach dictated by the 'MUR form' (294). Interviews with participants in that study also indicated that MURs did little to increase patients' knowledge and use of their medication, although some felt reassured about their medicines.

It is worth noting that the requirement to fill in the MUR form was removed in 2012, and replaced by a dataset to be collected following the MUR and a list of suggested questions designed to help shape the consultation (168). However, dMUR feedback received from community pharmacists in this PhD study (during 2014-15) showed that this form was still being used by a number of them. It may be that more support is needed to develop pharmacists' consultation skills to build their confidence in tailoring MURs to the individual patient's needs and addressing more complex issues such as underlying beliefs about medicines (289).

Identifying and addressing underlying beliefs about the necessity of medicines and any concerns which may affect a patient's motivation to adhere to their regimen is an important opportunity for the dMUR consultation. A fine line needs to be walked between empowering the patient with the knowledge they need to motivate them to manage their medicines, and overloading them so that they stop paying attention. Exploring the patient's needs and identifying the information that is relevant and important to them may be the key to this (302). However the extent to which community pharmacists are currently prepared to meet this challenge has been thrown open to question (289). Consultation skills training for pharmacists is available but as yet there is little evidence that it has been applied to MUR consultations to make them more patient centred (289).

Asking the patient to explain their understanding of the changes made in the hospital and why they were taking each medication, rather than simply asking the closed question of whether or not they understood, might be more productive in

highlighting gaps in knowledge and targeting where extra advice may be needed. This approach was taken during at least one of the study dMURs; interestingly a joint dMUR with Participant 7 and her son, who was her main carer (Section 7.4.3). This consultation had helped the son gain a better understanding of his mother's medication, and also the more clinical role of the community pharmacist. Increased awareness, among both patients and those who care for them, of what community pharmacists can offer could lead to more appropriate utilisation of HCP within the MDT. Thus, each member of the team is consulted according to their particular skills, avoiding the duplication of effort and more efficient use of healthcare resources.

Another benefit of a well conducted dMUR is the identification of which patients may need more support following their recent discharge, as a frail elderly patient may never reach their previous level of functioning following a hospital admission. This can provide reassurance to carers that the community pharmacy will work in partnership with them to support safe and effective management of medications for the vulnerable patient. This was also demonstrated during Participant 7's dMUR, with her son being reassured by the fact that now the community pharmacist knew they '*had to be a buffe*r' between the GP and his mother, in terms of medicines management.

The opportunity to ask questions of the pharmacist about new medicines was generally appreciated by participants. The resulting advice given had allowed one participant to relax the restricted diet she had imposed on herself following the initiation of warfarin by the hospital. Other topics discussed during dMURs included the importance of checking interactions between prescribed and over the counter medicines, the logistics of obtaining further supplies of medication started by the hospital, notably warfarin, and providing brief intervention advice, e.g. smoking cessation. These type of interactions demonstrate the potential for dMURs to provide a platform on which follow-up interventions or signposting to other services could be built.

Although most interviewees could describe what had happened during the dMUR, some aspects had been forgotten by the time of the interview, which was typically about 2 weeks later. It also became apparent during interview that some

participants had queries which had not been addressed during the dMUR, either because they had only arisen subsequently, or had been forgotten during the original dMUR. These examples give further support to the idea that multiple contacts might be needed as part of the dMUR process in some cases to fully reinforce and monitor changes.   Follow-up appointments could also be used to ascertain whether any recommendations submitted to the GP have been actioned. The NHS Summary Care Record, to which community pharmacists now have access, could be used to assist with this. Previous research has suggested that pharmacists get little feedback from GPs regarding recommendations forwarded to them following an MUR, so following up with the patient in this way could help 'close the loop' (286,288,303). These further appointments would, however, require appropriate remuneration for the community pharmacist.

One aspect of the dMUR process that appeared to vary between community pharmacists was the method of organisation of the dMUR. When describing their dMUR experience, most participants indicated that they had been contacted by telephone to arrange the dMUR, but some had taken place opportunistically when the participant had happened to be in the pharmacy. Although this approach may work for non-targeted MURs, where timing of the appointment is less important, dMURs are designed to be carried out within the first four weeks post-discharge. If the patient has been discharged from hospital with a month's supply of medication (as is often the case at SONT), they may not visit the pharmacy until towards the end of this time period. Indeed, in view of the difficulties with mobility experienced by many study participants in the early weeks post-discharge, it may well be that they themselves do not present at all unless specifically arranged, sending a representative to collect their medicines instead and thereby missing out on the opportunity for their dMUR.

Difficulty in leaving home, due to ill health or poor mobility, was the most commonly reported barrier to dMUR discussed by interviewed participants. As the intention was to screen out housebound patients at the recruitment stage of the study (unless their community pharmacy offered domiciliary visits), participants who reported during interview that they were unable to attend the pharmacy had

previously specified that they would be able to do so. The real size of this problem is therefore likely to be much bigger than described by the interviewed participants.

Some participants could attend the pharmacy, but only if a carer was available to assist. However this type of dMUR would be more labour intensive to organise, both for the hospital team, as consent from both patient and carer and their contact details need to be obtained and recorded in the referral, and for the community pharmacist to organise a convenient time for all parties to attend the dMUR. Still, as demonstrated during the interview with Participant 7 and her son, these dMURs may be worth the effort in terms of the benefit they provide.

Patients' other commitments could also be a barrier to dMUR provision. The few weeks following discharge can be hectic as patients re-adjust to home life and recover from their illness. As described by the interviewed participants, and reflected in the participant questionnaire data, there may be numerous other healthcare contacts, so that the dMUR may be perceived as unlikely to add anything to what their GP or the hospital can provide. It has also been found previously that patient willingness to have a discussion with a pharmacist because of recent hospital discharge is lower than other reasons for doing so, although the reasons for this are not clear (174). It could be that dealing with the aftermath of a hospital admission is perceived as beyond the competence of the community pharmacist, as it has been suggested that patients prefer to consult a physician for all but the most minor health issues (304).

Some participants in this study who had not had a dMUR indicated that they would have liked to have had one. Unsurprisingly, these participants tended to be those who had poor recall of events in hospital including advice regarding medicines. They also tended to be those who had difficulty leaving home in the early weeks post discharge (and so would have struggled to attend a dMUR at the community pharmacy). Paradoxically, the very patients who may be more difficult to interact with in the hospital to discuss and gain consent for the dMUR, and to physically access in the community to deliver it, may be those who stand to benefit the most from the consultation. These findings regarding the barriers to dMUR reflect other research, where poor patient mobility, low perceived need for the service,

preferring to speak to their GP and having carer support with managing medicines have been identified, with poor mobility being the most common barrier (305-307).

Participants who had not had a dMUR tended to express more unresolved information needs regarding medicines than those who had. These related to indications for new medicines, duration of treatment, side effects, how to take medicines, monitoring requirements, interactions with over the counter medicines, goals of therapy and obtaining further supplies of medication post-discharge. All of these points could have been addressed during a dMUR following receipt of medicines-related discharge information from the hospital. However, some (such as precise indication and duration of therapy) may have been difficult for the community pharmacist to address conclusively without such information, limiting the potential of a dMUR conducted under these circumstances. This may help explain why dMUR provision is so low in the absence of formal referral systems from secondary care.

Views on the value of a dMUR may be influenced by the existing relationship a particular patient has with their community pharmacist. Previous positive experience and the length of the relationship were important factors, with participants who had been using the same community pharmacy for a long time tending to have a more positive view. It would be interesting to link this finding with quantitative measures such as enablement in a larger study. Consistency of the responsible pharmacist, so that familiarity and trust was established, was voiced by one participant as an important factor in whether she would feel comfortable participating in a dMUR. Previous research has also found that patient satisfaction with pharmacy services tends to be higher when patients are loyal to one pharmacy where they have a good relationship with the staff and appreciate the overall atmosphere (308).

This raises issues for service provision from community pharmacies that are largely dependent on locum cover, or 'transient' pharmacists who quickly move on elsewhere. The 2013 General Pharmaceutical Council (GPhC) Registrant Survey revealed that 1 in 4 pharmacists working in the community setting are locums, compared to just 4% in hospitals (309). Moreover, over a quarter of community

pharmacists work part-time, which has further implications for consistency of pharmacist in the pharmacies they work in.

Another aspect of their interaction with community pharmacy which was valued by participants was the opportunity to have a private consultation. Participants' comments suggested that patients wouldn't necessarily expect a community pharmacy to have a private consulting room, further highlighting a need for patient education around community pharmacy services. These findings match those of others, where a perceived lack of privacy and confidentiality has repeatedly been raised as a barrier to use of extended pharmacy services, and it has been found that patients and the public are unfamiliar with the private consultation rooms offered at UK pharmacies since the introduction of the 2005 community pharmacy contract (304).

In such cases, experiencing a dMUR could positively impact on patients' overall attitude towards community pharmacy. This has been shown in previous research, where those who have experienced a formal community pharmacy service in the past have higher expectations and are more willing to use other services in the future (174,308). One example from the current study of how experiencing a dMUR had improved interviewees' perception of community pharmacy is the son of participant 7, discussed above, who had gained an insight into how the community pharmacist could provide support to ensure optimal use of medicines for his increasingly frail mother after attending her dMUR with her. It therefore seems that whilst having a positive existing relationship with a community pharmacist is linked to a positive dMUR experience as discussed above, a positive dMUR experience can also improve relationships going forwards, which has been found during other research (174).

However, for some participants in this study, the fact that they were already used to using the community pharmacy as a first port of call for advice on medicines may have reduced the impact of a separate dMUR consultation. Two participants described discussing medicine changes during their recent admission with their community pharmacist. Despite this, neither had been offered a dMUR at the time of their initial presentation to the community pharmacy. This suggests that sometimes community pharmacists may undertake at least some of the actions

required for a dMUR on an informal basis, but not actually acknowledge or develop the consultation as such.

A possible reason for this is that community pharmacists are more comfortable responding to ad-hoc requests for advice than in conducting formal MUR consultations, as suggested during previous observational research (294).   In one interview study of the effect of the MUR service on pharmacists' professional status, pharmacists described MUR activities involving advice giving and using their knowledge of drug interactions as '*just doing what we have always done*' (173). Some expressed unease about financial incentives and felt uncomfortable asking patients to sign MUR forms which would be submitted for payment. Additionally, it was suggested by the authors that MURs create an artificial interaction, and that advice offered in these situations, rather than occurring spontaneously as part of the everyday exchanges which patients are used to experiencing, may be resisted. However it could be that the development of these impromptu interactions into full MURs where appropriate, as in the case of the two participants described above, could be rewarding for both pharmacist and patient.

8.2: dMUR DATA

In this study, two-thirds of referred participants received a dMUR; more than twice that reported in a recent study of an e-referral system in North-East England (18). The higher completion rate in the current study may be because the researcher contacted all community pharmacists at 4 weeks post hospital referral to prompt completion of the dMUR. Such an approach, whilst feasible in this study, is unlikely to be sustainable on scale-up when accounting for secondary care pharmacy staff workloads. However, the ability to build a 'prompt' into an e-referral system may be a workable solution to help increase completion rates, and may allay concerns expressed during the hospital pharmacist focus group that some community pharmacists might not be 'pro-active' enough to follow up dMUR referrals (Section 7.1.3).

The most common reason for dMUR non-completion at 4 weeks was participants' inability to visit the pharmacy, which tallies with data from semi-structured interviews,

and was also a barrier in the e-referral study referred to above (18). This reinforces that poor mobility affecting the elderly post-discharge population, along with the complexity of providing domiciliary dMURs (see Section 8.3.2), is a major barrier to dMURs being conducted.

Nearly one-third of participants also failed to receive a dMUR within 4 weeks as they were not contactable by the community pharmacy. This issue was also found by the researchers evaluating the e-referral system. The reasons for this are unclear, although within the study around one fifth of patients were re-admitted to hospital within four weeks of discharge, and through participant interviews it was apparent that patients had multiple appointments as part of their care package post discharge. It is therefore possible that patients may not have been at home at the times community pharmacists tried to contact them. Alternative possibilities are that patients were not able to get to the phone in time due to mobility issues, were unfamiliar with the community pharmacy's telephone number and so did not answer, or that the contact details on the referral form were incorrect (18).

The same number of participants had not received their dMUR as the referral had never been received by the pharmacist responsible for conducting dMURs within that pharmacy. This reinforces that faxed referrals used in this study were not ideal, and additionally they do not have the same facility for audit trail as does an e-referral system, which allows for tracking of referrals (310).

Most commonly, dMUR interventions in this study involved the provision of information or adherence aids to improve patient understanding of their medication and how to use it in the most effective, convenient and safe way. This type of medicine support is in line with the ethos of the MUR service as a whole. However, 20% of dMURs involved intervention to reconcile unintentional discrepancies between discharge information and medications subsequently taken by the patient or prescriptions issued by the GP surgery. This is lower than in previous studies of medication discrepancies following discharge, although overall numbers in this study are too small to draw any conclusions (82,311). Reporting discrepancies was not a specific requirement of community pharmacists in the current study as this was not a pre-defined outcome measure. It is possible that other discrepancies were present but were not reported to the researcher by community pharmacists, possibly

because they were resolved outside of the dMUR consultation, or because of their minor nature (for example 'as required' medicines that were no longer being taken). Consideration needs to be given as to whether medication discrepancies would be a useful outcome measure for future studies of the dMUR service.

The timely information transfer from hospital to community pharmacy in this study allowed community pharmacists to act on the discrepancies identified before the patient's GP, thereby enhancing standards of care. All interventions of this nature were given a score of at least 4 (significant and resulting in an improvement in the standard of care) by the Delphi panel.

Following the Delphi review, almost 60% of interventions made during dMURs were deemed to improve patient care. In addition to interventions to resolve medication discrepancies, other intervention types assessed as improving quality of care (Table 7.13) could be broadly categorised into three groups. These included interventions that were expected to increase adherence to treatment (such as provision of compliance aids or counselling on how to take medicines to reduce side effects or fit in with daily routines), lifestyle advice specific to clinical conditions diagnosed during the recent admission (for example diet and exercise advice to a patient with angina, or smoking cessation advice to a patient with COPD) and onward referral to another HCP where a significant issue with treatment was identified (such as hypotension in a patient whose admission had been related to this and bleeding in a patient recently discharged on warfarin and clopidogrel). Interventions involving anticoagulant and cardiac medicines were always viewed as significant by the Delphi panel.

Interventions made during dMURs that were assessed as *not* improving the quality of care included explanations of repeat prescription ordering systems, updating of community pharmacy records, explaining indications for single medicines which may not have been viewed as 'essential' by the panel (e.g. betahistine), removing items from MCAs to be dispensed separately (with free text comments indicating the view that this defeated the purpose of the MCA), and interventions which were viewed as constituting clinical advice that may not have been appropriate (for example recommending a steroid inhaler for a patient discharged from a first exacerbation of COPD). Concerns have been raised in the past regarding inappropriate clinical recommendations made as a result of general MURs conducted in the absence of

sufficient clinical information (256,286). This non-clinical remit may be harder than ever to adhere to during dMURs if community pharmacists are provided with more clinical information by hospitals, and highlights the importance of collaborative working between hospitals, community pharmacists and GP teams (including practice pharmacists), with each team member playing to their strengths.

Although viewed as not improving the quality of care by the Delphi panel, it has already been discussed that improved patient knowledge of repeat ordering systems and accuracy of community pharmacy medication records may conceivably prevent DRPs in the future, by reducing the likelihood of patients running out of medicines or re-ordering medicines that have been stopped, and assisting with medicines reconciliation if a patient is readmitted to hospital (Section 8.1.1). This highlights the difficulty of assessing outcomes using qualitative consensus methodology, as it is not possible to predict accurately what the outcome of a given intervention will actually be, and the outcome assigned will always be based on the subjective opinion of the panel. However the methodology used in this study accounted for this as far as possible, by selecting a panel of experts with practice experience in the field in question, from both medical and pharmacy professions, and applying the Delphi process with due rigor. Overall, the significance of the interventions as assigned by the Delphi panel in this study represents a 'best estimate' of their value.

Assigning a monetary value to the interventions made by community pharmacists during this study appears to show a four-fold return on investment in the MUR service, even when using the most conservative estimate of value delivered per dMUR conducted (£112.53 of value set against the MUR fee of £28, Table 7.13). This figure does not, however, take account of hospital pharmacist time associated with patient recruitment, referral and follow-up. If these costs are factored in, there is still a substantial net cost saving to the NHS, of £42.53-£184.53 per completed dMUR.

Further savings could be realised if the dMUR uptake rate by eligible patients could be increased, and/or if referrals were managed by pharmacy support staff. E-referral also has the potential to reduce costs due to the reduced time needed to make referrals, although in this case the initial outlay for the system needs to be factored in (18). Preliminary work at SONT (Appendix 3) estimated that at least 5 potentially

eligible patients could be identified per day. Experience during the recruitment phase of this study suggests that just over half of these would actually be eligible. This equates to at least 780 referrals per year if all eligible patients were referred. If all these patients received a dMUR of the quality experienced in this study (producing £112.53 - £254.53 of 'value' as per Table 7.13, page 217), this would have an estimated net value of £33,173 - £143,933 in terms of improvements in the quality of patient care, after adjusting for hospital staff costs and MUR fees. If these referrals were managed by a Band 5 pharmacy technician, the overall net cost saving to the NHS resulting from dMUR referrals from this one hospital Trust would be around £72.93 - £214.93 per patient, or £56,885 - £167,654 per annum. This again represents a 4-fold return on investment for the NHS in terms of improved quality of patient care.

It must be noted that these savings are not immediately recognisable and are estimates only, using the application of economic modelling to opinions of an expert panel as to the clinical significance of community pharmacists' interventions. However, in comparison, the Welsh DMR has been estimated to provide a 3:1 return on investment as a result of avoided A&E attendances, hospital admissions and drug wastage (20). Therefore, although the current study is small and the cost savings presented are only theoretical, it does seem to suggest that dMUR referrals could provide similar return on investment.

8.3: MEDICINES SUPPORT REFERRAL SERVICE: BARRIERS AND FACILITATORS

8.3.1: Participant Recruitment by Hospital Pharmacists

Recruitment rates fell well short of those anticipated. Focus group findings in addition to a wider survey identified a number of possible reasons, as well as potential solutions. Perceptions of hospital pharmacists in this study support what has been published previously: that too much information at the point of discharge and the desire to get home quickly may limit patients' receptivity to advice on

discharge (77,81). Therefore, follow-up via a dMUR in a calmer environment could be beneficial.

Hospital pharmacists also identified some general principles of hospital policy and procedure that could hinder transfer of medicines related care. Key concerns related to poor discharge communication about medicines, the timeliness of information transfer and integration of medicines information with primary care records. These concerns reflect findings elsewhere as reported in Section 3.1.2 (42,68,75,76,82,312).

Poor or absent communication of medication changes on discharge summaries was identified by the majority of hospital pharmacists as a factor that needed to be improved in order for the dMUR referral service to be used effectively. The lack of clarity in written discharge information was largely attributed to the electronic (e-) discharge system at SONT which did not allow automatic flagging of medicines discontinued. It could be that if electronic transfer of discharge information to GP practices becomes routine, community pharmacies could also receive a copy of this information at the same time. In fact, improvement to the e-discharge system so that good quality referrals were easier and quicker to make was the most frequently mentioned solution for the dMUR referral service.

Electronic discharge information has been called for by community pharmacists for two decades, and e-referral to community pharmacy has subsequently been introduced in a number of areas of the UK, although it is far from becoming routine practice (120,121,299,313).

The most clearly stated barrier to making dMUR referrals was a lack of time. This has also been cited by others as a barrier to hospital pharmacists recruiting patients for post discharge referral (20,314). During this study and elsewhere, it has been reported that it takes an average of 20 minutes to refer a patient using a paper/fax system (310). This does not include the time taken to educate the patient and to gain consent for information to be shared between the hospital and the community pharmacy. It has been suggested that referral times can be reduced substantially using an electronic system, which, as discussed above, is

something that the hospital pharmacists involved in this study would welcome (299).

Lack of time to make dMUR referrals was linked with a lack of funding, meaning that other duties (which were funded) took priority for hospital pharmacists. Investing in hospital pharmacy staff was almost universally acknowledged as likely to make a substantial improvement to the dMUR referral service (equal to electronic transfer of information to community pharmacy). It would be interesting to investigate whether the concept of payment for dMUR referrals would encourage NHS pharmacy managers to invest in more staff time to allow referrals to community pharmacy to become more prevalent.

The need for increased staff was also found in a post discharge domiciliary service in Portsmouth (314). Hospital staff resources are identified as both a barrier and a driving force to post-discharge referral by the RPS, which cites the example of a local commissioning for quality and innovation (CQUIN) indicator as one mechanism to support the creation of efficient and effective referrals from local hospitals (310). However, as a CQUIN does not actually generate new money for a Trust, pharmacy managers would have to negotiate internally for additional investment to deliver on such a CQUIN.

Hospital pharmacists also acknowledged that referring patients to community pharmacy was not 'normal practice' for them, with many admitting to forgetting to look out for patients to refer.   This indicates that shifts in culture and working practices are needed among hospital pharmacists if referral to community pharmacy is to become routine. Integrating promotion of dMURs and the dMUR referral process into the established activities of hospital pharmacy, for example during routine discussions with patients regarding their medication, as well as greater promotion of dMURs to patients in the community, were identified as substantial facilitators to the referral service. Previous research suggests that awareness and understanding of MURs in general (and dMURs in particular) among patients and the public is low (174,289,315). It could be that increased awareness of the dMUR service among patients would mean greater acceptance towards referral.

A feeling of being distanced from community pharmacy services, and an uncertainty as to what actions community pharmacists would take as a result of their referral, was expressed by some hospital pharmacists. It has been suggested elsewhere that a local 'champion' or project manager with protected time to facilitate the roll-out of a referral system and drive forward the necessary behavioural and process changes at the hospital end is an important factor for successful implementation (310). Additionally, feedback on interventions made by community pharmacists as a result of the dMUR referral could reinforce the value of the service and recognise the hospital pharmacist's contribution to ongoing care, which has been called for by others (17,20) . It has also been shown that an opportunity for hospital pharmacy staff to shadow those involved in providing post discharge medication reviews can improve attitudes and increase the number of referrals (314).

Cardiac patients, patients prescribed new medication during hospital admission and patients using high risk medications such as anticoagulants were identified by focus group participants as those most likely to benefit from dMUR referral. These patient groups are already targeted nationally by the MUR service (9). However there was some doubt as to how individual ward pharmacists would cope with the additional task of selecting such specific patient groups for referral. Questionnaire results also revealed a difference in opinion of whether to focus on specific patient groups. Therefore the decision to specify a broad target group of patients over the age of 65 who, in the pharmacists' professional judgement could benefit from a dMUR (e.g. multiple medicine changes), appears appropriate. It has been suggested during previous quasi-experimental research and service evaluation that the clinical judgement of ward pharmacists as to which patients are at risk of DRPs post-discharge could be a valid way of identifying patients who can benefit from pharmaceutical intervention on transfer of care (18,122,150). This can simplify the recruitment process by removing the need for specific lists of criteria or risk-scoring mechanisms.

8.3.2: Community Pharmacist dMUR Provision

There was an almost universal willingness (95% of those approached) of community pharmacists to be involved in this study. They held positive opinions of the dMUR service and could see the benefit to patients regarding identification of medicine non-adherence and avoidance of medicine errors. These positive attitudes mirror those of the hospital pharmacists involved in the study.

However, running the current service posed challenges to community pharmacists. Around a third of questionnaire respondents felt that it was hard to engage patients in having dMURs and this was exemplified by patients not attending appointments or reporting themselves unable to attend when contacted to arrange the dMUR.

In particular, the difficulties perceived in providing dMURs other than face-to-face in the pharmacy limited the scope of the project, with only 1 in 7 offering domiciliary visits. Whether this was a logistical inability to do so or uncertainty as to whether permission would be granted by the primary care organisation was unclear. However, responses did indicate some degree of confusion around the procedure required to obtain permission to carry out telephone and domiciliary MURs. This is possibly due to these pharmacists not having performed such MURs previously, as reports indicate that the majority of MURs take place in the pharmacy (102,286,316,317).

Contractually, a pharmacist has to gain approval by the local NHS England Team each time they wish to provide the MUR service at another location, or by telephone (168). Additionally, NHS England requires that any pharmacist undertaking an MUR off the pharmacy premises must have obtained and supplied to them an enhanced Disclosure and Barring Service (DBS) certificate before providing the service. These administrative burdens placed on pharmacists could be seen as barriers to extending this service beyond the confines of the pharmacy. Legally, a community pharmacist can only leave the premises unsupervised for a maximum of two hours per day, during which time no prescription medicines may be handed out (even if assembled and checked) or pharmacy medicines sold (318). Although this should be ample time to provide a domiciliary dMUR, previous research has shown community pharmacists may feel professionally uncomfortable

in leaving the premises unsupervised (319). Additionally, being absent from the premises and therefore unable to hand out dispensed medicines or sell pharmacy medicines may be seen as potentially damaging to business. Furthermore, the associated costs, for example initial outlay for DBS clearance (although this should be reimbursed by the local NHS England Team), and travel costs to a person's home each time they provide off-site dMURs, may also be off-putting for community pharmacists.

One pharmacist in this study did obtain the necessary permissions and conducted a domiciliary dMUR. Another attempted to obtain DBS clearance, but the length of the process was prohibitive and in the end this participant did not receive a dMUR. Further exploration of the specific barriers to domiciliary MURs as perceived by community pharmacists would be valuable in order to understand fully the difficulties involved and propose solutions. This is particularly relevant for the patient population under study here, as so many reported problems in accessing their community pharmacy for a dMUR.

Nearly half of community pharmacists felt that dMURs were more complex than other types of MUR. Given the number of medication changes which take place for older people during a hospital admission this is not surprising (77,104). It might also be expected that reviews involving these patients would result in a longer length of time needed to perform a dMUR compared to a 'standard' MUR, which under the current system for remuneration and pressures faced by community pharmacists, may be a restriction on their provision. As discussed in Section 8.1.2, whilst taking longer than a 'standard' MUR, the majority of dMURs in this study seem to have been completed more quickly than other post-discharge medication reviews. It may be possible that the referrals from the hospital provided a focus for the dMURs and allowed the pharmacist to spend less time 'fact finding' with patients, although this is unsubstantiated.

Community pharmacists in this study wanted more patients referred (with a fuller data set) but reported performing few dMURs outside the study. Reasons for this given by community pharmacists during previous qualitative research include not knowing patients have been in hospital, no access to discharge summaries and patients being housebound (165,320). The first two of these barriers are

addressed by referral systems such as the one presented in this thesis, and the need to improve provision of the service to housebound patients is one of the main findings of this research.

The difficulties in providing this type of service have also been observed in studies based in Northumbria and Kent, where almost 30 and 65% of people respectively were prevented from accessing a dMUR due to mobility or poor health (306,307). The fact that these patients were housebound may in itself indicate that they are frailer and more vulnerable, and therefore more in need of the support a dMUR may provide.

All patients but one approached during recruitment were able to nominate one particular community pharmacy to provide their dMUR. The results of this research also concur with other recently published questionnaire data indicating that 95.6% of medical inpatients with medication changes used the same pharmacy regularly (89). This loyalty can be viewed positively as data suggests patient loyalty is key to the successful transfer of information between hospital and community pharmacy (120,123,124).

8.4: OVERALL DISCUSSION: IDENTIFYING THE WAY FORWARD

It has been suggested that, because of the link between DRPs on transfer or care and adverse clinical outcomes, pharmacists may be the preferred HCP to intervene and reduce the risks involved in care transitions (159). Since work on this PhD project began in 2012, there has been a sharp increase in the volume of research and recommendations for practice published on the role of pharmacists in transitions of care and supporting medicines adherence in older people generally.

Evaluating the dMUR referral service against the findings and recommendations from the published literature indicates that the intervention incorporates many of the components necessary for a positive effect on patient outcomes, and also identifies other aspects which may increase its effectiveness.

For example, a systematic review published by Nazar et al in 2015 included 14 controlled trials involving community pharmacists in the transition from secondary to primary care (160). The authors concluded that medication errors following

discharge can be reduced by interventions involving community pharmacists; however impact on other outcomes such as readmission, mortality, medication adherence, QoL and patient satisfaction was not significant. All the studies included in that review differed in important ways from this PhD study: none evaluated dMURs, most did not focus on older patients and two excluded them entirely. This study appears to be the first to investigate the effects of this intervention in this patient group.

Ten of the 14 trials involved in Nazar's review involved either additional training or funding for community pharmacists providing the interventions, at least eight involved domiciliary visits from the community pharmacist, and six included repeated contacts between community pharmacists and patients. All of these factors have been identified by other researchers as integral to successful interventions to support transfer of medicines related care and/or medication adherence in the elderly (135,298,321). However, none of these key factors were possible within the constraints of the dMUR referral service studied here, which may have limited its effectiveness. Therefore, additional training, support for domiciliary visits and funding to provide follow-up appointments are all recommendations arising from this PhD research to enhance the dMUR service.

Other components of pharmacist interventions from continuity of care programmes that have been shown to improve clinical outcomes include combining interventions in hospital and primary care, sharing of patient information between the two sectors, close collaboration with other HCPs and tailoring of interventions, for instance by assessing individual patient knowledge of prescribed medications and adherence (159,321).   A successful review should also include the involvement of carers (135,298).   The extent to which these factors were successfully applied in the intervention studied in this thesis is discussed below.

Feedback from hospital pharmacists involved in this study indicated that for a referral service to work, it needs to be quick, simple and regularly promoted until it became part of routine practice. It would be integrated with the hospital's e-discharge system and staff would be supported with adequate time to ensure that patients are properly engaged and all necessary information regarding medicine changes are included. These findings are supported by the guidelines given in the

RPS toolkit on post discharge referral (310). Giving community pharmacists access to the full discharge summary (or suitably targeted fields as made possible by PharmOutcomes) would allow them to gain an understanding of the clinical and social follow-up planned for the patient and allow them to tailor their input accordingly.

However the provision of more detailed information from the hospital would only improve the quality of the intervention if it was used effectively by community pharmacists. Previous research on the content of MURs in general, and on other post-discharge medication reviews by community pharmacists, has indicated that they tend to follow a set formula of closed questions and information delivery in an instructional manner, circumventing more complex or indeterminate issues if these arise (288,294,315,322,323). This may result in consultations becoming 'routinised' and leaves little opportunity to address the patient's own specific agenda. Descriptions of dMUR interactions by participants interviewed in the current study suggested that the formulaic approach still tends to be the norm, although more patient focussed experiences were also described. It has previously been suggested that pharmacists can have a greater impact on patient satisfaction through greater interpersonal skills than through the provision of new services, and this is important in building concordant dMUR consultations (308). It has also been suggested that community pharmacists' consultation skills need to be developed if the MUR is to meet its intended aims, and this recommendation may be even more important for dMURs, given the complexities of medication changes which may occur on transfer of care (294).

The shortfall between the current MUR service and the needs of some patients was highlighted in Richard Murray's '*Review of Community Pharmacy Clinical Services'*, published in December 2016 (324). Murray recommended that MURs should be redesigned to include on-going monitoring and regular follow-up with patients, ensuring that they are an integrated part of a multifaceted approach to helping people with LTC that includes medicines optimisation, providing advice and helping people stay well. Furthermore, the report stated that MURs should evolve into full clinical medication reviews, utilising independent prescribing as part of the care pathway. For these to be safe and effective they would require access to a

patient's full medical record. Transfer of care and referral schemes to support dMUR provision were specifically advocated by the Murray review.

However by December 2017 there appeared to have been little progress towards realising Murray's aspirations (325). Many of the barriers to the development of clinical roles in community pharmacy identified in the Murray review are similar to those identified by this PhD research: lack of integration of community pharmacy with other parts of the NHS, low public awareness and expectation, contractual and financial constraints, workload issues, variation in development and use of skill mix and a lack of professional and clinical confidence. Solutions proposed are also similar: incentives to encourage better working relationships with GPs and other HCPs, better access to clinical records, public awareness campaigns, financial incentives for provision of enhanced clinical services, support for pharmacy professionals to develop improved consultation skills, a training and mentoring framework to support development of enhanced clinical skills, and development of the technician workforce to free up pharmacist capacity.

In return for making referrals and to sustain the momentum of referral systems, hospital pharmacists in this study and elsewhere have requested feedback from community pharmacists as to the outcomes of the dMUR (17,20,314). This could include further requests for clarification of information or suggestions for patient management by community pharmacists which would fulfil the two-way communication suggested as necessary for a beneficial medication review.

This study achieved a lower recruitment rate than many previous studies of post discharge pharmacist follow-up (see Section 8.5). However, a recent RCT involving faxing of discharge prescriptions from hospital to community pharmacy, using a similar recruitment process to this study, reported recruitment of 23% of patients identified by ward pharmacists (311). This similarly low recruitment rate demonstrates that recruitment of older patients from English hospital wards for post-discharge follow-up by their community pharmacist can be problematic. Lack of perceived benefit, poor health and mobility problems have been cited previously as common barriers to recruitment of elderly patients to research (176,177). All of these barriers were present in this PhD study, where the main reasons for exclusion were that patients were not in charge of their own medication at home, or

expected to be housebound in the weeks following discharge and therefore unable to attend for a dMUR. These patients represent some of the most vulnerable to DRPs and therefore may have the most to gain from the service. Consideration needs to be given as to how the dMUR referral service might be extended to include such patients.

The PPI group for this study reviewed both the participant information and consent forms and agreed they provided a reasonable compromise between readability and providing all the necessary information. However some potential participants who cited an unwillingness to become involved in research as their reason for refusal may have been put off by the volume of information presented to them and indeed some patients struggled to read it at all. Burdensome recruitment processes have been cited by previous researchers in this field as a reason for low recruitment rates and it may be that consideration needs to be given to how recruitment processes could be simplified for elderly patients, particularly in the hospital setting where potential participants have so much else to deal with (129,133).

It must be remembered that even if all eligible patients were to receive a dMUR, a large proportion of patients who could potentially benefit will still be excluded, either because they are housebound or have carers managing their medication. The recommendation that post-discharge consultations between patients and community pharmacists should be conducted at home echoes a recurring theme throughout this thesis (321). A study of home medication reviews conducted by community pharmacists in the Netherlands suggested that patient interviews at home may elicit more and other DRPs to those conducted in a community pharmacy, with a possible explanation being that patients feel more comfortable at home and therefore are more likely to share their experiences and concerns about their medicines (326). Furthermore, all medicines are available at home, whereas patients invited to the pharmacy might forget to bring some of their medicines, especially those that are used intermittently. The authors also suggest that certain medication-risk factors, for example, lack of medication administration routine, multiple storage locations, hoarding and medication storage conditions may only be identified by home visits. The recent International Pharmaceutical Federation (FIP) Report, *Use of Medicines by the Elderly: The Role of Pharmacy in Promoting*

Adherence also highlights the advantages of medication review occurring in the patient's own home, in terms of the level of detail that can be reached regarding problems that patients encounter with their medicines, such as polypharmacy and interactions, and the opportunity to assess the usage of over-the-counter medicines and alternative medicines (298).

Therefore if the current study had involved domiciliary dMURs as routine, the number and significance of the interventions made may have been greater, particularly as the elderly housebound population may be frailer and at greater risk of DRPs compared to more mobile patients (327). However as acknowledged by the FIP, home medication reviews are time consuming for pharmacists and divert them from their dispensing workload, and remuneration arrangements are often cumbersome or inadequate (298).

Workload pressures which may impact on the provision of the dMUR service by community pharmacy could be addressed by taking a team approach to actioning the referral and completing the dMUR. For example support staff could be involved in ensuring faxed referrals are not ignored or lost, booking dMUR appointments, 'chasing up' patients who are difficult to get hold of, completing accuracy checks of prescriptions thereby allowing more time for the pharmacist to complete the dMUR and explaining the project to new employee or locum pharmacists.

A pilot study of a domiciliary MUR service across the Nottinghamshire and Derbyshire region indicated that the service was feasible, although less than a quarter of pharmacies invited to take part actually did so (316). This was despite being paid £56 per domiciliary MUR in addition to the £28 MUR fee, which indicates that there are factors other than remuneration limiting the provision of such services. The authors suggest that pharmacies may not yet have reconfigured levels of support or organisational infrastructure to comfortably undertake such services. The requirement for community pharmacies to be under the direct supervision of a pharmacist in order to hand out prescriptions or sell pharmacy only medicines is likely to be a barrier in this respect. Additionally, experience in this PhD study suggests that some community pharmacists may be

put off by the process required to obtain permission to conduct a dMUR off premises.

Self-assessment by the pharmacists in the domiciliary MUR study, using the RiO score, suggested that over one-third of the MURs had contributed towards preventing a possible or likely emergency hospital admission or readmission. Additionally, over one quarter had resulted in the removal of unwanted or out-of-date medicines from the patient's home. This contribution to patient safety is unlikely to have been possible during an MUR conducted in the pharmacy, and may be relevant to an even greater extent when the patient has recently been in hospital, due to the frequency of medication changes which occur in this setting. This was demonstrated by the Portsmouth Hospital Discharge Medicine Review Service, where hospital pharmacy staff identified suitable patients for a visit by a domiciliary pharmacist within seven days of discharge to conduct an MUR style consultation and medicines cabinet check, with follow-up visits at five and 13 weeks (328). Service evaluation indicated that around half the patients visited had obsolete medicines requiring removal.

Around half the community pharmacists involved in this study were able to offer telephone dMURs, whereas only one in seven could offer domiciliary visits. There were therefore some patients approached for participation who, although unable to visit their community pharmacy for a dMUR or receive a domiciliary visit, would have been able to access the service via telephone. However no participants were recruited to the study on this basis, and in fact three patients refused to take part if a telephone dMUR would be their only option. Other patients were excluded because they felt unable to manage a telephone MUR (either because of cognitive or hearing difficulty). Unfortunately the exact number of patients this affected was not recorded separately from the umbrella group of those who were excluded because poor mobility prevented them from visiting the pharmacy in person.

The resistance by potential participants to receiving dMUR by telephone was predicted by the PPI group for this study, and it has also been found that nearly half of respondents to a public survey would be uncertain or unwilling to receive telephone follow-up from their pharmacist (174). This is in contrast to two large scale evaluations of community pharmacy services which have experienced

success with using telephone follow-up: the Wales DWR service and the NMS (20,292). The NMS evaluation found that the majority of consultations were carried out by telephone (292). Face-to-face appointments were described as difficult to organise or arrange because patients often did not attend and this was seen as potentially disruptive to workflow. However it was also acknowledged that telephone follow-up was not appropriate for all patients, for example where checking of inhaler technique or demonstration of how to take a medicine was required. Additionally, the NMS is different to the dMUR as it involves discussion regarding one medicine only. It cannot be assumed that telephone follow-up will be appropriate or acceptable to patients who require more complex interactions relating to their entire medication regimen.

The DMR is more similar to the dMUR as it involves follow-up of the patient's post discharge medication as a whole. The DMR evaluation also revealed that telephone consultation was the most common way of completing both part 1 (medicines reconciliation) and part 2 (follow-up discussion) part of the service (20). However, most community pharmacists who were interviewed as part of the evaluation reported that they tried to do the follow-up face-to-face as this was felt to be the better method to discuss adherence issues. Time, availability and financial constraints were seen as the barriers to this. It could be that, if more support was available for pharmacists to conduct domiciliary DMRs the service would have been found to be even more effective.

It should also be noted that the DMR service remunerates pharmacists for two contacts with the patient or their carer, whilst the dMUR is assumed to be completed in one consultation and may be with the patient only. Two telephone consultations may allow for clarification of points which were misunderstood or forgotten following the first consultation, and the discussion may be handed over to the carer if the patient has difficulty or is unwilling to use the telephone. Importantly, this PhD research targets older patients, who may have specific difficulties (such as hearing or cognitive impairment) which may limit their ability to participate in an effective telephone review.

Previous studies evaluating pharmacist telephone follow-up post-discharge have shown inconsistent effects on outcomes (77,131,148,200,329). It has been

suggested previously that face-to-face consultations with a pharmacist post-discharge may offer additional benefits over telephone interventions due to the use of nonverbal communication to assess for understanding, and the ability to review correct use of medical devices such as inhalers and injections (330).

Evidence of the need for caution and careful patient selection when conducting telephone medication review for complex elderly patients comes from an RCT in the USA which evaluated the effectiveness of a community pharmacy telephone medication therapy management (MTM) service on reducing hospitalisations among home health patients (331). The average age of participants (n=895) was 73 and they were taking an average of 14 medicines. The results showed no significant difference in 60-day hospital admissions between intervention and control group (20% vs 23%, p=0.19). However, when participants were evaluated based on their calculated risk of hospitalisation, those in the lowest-risk intervention group were significantly more likely to remain out of the hospital at 60 days (5% vs 16%, p=0.01). The authors suggest that these lower risk patients were better able to receive and retain guidance from a pharmacist over the phone and that face-to-face medication therapy management would better help the higher-risk patients. This subgroup may require more intensive assistance to take medication, and a telephonic MTM program may not be sufficient to meet their needs. The 30-day readmission rate in this PhD study was 19%, which, as discussed in Section 7.4.2, is higher than national figures and is comparable to the 60 day admission rate in the MTM study. Participants in this study were also older (mean age 78) than the MTM patients. These factors suggest that participants in the current study were high risk for readmission, and may not have benefited from telephone review of their medicines in the same way as a lower risk population.

Involvement of carers in the transfer of care intervention in this PhD study was limited by the prohibition on conducting dMURs directly with them. Advice given during a dMUR may arguably be even more important for patients who require carer support with their medicines, as they may be frailer and therefore more vulnerable to DRPs. The carer may also not have been present in the hospital at the point of the changes to the patient's medication being made or at the time when the hospital pharmacist was available for counselling, so may have missed

out on the chance to obtain advice. In a 1998 UK study of pharmacy discharge counselling, the authors raised a concern regarding the low level of counselling of relatives, many of whom were involved in medicines management at home (125). In that study, the relatives of 6% of patients were counselled, whereas follow-up interviews indicated that up to 30% could have benefitted from medication counselling of their relatives. More recently, a qualitative study involving interviews with seven older people and 12 carers revealed that, despite the carers assuming a significant responsibility for the administration of medicines, they were often disappointed with the lack of clear verbal or written information given regarding discharge medicines (86). This sometimes led to incorrect use of medicine at home and confusion and anxiety for both the older people and their carers.

The importance of involving carers in the discharge process, including medication management, has been emphasised by a number of guidance documents. *Moving patients, Moving Medicines, Moving Safely* advised that support should be given to *'individuals and their carers'* who require help to develop the knowledge, skills and confidence to care for themselves and their condition effectively (76). Similarly, one of the four key principles laid out by the RPS transfer of care guidance is that '*patients or their carers or advocates'* should be encouraged to be active partners in managing their medicines when they move, and know in plain terms why, when and what medicines they are taking (110).

Since the commencement of this research, NICE has recommended that carers and all health and social care practitioners involved in someone's move between hospital and home are in regular contact with each other to ensure the transition is coordinated and all arrangements are in place (111). Additionally, the FIP report makes repeated reference to the role of carers in supporting medication adherence in the elderly and indicates that carers should be included as appropriate in decision making, education and counselling and follow-up regarding medicines use (298). The dMUR referral service could be seen to fit neatly into this guidance, if it were not for the exclusion of carers from receiving a dMUR on behalf of the person they are caring for.   It is interesting to note that over half the patients in the domiciliary MUR study received care from family, friends or another informal carer (316). The extent to which these carers provided support with medication

management is not reported; neither is the degree to which carers participated in the MUR. The question of how to manage dMUR provision to elderly housebound patients who have carers managing their medication therefore remains. Allowing proxy dMURs with carers, either with the patient's consent or directly if the carer has power of attorney for health, could be a solution.

An important recent study in the context of this research is the TransitionRx study, based in Ohio, USA (202). The intervention consisted of a community pharmacy transition of care programme following faxed referral from two local hospitals. Community pharmacists called the patient to make an appointment at the pharmacy, to take place within 7 days of discharge, for a comprehensive medication review including self-management advice as well as written materials to take away. Telephone follow-up was provided two weeks later. Participants were on average younger than in this PhD study at around 66 years, but polypharmacy was even more prevalent (average of 10-11 medicines per participant).

TransitionRx found that emergency readmissions were significantly lower in the intervention group (6.9% versus 20%, p=0.019). However, when interpreting these results it is important to note that TransitionRx was not an RCT. Participants were assigned to study groups based on their own preferences and abilities – patients who felt they would be unable to attend the pharmacy were assigned to the control group and those who were uncontactable following discharge or did not attend their appointment at the pharmacy were reassigned to the control group. This may have led to important differences between groups as intervention group patients may have been more able and pro-active in managing their medication and health and therefore at lower risk of readmission than the control group, which in addition contained all participants who were housebound (and potentially more frail). However the authors do point out that their intervention group had statistically more chronic conditions than the control group, which in itself made this group high risk for readmission.

Other key differences exist between TransitionRx and the present study which may explain the success of the American intervention. Community pharmacists partaking in TransitionRx were already trained to provide comprehensive medicines management services as part of their routine work and also received

additional training on clinical practice guidelines for the conditions targeted by the intervention (congestive cardiac failure, COPD and pneumonia), and on how to refer patients for social support. Appointments with the pharmacist took place within a week of discharge (compared to 4 weeks for a dMUR) and lasted 30-45 minutes (compared to the majority lasting less than 20 minutes in this study). Pharmacists made an average of seven interventions per patient, five more than were made during the average dMUR in this study. Finally, the additional two-week follow-up telephone call may have increased the effectiveness of the intervention by reinforcing initial advice and addressing any new problems that had arisen.

A 2017 quasi-experimental study of collaborative medicines management on transfer of care by hospital and community pharmacists in Hawaii also provided special training for participating pharmacists (332). Community pharmacists worked with patients for up to a year after discharge and also engaged with the patients' physicians. The researchers estimated a 36.5% lower medication related admission rate of patients aged $\geq$65 at hospitals providing the intervention compared to those which did not, representing a 2.6:1 return on investment. Again, key aspects which were not present in this PhD study include additional training for community pharmacists, repeated follow-up and collaboration with other professionals, which may contribute to enhancing the dMUR service.

Recent research has also been conducted in the UK to evaluate hospital initiated pharmaceutical transfer of care interventions for older patients. A prospective cohort study published in 2014 implemented person centred pharmaceutical care bundles for patients who were socially isolated and/or prescribed high-risk medicines on an older people's medical ward (102). Patients discharged from the intervention ward were offered a referral to their community pharmacy for NMS or dMUR if they met the eligibility criteria; patients who could not receive the service because they were housebound were offered the same services delivered by the hospital pharmacy team. An average of 18 patients per month were identified for community pharmacy referral, and only 17% of these stated during admission that they would be unable to attend due to being housebound. Unfortunately, the actual uptake of post discharge services from community pharmacies was not

studied. The authors state that 90% of hospital pharmacy follow-up was possible by telephone, which, together with the positive results of the last study discussed, is at odds with the hypothesis generated by this PhD project that pharmacy post-discharge follow-up of older people by telephone may not be appropriate. Telephone calls were reported to last only 5 minutes so it might be that patients followed up by telephone had relatively simple medication related needs. Home visits lasted approximately 20 minutes plus travel time, which is similar to dMUR consultations in this PhD study. During the intervention period, the emergency readmission rate was significantly lower on the intervention ward (17% vs 22%, $p<0.05$) than on the control ward, although the authors caution that the study was not powered to detect this difference. These readmission rates are similar to those found in an evaluation of the Leeds IMPACT project where hospital pharmacy liaised with community pharmacy at transition of care for patients admitted to care of the elderly wards who were deemed at high risk of DRP (333).

Emergency readmission rates in the UK studies mentioned above, which involved similar populations to this PhD study, are similar to the readmission rates reported here (102,333). The observed reduction in readmissions in these other studies, although neither were suitably powered RCTs, is encouraging. The effect sizes observed could be used as the basis of a power calculation for a future RCT of dMUR referral. Possible differences between groups in the current study in the length of readmissions, as well as A&E visit rates, adherence scores and self-reported physical health at 6 months also warrant further investigation. Additionally, the fact that no preventable medication related readmissions were observed among patients who had received a dMUR is an encouraging finding of this research. Although this observation cannot be said to be causative, the relationship between dMURs and preventable medication related readmissions should be researched further.

A 2017 RCT studying the effect of faxing discharge letters from an English hospital pharmacy to patients' community pharmacies found that the number of medication discrepancies in GP records and patient's descriptions of their medication regimens were significantly decreased in the intervention group (311). In that study discrepancies were detected in the control group in 42% of patient reports

and in 36% of GP records, whereas interventions to correct discrepancies of either type were reported for 20% of dMURs in this PhD study. As community pharmacists in the present study were not requested to report medicines discrepancies specifically, it could be that other discrepancies were identified but were resolved separately to the dMUR and as such were not reported. It is also possible that other discrepancies were present but were not resolved by the community pharmacists – in the previous study, discrepancies were still present in 19% of intervention group patient reports and 27% of these patients' GP records at 3-week follow-up with the researcher. Although community pharmacists in the previous study were told that they could use the discharge letters to facilitate dMURs, no participants had received a dMUR by follow-up. Suggested reasons for this included patients being housebound and the fact that dMURs may still have been conducted after this time. This reinforces the need for better provision of the service to housebound patients and the importance of early follow-up by the community pharmacist, even if the full dMUR consultation cannot take place until a later time. It would have been interesting to see if the residual rate of discrepancies in the intervention group could have been reduced further by a dMUR consultation.

8.5: LIMITATIONS

This work is limited by the small-scale nature of the study involving one hospital and the associated community pharmacists. This means that findings cannot be generalised to other settings. However this was not the purpose of this study, which was designed to assess the feasibility of the dMUR referral service and the chosen outcome measures and data collection tools, as well as identify ways in which the service could be improved, in preparation for a future RCT, the results of which would be generalisable.

Less than one in five patients identified as potentially eligible for the dMUR referral service were actually recruited to this study. Previous RCTs of post discharge pharmacist follow-up of older patients have reported recruitment rates ranging from

23% to 83% (126-129,131-134,311). The reasons for the low recruitment rate in this study are multifactorial and are discussed below.

During the study, the researcher was only able to dedicate approximately one hour each working day to recruiting patients. This lead to over a quarter of potential participants being discharged either before approach by the researcher or before the researcher could return following the initial approach. A bid for funding to allow more time to be dedicated to the recruitment process was unsuccessful.

Although it was originally intended that ward based pharmacy technicians would be involved in identifying and referring patients during this study, this was not possible due to shortages of ward based technicians and other demands on their time. This is unfortunate as it has been shown that pharmacy technicians can be successfully involved in post-discharge referral services (17,328).

8.5.1: Rate of Ineligibility of Patients Identified

Just over 40% of the patients identified to the researcher were ineligible for the study for reasons other than early discharge or not fitting the age criteria. This falls within the upper end of the range found by a systematic review of RCTs involving older people published in the journal of the BGS, where exclusion ranged from 3.4% to 49% (176).

The most common reason for ineligibility in this study, affecting nearly one-third of patients excluded, was that they were not expected to manage their own medication on discharge from hospital, but would be assisted by a formal or informal carer. This was unanticipated, as ward pharmacists were asked only to refer those patients who they would expect to be self-medicating at home, and is also higher than the 8% of patients who were excluded for this reason in the Northumbria project (307). This may reflect that ward pharmacists sometimes find it difficult to ascertain whether or not a patient manages their own medications at home, or patients' circumstances change during their admission.

Being housebound was the second most common reason for patients being excluded from this study, and is discussed extensively in other parts of this thesis. Almost the same number were not well enough to engage in discussion with the researcher regarding the study, either because of the severity of their medical

condition or their cognitive impairment, which may have been acute or chronic. It seems unlikely that these patients would have been able to attend the community pharmacy in the first few weeks after discharge, which begs the question what, if any, alternative support they may have received with their medication. It may be that these patients would be more appropriately screened for post discharge medicines support in primary care post discharge, when their clinical status and home circumstances are more certain, for example by pharmacists based within GP surgeries, in line with the ethos of the CQC report *Managing patients' medicines after discharge from hospital* (68)*.*

Just over one in 10 excluded patients were unable to enter the study because they were being discharged to a residence outside the study's catchment area (either their own home or that of a relative with whom they were moving in following their hospital stay). As the community pharmacy who would be continuing the patient's supply of medication was not signed up to receive referrals in these cases, the patients had to be excluded.

8.5.2: Rate of Refusal of Potential Participants

The refusal rate of patients fully screened by the researcher was 32.3%, which falls within the range found by studies included in the BGS review, where refusal rates of up to 54% were reported, although typical rates were found to be 12-15% (176). The relatively high refusal rate in this study may reflect that patients were being recruited from the hospital environment and had recently been acutely unwell, whereas none of the studies in the BGS review recruited from the acute sector.

In terms of patients who were eligible to participate in the study, 54.5% refused. This is higher than in an observational study evaluating the identification of post-discharge DRP among older patients by community pharmacists in the Netherlands, which reported a 31.5% refusal rate of eligible patients (334). The most common reason for refusal was that patients felt 'too sick' to participate. In that study, community pharmacists were able to provide home visits where necessary, which might explain why the refusal rate was lower than in this PhD study. Additionally, participation in an observational study may have been viewed as less off-putting than a randomised controlled study such as this one.

In order to plan future work on both the referral service itself and the study of medicines support on transfer of care for older patients in general, it was desirable to separate refusals due to a reluctance to get involved with research from those that were because of the dMUR service itself. One in five eligible patients cited an unwillingness to be involved in research as the primary reason for their refusal to take part in this study. A similar number gave their age or state of health as the main barrier to their participation, with one in six citing time or work constraints. These patients may have viewed the commitment to the research as more burdensome than simply agreeing to attend for an MUR; however this was not necessarily the case, with comments such as *I've got enough appointments* commonly being given as justification for refusal. These comments suggest that it was as much the dMUR itself that was being turned down as the involvement in a research project. This indicates that the concept of the dMUR was either not fully understood by these patients, or not viewed as a useful service for them, given everything else they had going on at that point in time.

Indeed, a third of patients who refused did so because they did not see the point of having an MUR with their community pharmacist, with several of these actually saying they would rather go and see their GP with any problems or queries over the changes to their medication. This suggests a lack of awareness of or belief in the skills of the community pharmacist in undertaking this kind of role. It has already been discussed (Section 8.3.1) that previous research has shown a lack of understanding among patients and the public of MURs in general, and dMURs in particular (174,289,315). In a survey of 1000 members of the public, a quarter of respondents indicated that they would not go to their pharmacist to discuss problems with medicines, primarily due to low expectations that the pharmacist would be able to resolve the problem, with the majority preferring to see their GP (174). Indeed, among those who had participated in MUR or NMS services, less than a third had experienced resolution of medicines related problems. Willingness to have a discussion with a pharmacist because of recent hospital discharge was lower than other reasons for doing so, although the reasons for this were not explored.

In the hospital inpatient survey discussed in Section 3.1.2, only one in 10 respondents considered the community pharmacists as a source of information and support regarding medicines post-discharge. This was confirmed in post-discharge interviews, where just 2% of interviewees reported that they had discussed their medicines with a pharmacist in a private area, despite many participants reporting a problem with one or more medicines post-discharge (89). The role of the community pharmacist in supporting patients with their medicine post-discharge therefore seems to remain underdeveloped, possibly due to poor patient understanding, and consideration needs to be given to how to resolve this.

In contrast to those patients who were reluctant to access their community pharmacist for advice regarding medicines post-discharge, one in five of the patients who refused to participate stated that they already had good links with their community pharmacist and would rather organise their own follow-up. In terms of study design, it may be that the possibility of being randomised to the control group, and thus 'missing out' on a dMUR influenced these patients' decision to refuse to participate. It would have been interesting to see if any of these patients actually self-referred for a dMUR following discharge and if they did, whether the community pharmacist had enough information to adequately support them with the changes to their medication. This situation seems unlikely, however as all evidence to date suggests that dMUR provision is low in the absence of formal referral systems (165,306,310,311,335).

One patient believed that his community pharmacist would automatically receive all the information about the changes to his medication, so did not see the benefit of participating in the study, even when advised that community pharmacies are not routinely informed of medication changes made during admission. Although this was an isolated case during this study, this further suggests poor public understanding of the role of community pharmacists in the healthcare system.

Selection bias may have been introduced through the exclusion of patients who were too unwell to approach in hospital, housebound, or relied on carers to manage their medicines. All these patient groups are likely to be frail and at high risk of DRP, and therefore potentially more likely to benefit from dMUR. Their exclusion could also contribute to the apparent lack of effect of the intervention.

8.5.3 Participant Dropout, Loss to Follow-up and Protocol Deviations

Only 41% of participants completed this study as per protocol, which is in keeping with research conducted by others indicating that studies involving older patients experience high attrition rates (177). Death, or deterioration in health leading to participants being readmitted, moving address to live in locations where their care needs can be better met, or simply being no longer able to complete follow-up measures all contribute to this and were all observed during this study (119,126,129,132,143).

It also became apparent during the study that the medication support needs of older people may change following a stay in hospital, so that some patients who have been responsible for managing their own medication prior to admission required support to do so following discharge. As such, a number of participants who were recruited on the basis of independently managing with their medication at home may not have fitted this criteria had they been screened post-discharge. Some of these cases were discovered during semi-structured interviews. Where these participants did retain some independence with regards to their medication (for example retrieving their own doses from a carer filled MCA) they were not excluded, rather their experiences and those of their carers were used to inform discussion of how the dMUR service could be modified to support their needs.

More participants were lost from the intervention group than the control group, due to difficulties in dMUR delivery. Therefore in the PP analysis the intervention group is likely to have been more 'well' than the control group, as any participants who became housebound or felt too unwell to attend their dMUR following discharge would have been excluded, whereas they may have been able to complete the requirements of the control group.

8.5.4 Limitations in Measurement and Interpretation of Outcomes

Self-reported measures, including the MMAS, can easily be distorted by the patient and lead to an over-estimate of medication adherence (67,290). Completing an adherence scale also requires recall and cognitive capabilities, which may be less than optimal in some elderly patients (290). However these drawbacks would be expected to affect both intervention and control groups equally. Ideally more than

one measure of adherence would be been used but the resources and time available for this study meant that this was not possible. The MMAS has been successfully triangulated with other methods of measuring adherence (see Section 5.6.4), which increases confidence in its use as the sole measure of adherence in this study.

Apart from small participant numbers, one explanation for the lack of difference in HR-QoL between intervention and control groups is that the SF-12v2 is not sensitive enough to pick up differences in health that advice given during a dMUR could generate. A recent systematic review and meta-analysis concluded that existing HR-QoL measures lack sensitivity and specificity to pharmaceutical care and are insufficient to reflect the true impact of these interventions (336). The SF-36 measure had the most evidence, with a moderate impact of pharmaceutical care activities on social functioning, general health and physical functioning identified by meta-analysis. The SF-12 was chosen in preference to the SF-36 for this PhD study as, in addition to being much shorter than the SF-36 (and therefore placing less burden on participants), it has been found to reproduce the physical and mental component summary measures with at least 90% accuracy (226).

A recent content analysis of HR-QoL measures found that, although the SF-36 may be suitable to evaluate the impact of pharmaceutical care on HR-QoL to some extent, suitability to comprehensively capture the burden of medicine on physical, social and psychological wellbeing is unlikely (337). Looking at all measures collectively, no single tool was specifically designed for measuring the burden of medicine on quality of life, nor did the measures appear suitable to evaluate the impact of medicine-focused interventions on HR-QoL. The authors called for development of an alternative measure suitable for evaluation of the burden of medicine and the impact of pharmaceutical care interventions on quality of life.

Alternatively, a longer timescale might be needed to see an effect of pharmaceutical care interventions on HR-QoL. In the meta-analysis, most of the studies using the SF-36 measure evaluated comprehensive medication review interventions and had a follow-up period of 12 months and more (336).

A further limitation in interpreting the HR-QoL results in this study is that a number of forms were received with missing answers. Although the SF-12v2 scoring software does have the capacity to estimate some scores where one or more items on the survey are not completed, some of the forms returned had too many missing items for this to be possible. These forms were excluded from the results.

Possible reasons for missing answers are that the type-face was too small or the questions were somewhat repetitive and therefore participants may have fatigued or taken the view that there was no need to complete all items. Alternatively respondents may have had difficulty in understanding some questions. Although the patient and public involvement group had indicated the questionnaire was suitable, it is possible that they were in better physical and mental health than some of the actual participants in the study. The SF12-v2 user's manual does state that elderly respondents are more likely to have missing items than younger respondents, which fits in with the number of incomplete forms returned in this study (226).

This is the first time the PEI has been used for pharmacy consultations and as such it is not validated in this setting. However this research could form a platform for further use and validation of this tool in similar settings.

Response bias is also a limitation of this research, in that participants who were more adherent or less sick may have been more likely to return their questionnaires. However this would be expected to affect intervention and control groups equally. The low HR-QoL scores returned by participants also goes against the suggestion that those in poor health would not have returned their questionnaires. Other shortcomings of the questionnaire used in this research, such as participants over-stating adherence, would also be expected to affect intervention and control groups equally.

It has been discussed in other parts of this thesis that some of the outcome measures used may not be sensitive to the effect of dMUR interventions. The use of all readmissions, rather than preventable, medication related readmissions as a quantitative outcome is one example of this. However the detection of preventable, medication related readmissions relies on the application of criteria

which will always be somewhat subjective.   Particularly, the involvement of the researcher in the case note analysis of readmitted participants in this research could be seen as open to bias. However this was seen as preferable to leaving interpretation and application of the scoring criteria to one person alone. Subjectivity is still a possibility in the application of such criteria and in a future trial it would be preferable for the criteria to be applied using a larger panel which did not include any members of the research team. Never-the-less, this study demonstrated that such criteria can be applied and analysing the results statistically would be desirable for a future RCT if an adequate sample size could be recruited.

Confounding is also possible in that patients who were well enough to attend the pharmacy for a dMUR may have been intrinsically less likely to be readmitted to hospital. It is not known whether a dMUR would actually have prevented the readmissions among intervention group participants who were unable to attend their dMUR, had they completed the intervention as planned.

The intention to use the number of GP visits in each group as an outcome measure was limited in this study by difficulties of participants with completing the study diary. During a future RCT this information should be collected directly from GP surgeries if possible. Other measures that could not be studied during this research due to lack of resources include all medication discrepancies and all ADEs. These may be more sensitive to community pharmacy interventions than readmissions or overall HR-QoL and consideration should be given to the practicalities of using these outcomes in future work evaluating the dMUR service.

A further limitation of this research is the possibility that the interaction between participants and the researcher, a pharmacist, may in itself improve medicines use among patients who had not received a dMUR and skew the results of the study, a phenomenon known as 'measurement effect'. This was most likely during the participant interviews, due to the digression, at times, of the researcher from the role of interviewer to the role of HCP. It was found that interviewees often asked for advice regarding medicines in response to the open question: *Is there anything else about your medication that you'd like to talk about?'* at the end of the interview. This question was not intended to result in such requests; however

knowing the interviewer was a pharmacist may have led some participants to misunderstand or opportunistically ask questions regarding new medication which remained unanswered. In addition, there were other instances where a lack of knowledge was demonstrated by the participant, which could have resulted in harm (for example where changes to medicines made in hospital had not been initiated properly by the patient at home). This type of situation posed a difficulty for the interviewer, who was a practising pharmacist as well as a researcher. Ignoring a lack of knowledge regarding medication which could realistically cause a patient harm would have been a breach of professional ethics on the part of the researcher. Therefore, despite a knowledge of the need to separate these two roles to avoid contaminating the study data, the presentation of a patient with clear information needs caused a number of digressions from the role of researcher into the role of healthcare professional. This may have affected the outcomes of the study as some control group participants were in effect given a dMUR during their interview. This could have affected their medicine taking or self-care behaviour in a similar way to the study intervention and therefore reduced any differences in outcomes (such as readmission rate, quality of life and medicines adherence) between the intervention and control groups. Conversely, extra information given to intervention group participants could have increased the apparent effect of the intervention, increasing the difference between the groups. Even re-visiting the points discussed during the dMUR may have reinforced them in the minds of the participants, thus increasing treatment effect. As this was a feasibility study and the role of statistical analysis of outcomes was limited, statistics were not re-run with the exclusion of these patients. However in a future RCT, it is recommended that interviews, if included in the study design, should be conducted by a researcher who is not also a pharmacist.

In addition, interviews with some participants were made difficult because of the cognitive impairment of the participant. In two cases (one intervention and one control), most of the interview was conducted with the participant's offspring, and in several other cases, family members were present and contributed to the interview to some extent. Therefore some of the views presented may have been those of the participant's family rather than the participant themselves. Rather than being a

limitation, this observation goes to illustrate the importance of involving family and other care-givers in medicines optimisation activities, particularly where the patient is frail and elderly, or has cognitive impairment.

Several themes not included in the original interview schedule were identified during the coding of transcripts and construction of thematic charts for the framework analysis of the interviews. A limitation of this analysis is that it did not begin early enough in relation to conducting the interviews, due to time pressures on the researcher. Had it been possible to start the analysis earlier, these emerging themes could have been incorporated more formally into the schedule for later interviews and therefore explored more deeply.

It is important to remember that the interventions made by community pharmacists in this study were not outcomes in themselves, and their conversion into cost savings is an estimation, as it is difficult to demonstrate a direct effect of the interventions made. However, the use of the Eadon-ScHARR model to assign clinical significance and monetary value to each intervention provides an insight into the effect of these interventions on patient care. It should also be noted that using a Delphi process to gain consensus is still based on subjective opinion and results are unlikely to be reproducible (272). This is particularly pertinent here as consensus regarding the score to award the majority of interventions was defined by stability in the opinions of the reviewers, not agreement as to the score awarded.

A larger study involving more interventions would help to validate these results, and if potential clinical significance and cost avoidance could be linked to other outcomes such as reduced readmission rates, this would help to demonstrate causality of the intervention on improvements in these outcomes. A further limitation of the Delphi process in this research was that a relatively small panel could be convened and two members of the panel dropped out before the end of the process. This led to an over-representation of pharmacists compared to doctors on the panel (five and two respectively), which may have affected results as different professionals may score interventions differently. If applying this methodology again in the future, attempts will be made to convene a larger panel with more representation from the medical profession.

CHAPTER 9: CONCLUSIONS

Bottom Line: There is potential for improved patient care and a positive return on investment when community pharmacists provide dMURs for older patients following referral by hospital pharmacists. However, operational barriers exist to delivering dMURs to the frail elderly and there is a need to improve communication channels between health care practitioners to deliver a holistic package of care post discharge.

Transfer of medicines related care from hospital into primary care remains suboptimal, and information overload at the point of hospital discharge may prevent older patients from absorbing medication counselling. Community pharmacy dMURs are well placed to address these issues.

The lack of significant differences in patient outcomes between intervention and control groups in this study is unsurprising as feasibility studies are not designed to detect them. Although patient numbers in this study were too small to draw firm conclusions, results of this research include a number of interesting trends for further investigation. These include trends towards shorter length of stay on readmission for intervention group patients and a reduction in A&E visits at 6 months for patients who completed their dMUR as planned compared to the control group. Results also suggested that dMURs may prevent deterioration in medication adherence and physical health over time compared to patients who are not referred, and that preventable medication related readmissions may be decreased by the provision of dMURs. This study also suggested that dMUR referrals may provide a 4-fold return on investment to the NHS in terms of improved quality of care.

Consistency of the responsible pharmacist in a community pharmacy may increase uptake of and benefit derived from dMURs due to the relationships which develop between community pharmacists and patients. In turn, the experience of having a dMUR may improve patients' perceptions of community pharmacy. However, the format of a typical dMUR consultation may not be optimal to improve patients' understanding or use of medicines. The approach of encouraging the patient or

carer to take the lead may be more useful in highlighting knowledge gaps and targeting advice. Broadening the consultation to incorporate patients' physical and social circumstances may also help them to benefit from the dMUR. Participant demographics indicate that this study involved patients at relatively high risk of post-discharge DRPs and readmission. These patients may be more in need of medicines support and it is likely that this type of dMUR will be more complex and require longer consultation times than standard dMURs. Follow-up consultations may be required in order to review the success of interventions made during the first consultation and address any new problems that have arisen

To fulfil these requirements, community pharmacists require detailed information from the hospital regarding why changes were made as well as specific indications and duration of treatment for new medicines where these may vary. Additional post-discharge changes to medicines may occur before the dMUR consultation takes place and community pharmacists need to be prepared for this.

Lack of time of hospital pharmacists is a major barrier to recruiting appropriate patients for a dMUR referral system and making good quality referrals.

A major barrier to older patients accessing dMURs in their current format is being housebound due to poor mobility or health, due to difficulties experienced by community pharmacists with providing domiciliary MURs.   Despite being a possible solution for where medication support needs are relatively simple, telephone dMURs may not be acceptable or feasible for older patients with complex medication regimens.

Carer management of medication is another major barrier to provision of dMURs for older people. A lack of perceived need for dMUR by some patients and preferring to talk to their GP regarding medication changes made in hospital are also barriers. Elderly patients may have numerous appointments in the post-discharge period and consideration is needed as to how to integrate dMURs and community pharmacy in general into their overall care package. Better communication to GPs of the dMUR referral by the hospital and its outcome by community pharmacists may increase the usefulness of the service by encouraging collaborative working.

Chapter 10: Recommendations

10.1: RECOMMENDATIONS FOR FURTHER RESEARCH

1. The feasibility study reported within this thesis should be scaled up to a full pilot study, followed by an adequately powered RCT, in order to justify the additional cost to the NHS of an enhanced dMUR referral service.

   Trends in outcomes identified in this study indicate that using the same outcomes to investigate these trends further would be a rational approach. Additional outcomes that should be investigated if sufficient resources were available include number of GP visits, medication discrepancies and adverse drug events.

   Any future RCT investigating post-discharge follow-up of older patients should recruit adequate sample sizes to account for potentially high attrition rates, and adequate time should be allowed for recruitment. Written information should be as concise as possible and potential participants should be given the opportunity to discuss participation with others (for example family members or carers). Involvement of clinical staff known to the patient in the recruitment process is recommended where possible.

2. The concept of multiple contacts between community pharmacist and patient as part of the dMUR process, as recommended in section 10.2 below, should be investigated in practice. This could be done as a service evaluation with qualitative feedback from patients and pharmacists as to the feasibility and utility of the re-designed service. Other outcomes of interest would be the number and type of interventions made at each contact, patient enablement following the main dMUR consultation, medication adherence, number and nature of GP contacts and readmissions during the follow-up period (which should be at least 6 months).

3. Qualitative research should be undertaken to explore further the specific barriers to domiciliary and telephone MURs as perceived by community pharmacists. Focus group methodology would be a suitable initial way to

approach this, allowing for discussion and development of ideas among pharmacists who may have different perceptions.

4. The role of telephone dMURs in older people should be further investigated. Preliminary qualitative findings from the PPI group for this research and feedback from potential participants could be expanded, initially by surveying a larger number of patients as to their views on such a service.

5. Alternative ways of identifying patients who may benefit from post discharge medicines support should be explored, for example the feasibility of screening by GP practice pharmacists post discharge.

6. Further qualitative work should be carried out to investigate the reasons why dMURs appear to be such a low priority for patients, and the perceptions of patients who have received the service as to its utility.

10.2 RECOMMENDATIONS FOR PRACTICE

1. The contractual barrier of applying to NHS England separately each time a domiciliary or telephone dMUR is required should be removed.

2. Greater carer involvement in dMURs should be facilitated by allowing proxy dMURs with carers, either with patient consent or directly if the carer has power of attorney for health.

3. The dMUR service should be re-designed to involve at least two parts. An initial contact should be made within 7 days of discharge to reconcile medication discrepancies, address any immediate issues and confirm an appointment for a full dMUR consultation. This consultation should take place at a mutually agreed time but experience from this work suggests that 4-6 weeks post discharge may be appropriate. Further follow-up may then be required in some cases to check understanding of and reinforce advice given and to evaluate the outcome of any actions recommended to the patient or GP.

4. Remuneration for the dMUR service should reflect the longer time needed for dMURs compared to 'standard' MURs, the organisation and provision of follow-up consultations, and travel expenses and/or locum cover where domiciliary visits are made.

5. Electronic referral from hospital to community pharmacy should be implemented more widely. Referrals should include (with patient consent) a copy of the discharge summary with full details of why medicines were changed and the indication, duration of treatment and monitoring requirements for new medicines, as well as the planned social and clinical care package for the patient. The dMUR referral should also be documented on the discharge summary to facilitate collaborative working between professionals.

6. Hospital pharmacies should be remunerated for making dMUR referrals. This would allow for investment in staff time in order to engage appropriate patients and increase the volume and quality of referrals.

7. Older people with multiple medication changes should form a key target group for dMUR referral.

8. Pharmacy support staff should be involved both in engaging patients and making dMUR referrals from hospital and actioning them in community pharmacy.

9. Prompts for community pharmacists to action dMUR referrals may be helpful in increasing completion rate.

10. Local champions for dMUR referral by hospitals should be identified to promote the service and encourage referral until it becomes routine practice.

11. The concept and purpose of dMUR should be promoted to patients more widely both in hospitals and the community.

12. Provision of targeted, clear and concise written information to back up verbal discussions during dMURs may help patients to gain benefit.

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Transitional care of older patients utilising community pharmacists via the dMUR service

by

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A thesis submitted in partial fulfilment for the requirements for the degree of
Doctor of Philosophy at the University of Central Lancashire

Volume 2 of 2 (APPENDICES)

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Appendix 1: Literature Search Strategy

For all databases, search terms included Medical Subject Heading (MeSH or MH) term and keyword searches as reproduced below

Cochrane Library: 21/04/17

ID	Search	Hits
#1	MeSH descriptor: [Patient Discharge] explode all trees	1360
#2	MeSH descriptor: [Pharmacists] this term only	564
#3	MeSH descriptor: [Aged] explode all trees	1071
#4	hospital near/4 discharge:ti,ab,kw (Word variations searched)	6096
#5	pharmac*:ti,ab,kw (Word variations searched)	88190
#6	elde* or older:ti,ab,kw (Word variations searched)	62595
#7	#1 or #4	6852
#8	#2 or #5	88190
#9	#3 or #6	62974
#10	#7 and #8 and #9	**79**

Title screening: 21 relevant titles identified

Embase: 21/4/17

	Search Terms	Results
11	Remove duplicates from 10	**1418**
10	7 and 8 and 9	1821
9	3 or 5	1,580,314
8	2 or 6	6,124,893
7	1 or 4	136,309
6	(elde* or older).ab,kw.	1,367,384
5	"pharmac*".ab,kw.	1,541,204
4	"hospital discharge".ab,kw.	64,145
3	pharmacist/	82,089
2	aged/	5,378,914
1	hospital discharge/	96,846

Title screening: 131 relevant titles identified after removing duplicates from Cochrane Library search

Medline: 21/4/17

#	Query	Results
S10	S7 AND S8 AND S9	668
S9	S3 or S5	2,683,623
S8	S2 or S6	514,698
S7	S1 or S4	49,228
S6	AB pharmac*	508,424
S5	AB older adults or elderly or seniors or geriatrics	218,583
S4	AB hospital discharge	31,051
S3	(MH "Aged")	2,614,717
S2	(MH "Pharmacists")	13,153
S1	(MH "Patient Discharge")	23,104

Title screening: 16 relevant titles identified after removing duplicates from Cochrane Library and Embase searches

CINAHL: 30/4/17

	Search Terms	Results
S10	S7 AND S8 AND S9	129
S9	S4 OR S6	37,777
S8	S3 OR S5	622,581
S7	S1 OR S2	16,359
S6	pharmacists or pharmacy	37,777
S5	older people or older adults or elderly	118,064
S4	(MH "Pharmacists")	10,384
S3	(MH "Aged")	589,505
S2	(MH "Transfer, Discharge")	4,418
S1	hospital discharge	12,115

Title screening: 17 relevant titles identified after removing duplicates from Cochrane Library, Embase and Medline searches

Web of Science: 30/4/17

	Results	Search Terms
# 4	632	#3 AND #2 AND #1 *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI* *Timespan=All years*
# 3	703,770	TS=pharmac* *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI* *Timespan=All years*
# 2	1,359,186	TS=(older OR elder*) *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI* *Timespan=All years*
# 1	63,594	TS=hospital discharge *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI* *Timespan=All years*

Title screening: 26 relevant titles identified after removing duplicates from Cochrane Library, Embase, Medline and CINAHL searches

Pubmed: 01/05/2017

Search	Query	Items found
#14	Search ((((("Pharmacists"[Mesh]) OR pharmac*[Title/Abstract])) AND (("Aged"[Mesh]) OR ((older[Title/Abstract] OR elder*[Title/Abstract])))) AND (("Patient Discharge"[Mesh]) OR hospital discharge[Title/Abstract])	294
#13	Search ("Pharmacists"[Mesh]) OR pharmac*[Title/Abstract]	298106
#12	Search ("Aged"[Mesh]) OR ((older[Title/Abstract] OR elder*[Title/Abstract]))	2876447
#11	Search ("Patient Discharge"[Mesh]) OR hospital discharge[Title/Abstract]	40349
#10	Search pharmac*[Title/Abstract]	294796
#9	Search (older[Title/Abstract] OR elder*[Title/Abstract])	509420
#8	Search hospital discharge[Title/Abstract]	20997
#7	Search "Pharmacists"[Mesh]	13221
#5	Search "Aged"[Mesh]	2656660
#3	Search "Patient Discharge"[Mesh]	23204

Title screening: 5 relevant titles identified after removing duplicates from Cochrane Library, Embase, Medline, CINAHL and Web of Science searches

Database of Abstracts of Reviews of Effects (DARE) and the NHS Economic Evaluation Database (NHS EED): 1/5/17

NB// These databases ceased to index new research at the end of March 2015

Line	Search	Hits
1	MeSH DESCRIPTOR Patient Discharge EXPLODE ALL TREES	257
2	MeSH DESCRIPTOR Aged EXPLODE ALL TREES	9686
3	MeSH DESCRIPTOR Pharmacists EXPLODE ALL TREES	140
4	(hospital discharge)	587
5	(pharmac*)	8595
6	(older OR elder*)	4708
7	#2 OR #6	12390
8	#3 OR #5	8595
9	#1 OR #4	783
10	#7 AND #8 AND #9	58

Title screening: 6 relevant titles identified after removing duplicates from Cochrane Library, Embase, Medline, CINAHL, Web of Science and PubMed searches

NIHR dissemination Centre: 1/5/17

2 relevant titles identified (since March 2015)

ClinicalTrials.gov Registry: 5/5/17

Found 37 studies with search of:	"hospital discharge" AND pharmacist | Senior (aged 65+)

Recognised Terms and Synonyms:

pharmacist: 673 studies

hospital discharge: 1165 studies

discharge from hospital

discharge hospital

17 relevant titles identified after removing duplicates from previous searches. Of these, one study had been terminated as unable to recruit and 5 were 'status unknown' (completion date has passed and the status had not been verified in more than two years)

Health Management Information Consortium: 5/5/17

	Searches	Results
5	1 and 4	71
4	2 or 3	11048
3	pharmac*.mp. [mp=title, other title, abstract, heading words]	11048
2	exp Pharmacists/	2138
1	hospital discharge.mp. or exp Patient discharge/	2354

13 relevant titles identified after removing duplicates from previous searches

Electronic Theses Online System (EThOS): 5/5/17

Hospital discharge [Abstract] AND Pharmacist [Abstract]: 3 results, none relevant

NHS Evidence: 14/5/17

"Hospital discharge" AND Pharmacist: 695 results, 20 relevant titles identified after removing duplicates from previous searches

Pharmaceutical Journal: 19/5/17

18 relevant titles identified after removing duplicates from previous searches

Appendix 2: Patient and Public Involvement (PPI)

Questions Addressed During PPI Group Meetings

1) What do you think of the level of medicines support you were given during your last hospital stay?

2) Do you use same community pharmacy regularly?

3) Were you aware of medicines use reviews (MURs) before today? (In general, or in the context of discharge from hospital)

4) What do you think of the idea of your community pharmacist going through your medicines with you after you have been in hospital?

5) How likely would you be to go for a post discharge MUR (dMUR) if your community pharmacist contacted you to arrange one?

6) How easy would you find it to attend the pharmacy for a dMUR?

7) How soon after being discharged do you think the dMUR should be?

8) What would you want to get out of an MUR?

9) Which of the following do you think are factors which might lead a person to benefit from a dMUR?

    a. Medicines changed in hospital (how many changes?)

    b. Taking a lot of different medicines (how many is a lot?)

    c. Taking particular medicines which are more likely to be associated with an admission to hospital:

        i. Water tablets

        ii. Anti-inflammatory or morphine related painkillers

        iii. Blood thinning medicines (Aspirin/clopidogrel/warfarin)

        iv. Medicines for diabetes (tablets or Insulin)

        v. Digoxin

        vi. Some blood pressure/heart medication (ACE-Inhibitors / beta-blockers)

        vii. Steroids

        viii. Sleeping tablets

         ix. Antidepressants

d. Difficulty taking medicines (e.g. due to physical difficulty or forgetfulness)

e. Any other suggestions?

10) Does anyone have any comments on the participant information leaflet for the study? (Is it easy to understand, large enough font, is there anything else you would want to know?)

11) Some people would not be referred for a review as part of the study. Do you think that is ok?

12) Would you be happy for your community pharmacist to receive the kind on information on the referral form?

13) What do you think of the participant consent form? Is there anything else that should be specified on there?

14) Would it be OK for the researcher to contact a participant's GP to find out how many times they had seem them since being discharged?

15) Would it be OK for us to consult a participant's hospital records to see if they had been re-admitted? If they had been readmitted, would it be alright for us to look at their case notes to find out why?

16) How willing would you be to be telephoned and asked questions as part of the study follow-up? What about filling in something that was sent in the post?

17) Please look at the following examples of follow-up questions that might be asked. Do you have any comments / concerns? How would you feel about answering these questions?

18) Some people might be visited at home and interviewed in more depth about their medicines-related experiences since discharge. How would you feel about that?

19) Is it acceptable to repeat follow-up at six months?

20) What would you most like to achieve as an overall outcome of a dMUR? (For example fewer visits to your GP, a lower risk of going back into hospital, improved quality of life?)

21) Would participants want to know about results of the study? If so, how should we inform them?

22) How would you feel about each of these people approaching you to discuss taking part in the study?

   a. Chief researcher
   b. Research assistant
   c. Your own ward pharmacist
   d. Your hospital doctor

23) How should we approach our potential participants? (Leave information leaflet first? Talk first and only leave info leaflet if interest shown?)

24) We have decided not to contact peoples' GPs to see how many times they had been to see them after discharge. Instead, we would like participants to keep a kind of diary of if and when they had been to their GP, and if they had been back into hospital. Is this something that sounds reasonable? What do you think of this example diary?

25) The following have been identified as ways of encouraging people to return postal questionnaires. Which do you think would be the most suitable for our study? Do you have any other suggestions?

   a. Money or other incentive.
   b. Recorded delivery.
   c. Contacting participants before sending questionnaire
   d. Re-sending questionnaire
   e. Mentioning obligation to respond
   f. University sponsorship
   g. Personalised questionnaires.
   h. Hand written envelopes.
   i. Stamped as opposed to franked envelope for return
   j. Assurance of confidentiality

k. First class outward mailing

<u>Session 1 - 16th April 2013</u>

Four participants attended this first session. The objectives of the session were to orientate the group members with the rationale and plans for the study so far and, as potential end-users of the dMUR referral service, ascertain their feelings about its potential usefulness and usability for patients.

<u>Background</u>

In order to put the study into context for the group members some time was first spent discussing members' own previous experiences of being discharged from hospital with changed medication regimes. This discussion was also intended to enable the researcher to better understand the types of issues faced by patients in case modifications to the service or study design could be made which would increase quality.

Only one of the four group members (Participant A) at this session described a positive experience in regards to medication support during his last hospital stay. He felt the information he had been given about medication changes was "*very good*". The nurses had shown him how to use his new inhalers and he "*felt quite comfortable*" with the explanations given regarding them and other changes to his medication. This support had been given by nurses and doctors in the hospital, and participant A could not recall seeing a pharmacist during his admission. However he later revealed that his atenolol had been stopped whilst in hospital but he had not been told why. Therefore even this overall positive experience could have been improved.

Participants B and C both described having had extensive changes to medication whilst in hospital and being unable to recall receiving any explanation of why the changes had occurred or how to take new medication. This had led participant both participants to visit their own GPs after discharge specifically to discuss medicines started or stopped in hospital.

These experiences highlight the potential value of the dMUR referral service, where, armed with information from the hospital, community pharmacists could

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discuss patients' concerns and fill information gaps, potentially removing the need for a GP appointment.

MURs and Community Pharmacy

Understanding group members' prior knowledge of the MUR service and attitudes towards community pharmacy in general was also an important objective. It was hoped this would enable the researcher to anticipate the way potential study participants might respond to being approached about the study and the type of information needs they might have in order to decide whether to participate.

All 4 group members at this session reported using the same community pharmacy regularly, which was reassuring in terms of study participants being required to nominate a pharmacy to receive the dMUR referral from the hospital. However only 2 of the 4 members had heard of the MUR service previously (although not under this name).

Participant A had been offered medicines reviews in the past by his regular community pharmacy. He accepted the offers to review his medicines but didn't really feel he got anything out of them *("useless thing"*) largely because he felt that "*he [the pharmacist] couldn't change anything*". Participant A wasn't sure what the pharmacist could do during/following the MUR that would benefit him.

Participant D had also had an MUR, at the pharmacy attached to his GP practice. He said he was *"in and out in 2 minutes"* and felt it *"wasn't worth it"*. The pharmacist hadn't worn a name badge or introduced themselves. They had only discussed 2 out of his 4 regular medicines and *"didn't mention the other 2 at all"*. Participant D had been taking ranitidine since he was diagnosed with a stomach ulcer 25 years ago and didn't feel like it had ever been properly reviewed. When he asked his GP about it he was told *'just take it when you need it'*. He felt that still being prescribed this was a waste of money as he rarely got symptoms, yet still received a supply every month.

Participant B felt that personally she would not need an MUR as she *"questions anything and everything any how"*, by telephoning the pharmacist herself or seeing her GP, who *"tells me what they are all for anyway"*.

These experiences and attitudes raise the following questions of the current MUR service, some of which have also been described in the literature (173,174,286,289,294,315,338):

- Are MURs being targeted to patients who can benefit from them?
- Is there need for better explanation by community pharmacists of what an MUR is and is not in order to direct patient expectations?
- Is there a need to improve the quality of MURs in order to demonstrate a benefit of the service?

Participant D's experience in particular suggests a need for better communication by community pharmacists during MURs and the need to take time to address all a patients concerns regarding medicines. For example, helping participant D to make appropriate use of the prescription re-ordering system could save the NHS money and reduce his frustration, empowering him to take control of his own medication.

Views on the dMUR service

When asked what their personal feelings would be if offered a dMUR, all group members said they would be happy to see their pharmacist for a dMUR and *"could see the value of it".* However Participant A raised the concern that, the way the dMUR service had been presented by the researcher, he *"didn't know how [community pharmacists] would find the time"*. This echoes group members' earlier feelings (and reports in the literature) that community pharmacists are failing to fully realise the opportunity offered by MURs, being constrained by situational pressures (294).

When asked how likely they would be to go for a dMUR if one was offered, 2 of the 4 group members foresaw specific difficulties with attending the community pharmacy. Participant B was not allowed to drive for 4 weeks after leaving hospital so an MUR in this time would have been *"impossible".* Participant A stated that if his COPD deteriorated he would end up needing oxygen and would then find leaving home difficult. His medication would have to be delivered and he would be unlikely to see the pharmacist themselves at all. He felt that lots of people might struggle to attend the pharmacy soon after discharge.

However, when asked about telephone MURs, all 4 group members said they would not want one, with participant B sating: "*I prefer to see a face*". Participant B maintained that even if she knew the pharmacist would be telephoning her for an MUR she "*still wouldn't like it*". Participant A agreed: "*I don't like discussing medication over the 'phone*". Participant C explained that he was "*hard of hearing*" and therefore struggled with telephone conversations.

Participant D could see that a phone consultation might be useful, but only if there was a specific issue to discuss. This scenario is more similar to the NMS, where there is only one medicine involved and follow-up consultations are often carried out by telephone (292). The others agreed with Participant D but said that they would only want a telephone consultation if they initiated it.

When asked about domiciliary MURs, all agreed when Participant A said "*that would be OK*", but were concerned about the cost and how the pharmacist would find the time.

In response to the question 'How soon after being discharged do you think the dMUR should be?' Participants C and D both agreed that 2 weeks after discharge would be optimum, whilst Participant A said that he needed 4-6 weeks to "*get into a routine*" with his new medication after discharge, so would not want an MUR before then. However Participant D maintained that people who were less confident might "*need someone there straight away to explain what they are for, what to do with them and to make sure you are taking them*".

Participant A said that it would be better for pharmacists to tell people about their medication changes whilst they were still in hospital, just prior to discharge, as they could access more people this way. However Participants C and D were both of the opinion that people do not always remember the content of discussions that happen in hospital, with participant C stating: "*its only when you get home that you get the leaflets out*" and this is when questions arise and the need for information presents itself. He expressed the view that medication should be explained to patient away from the hospital environment, as soon as possible after discharge, in their own home if possible.

When asked what they would like to get out of a dMUR, participants A and C both agreed they would like "*knowledge of exactly what each medicine is for*". Participant C would also want an "*explanation of side effects of medication, which are most relevant to particular medicines and what to do about them*", whilst participant A would want "*to have my own questions regarding medication answered.*" Participant D answered: "*reassurance that what you are taking is suitable, being taken correctly and still needed*". Echoing his earlier comments, he also expressed the view that that MURs would be good for "*cutting down waste*" as stockpiling of medication at home could be discussed and medication that has built up or is no longer being taken could be "*taken off the automatic re-ordering system that seems to exist.*" The other 3 members agreed that MURs could help prevent wastage of medication.

Other Points

Interestingly, all group members expressed frustration during this session at the difficulty they had in arranging GP appointments. This raises the question of whether, with proper promotion and targeting, there is a role for dMURs in freeing up appointments by answering questions patients have re medicines post discharge.

Session 2 – 21st May 2013

The objectives of this session were to use the PPI group members' perspective to gain an understanding of how potential participants might respond to being approached regarding participation in the study, and also their views on some of the ethical considerations that had arisen during early stages of study planning. Group members views on eligibility criteria were sought, in case they could suggest any further groups of patients who they felt might benefit from being targeted, or any of the current eligibility criteria were unsuitable from their perspective.

Drafts of study paperwork were shared with the group and comments on acceptability and suggestions for improvement invited. The relative importance of potential study outcomes was also discussed.

Eligibility Criteria

Some time was spent explaining the planned eligibility criteria for the study and obtaining the group members' feedback.

When asked about the number of changes to a person's medication that might be required in order for them to benefit from a dMUR, Participant D felt that "*Two or more, probably*" would be needed. He stated that this was because multiple changes "*might suggest other factors*" that would make patients particularly likely to benefit from a dMUR. Such factors might include co-morbidities or a deterioration in physical or mental condition compared to before hospital admission which meant that patients might need more help with managing their medicines.

When asked their opinion on the number of medicines a person would need to be taking in order to benefit from a dMUR, the initial criteria of 5 or more surprised participants D and F:

Participant D *"That's a lot of medicines"*

Participant F: "*I need a siesta every afternoon even without taking all those medicines!*"

However Participant C was already taking 8 medications and found the criteria of 5 or more reasonable. It was agreed that some patients might be used to managing multiple medicines, whilst others might have difficulties despite only taking one or two. Therefore some degree of flexibility in this criterion might be required during recruitment. This matches reports in the literature that ward pharmacists' own judgement of need can be a successful criteria for recruitment of patients to medication support services (150).

There have also been mixed reports in the literature of whether participants can nominate one particular pharmacy they would visit for medication support post-discharge (89,120,123,124). However all PPI group members agreed that they could nominate a pharmacy they would want to receive their dMUR referral.

During discussion about problems with medicines adherence as an eligibility criteria for the study, Participant F identified a difficulty in remembering to take medicines as an issue that could be addressed during a dMUR. This prompted a conversation regarding whether patients in hospital would admit to a difficulty in remembering to take medicines if approached and asked by a hospital pharmacist or researcher:

Participant D *Well I'd tell the truth*

Participant C *It depends how you were feeling, being in hospital you're not in a natural environment*

It was agreed, however, that if identified, difficulty in remembering to take medicines would be a valid indication for a dMUR. Physical dexterity was also raised as a barrier to adherence which could be tackled during a dMUR:

Participant E: *I do have difficulty taking the lids off bottles*

Participant D: *Some of the blisterpacks, they're hard to…*

Participant C: *Yes*

Participant D: *Aren't they?*

Participant E: *They cut some of my tablets down to half the dose, and I had to cut them in half with a breadknife! They were going all over the kitchen!*

<u>Participant Information</u>

When asked for comments on the participant information leaflet, all group members agreed that it was easy to understand, the font size was large enough and that there was enough information for study participants to know what was going to happen during the study:

Participant C "*It's all set out clearly*"

Participant E was however concerned that not all potential study participants would have the same ability to understand the written information as the PPI group members. It was agreed that verbal explanation and discussion with potential study participants prior to recruitment was vital.

When asked if there was anything else they would want to know, none of the group members could think of anything.

<u>Ethical Considerations</u>

The concept of randomisation and the fact this meant that some participants would not be referred for a dMUR as part of the study was explained to the group members, and it was asked if they felt this was acceptable. Participant D responded: "*Yes because I wouldn't expect to get one*". All group members agree that as dMURs were not a standard service, there were no concerns about randomising some participants not to be offered a dMUR during the study.

No concerns were raised regarding the participant consent form. When shown the referral form which would be sent to their community pharmacist, all group members agreed that they would be happy for the pharmacist to receive this information. All group members also agreed that their MUR action plan being shared back with the researcher would be acceptable.

All members felt that participants' GPs should be informed that they were taking part in the study, and would be happy for their GP to be contacted regarding the number of times they had visited since discharge if this was to be used as a study outcome.

When asked how they would feel about their hospital records being consulted to see if they had been readmitted and, if so, why, Participant D felt that this was a necessary part of the research: "*They've got to be, it's for their benefit, you've got to have unlimited access to information*". Participant C agreed: "*You've got their best interests at heart*"

<u>Data Collection</u>

Remembering group members' concerns regarding telephone MURs at the first session, some time was spent discussing the most acceptable method for data collection from participants during the study. Telephone follow-up was the least preferred method:

Participant C *It all depends how old they are*

Participant D *And condition's a factor as well*

Participant C *I don't like long telephone calls*

Participant E *And you don't know who is at the other end of the phone*

Participant D *Well that's another thing*

Participant E *And you're being rung up and asked personal questions*

However all agreed they would be happy to fill in a paper questionnaire that had been posted to them:

Participant E *I think that would be a better option*

Participant C/D *Yes*

Participant D however clarified that there should be a pre-paid envelope provided for participants to return the questionnaire.

Examples of draft follow-up questionnaires containing adherence, enablement and HR-QoL scales were shown to the group members and their comments requested. Regarding the adherence scale, Participant E pointed out that this scale might not produce accurate data: "*It might be difficult for older people if you were forgetting to take tablets to remember you'd forgot!*" This lead to a discussion about cross referencing the adherence scale with GP or community pharmacy prescription refill data. All group members agreed they would be happy for their GP or community pharmacist to supply this information.

Regarding the questionnaire in general, all group members agreed they would be happy to fill it in, but that seeing the questions had reinforced for them that telephone follow-up was not a suitable option:
Participant D *The questions aren't intrusive. It's a fairly honest sort of thing. [But you] couldn't do it over the 'phone*
Participant C *You need time read it from start to finish first, and time to consider where to put the tick*
Participant D *And where it says 'a lot or a little' you can actually see…*

When asked how they would feel about being interviewed at home in more depth, all group members felt this would be acceptable, and indeed necessary to obtain quality data:
Participant D: *Yes, because you can then compare that with questionnaires*
Participant E: *Wouldn't there be cost implications? A lot of time would be spent driving around.*
Participant D: *Yes but that's probably the only way to get data saturation*

In terms of how long the interview should take, Participant D felt this should be no longer than 15-20 minutes. Participant C queried whether interviewed participants would be expected to fill out questionnaires as well. When asked for his opinion on this, he suggested leaving the questionnaires with the participants along with a pre-paid envelope in which to return them.

In terms of repeating follow-up at six months, this was again agreed to be both acceptable and necessary to the research:
Participant D *I think it is [acceptable]*

Participant C *You usually get a follow-up appt at six months*

Participant D *You've got to keep track of people. I think a follow-up later on is a must*

<u>Study Outcomes</u>

One of the objectives of PPI in this research was to ensure that study outcomes were those which mattered to participants. When asked what they most would like to achieve as an outcome of a dMUR, group members had differing ideas. For Participant C, "f*eeling more able to live a normal life"* (ie improved HR-QoL) would be a priority outcome. Participant D felt that fewer visits to the GP and not being readmitted to hospital were both important outcomes, whilst Participant E agreed that avoiding readmission would be most important.

In terms of letting participants know about study results, all group members agreed they would want to know the study's outcome.

When asked for their ideas of how this should be done, letter was agreed to be the best option. Internet based methods of communication were not felt to be the most appropriate:

Participant D *No I don't think so*

Participant E *I'm a complete technophobe!*

Participant D *Not everyone has a computer or email. A letter is far better.*

Group members were also enthusiastic about an event being held to feed back to the study participants and were also happy to attend such an event to obtain informal feedback themselves:

Participant D *Yes – then we can talk to participants and get feedback. They might say things about service to us they wouldn't say to you!!*

<u>Other Points</u>

Various other comments were made by group members during this session which shed light on potential roles for and attitudes towards the MUR:

Participant D: (Commenting on dMUR service) *"This seems to be the way to go about it. A service like this might stop people like me being on all these silly things for years and years."*

This positive comment also reveals a potential expectation on the part of patients that their medicines might be altered and rationalised as part of an MUR or dMUR. The need to manage patient expectations regarding the extent of community pharmacists' power to make changes to medication also arose following session 1. The vast majority of community pharmacists are not prescribers and the extent to which they are able to liaise with GPs to make changes to prescriptions is variable (286,288,289,303,339). It might be that a shift in this direction is needed to fully realise the potential of the MUR but it is likely that much closer working between GPs and community pharmacists would be required than is the norm at present.

It arose during this session that something as simple as a transparent explanation of the concept of generic medication as part of the MUR or dMUR might be welcomed by patients:

Participant D: *I always use [names pharmacy] and they will keep changing the tablets. Not what they are, just the makes, but they never tell you. So you get home and get the boxes and think 'those aren't the same' then you have to waste a phone call saying 'these are different' and they say 'no they're not, they're just cheaper'. So why don't they tell you at the time? And that's another thing, probably for older people, they probably need that advice more than other people.*
Participant C: *Yes.*
Participant D *And they might think, 'ohh, I better get on the bus and go back.' It's not really on I don't think, to change all these things. I can understand why they do it, it's to save money, but it needs some explanation. We just need to know what we've got.*

This might be particularly relevant following a hospital discharge, as even if a patient's regular community pharmacy consistently uses the same generic version of a medicine, the hospital may well have dispensed a different version to top the patient up during admission or on discharge. This may lead to confusion, wastage or even overdose if patients double up on some medicines. A dMUR might therefore include a 'cabinet check' (which could be virtual if the dMUR takes place at the community pharmacy and patients bring along all stocks of medication from home).

Despite a generally positive attitude of all PPI group members towards the dMUR service, a point raised during session 1 (by participant B), that not all patients might be receptive to the concept, was repeated, on this occasion by participant F: *"I don't think I'd be the right sort of person because everything is organised so well between my doctor and the pharmacist."* Whether, with more careful explanation of the role of the dMUR service, such patients would realise unmet needs which could be fulfilled by a dMUR, is uncertain. However the fact that both participants B and F had received a full explanation of the service during the PPI group sessions and yet still felt a dMUR was not for them makes this unlikely. The reality that some potential participants might refuse to take part on these grounds, thereby limiting recruitment to the study, must be accepted.

Another repeated theme from session 1 was group members' frustration with the difficulty in making GP appointments, reinforcing the idea that there is a potential for dMURs to reduce pressure on GPs by answering questions that patients would otherwise have taken to the surgery.

Session 3 – 20th August 2013

This session focussed in more depth on the recruitment process for the study and the methods of follow-up to be employed.

Maximising Recruitment

All group members agreed that they would be most likely to participate if they were approached regarding the study by their hospital doctor, rather than a pharmacist or member of the research team. However concerns were raised that the doctors might simply be too busy to take on this role, and in this case, their nurse was suggested as the next best option. This suggests that patients would be more receptive to the idea of taking part in research if the topic was introduced by a healthcare professional they already knew and trusted. Engaging all medical doctors and nurses at SONT to approach patients regarding participation in the study was, however, not considered feasible within the resources available. This may place a further restraint on recruitment, if patients refuse because they are approached by someone unfamiliar. It is hoped that, if ward pharmacists are able

to build up a relationship with their patients, they could successfully take on the role of first approach to potential study participants.

Discussion also took place about how the approach to potential participants should be made. Options included leaving the participant information leaflet with the patient to read through first, or introducing the study first and only leaving the leaflet if the patient showed an interest in participating. All group members agreed that to have a general chat regarding the study and only leave the leaflet if interest shown was the best option. Some group members felt that the leaflet was too long and that this might be off-putting. However the need to present full information was also appreciated. Following discussion, it was decided to split the participant information into two leaflets. The first would give a general overview of the study and the dMUR service and would be designed to be left with potentially interested patients by a member of ward staff (doctor, nurse or pharmacist) following a brief introduction to the study. The researcher could then approach the patient to discuss participation in more depth and present part two of the information leaflet.

Data Collection/Follow-up

By this point in the study's planning it had been decided not to contact participants' GPs to see how many appointments they had had since discharge (Section 5.6.4). Copies of the 'diary' proposed instead in which participants could record healthcare professional contacts were circulated to group members. All members agreed that it was reasonable to ask participants to record the visits in the diary and that the format of the diary was easy to use.

Ways of maximising the return of the postal questionnaire were discussed, based on a Cochrane review on the subject (244). The methods felt to be most suitable by the PPI group members were:

- A follow-up contact by post with a second copy of the questionnaire. Two weeks after the first questionnaire had been sent was felt to be a suitable time period for this, and only one follow-up was felt to be appropriate. The group suggested encouraging participants by way of the covering letter to contact the researcher if they were having difficulty completing the questionnaire.

- Having the hospital's logo or frank on the envelope and wording the covering letter as coming from the hospital (as opposed to the University as suggested by the Cochrane review)
- Personalising the covering letter using mail merge.
- Including a stamped (not franked) addressed envelope in which to return the questionnaire.

Methods suggested by the Cochrane review that were felt to be definitely not appropriate included offering money as an incentive and contacting participants before sending the questionnaire. Recorded delivery or first class mailing were felt to be an unnecessary expense.

The latest draft of the follow-up questionnaire was reviewed by the group. Concerns arose that some questions might be missed as it was double sided. However it was also raised that using single sided production would increase costs and make the questionnaire more bulky and therefore off-putting to some participants. Printing 'PTO' on relevant pages and numbering the pages was agreed as a compromise.

Participant C also suggested changing some of the wording to the MMAS. '*Hassled'* was therefore replaced with *'inconvenienced'*, and *Medication regimen* with '*medication routine'* as these were felt to be more suited to older English participants.
Additionally, a phrase at the end of the questionnaire reminding participants to return it in the envelope provided was added.

Appendix 3: Estimating Eligibility for Medicines Support Study – Emergency Admission Unit (EAU) Pilot 3-14th June 2013

Eligibility Criteria Being Screened in This Piece of Work

- Under care of medical directorate
- Aged 65 years or older
- Using at least one medication prior to admission
- Self-medicating at home
- Can nominate a regular community pharmacy

Pharmacist / Ward Based Technician Roles

As part of medicines reconciliation, two additional questions need to be asked of **medical** patients **aged ≥65** (unless already obvious from the clinical notes):

1) Do you manage your own medications at home?
   If the patient answers yes:
2) Which community pharmacy do you normally use?

Annotate bed plan:

SM = self medicates

<65 = patient less than 65 years old

NRM = no regular medicines

S = surgical patient

Carer = carer manages medicines

NH = from nursing home

> *An Example*
>
> *SM from*
>
> *pharmacy name*

If patient unable to tell you the answer to one / both of the above, put "?"

Note on multidose compliance aids (MCA)

It may seem inappropriate to classify a patient as 'self-medicating' if they use an MCA prepared by some-one else (e.g. carer or community pharmacy). It is important to note, however, that patients who use MCAs may also use medicines not contained within the MCA, e.g. inhalers, liquids, patches, injections, 'when required' items and medicines with special administration requirements, such as warfarin, bisphosphonates, calcium /vitamin D supplements, soluble aspirin.   These medicines are often those that are more complex to take and thus may be subject to poor adherence. Therefore if a patient who uses an MCA plus additional medications views themselves as self-medicating, they should be classed as such.

Results

Date	No. new Patients Seen	Self med?	Regular chemist?	Unable to ask	Excluded					
					<65	NRM	Surgical	Carers	NH	Other
3/6/13	17	9	8	1	2	1	0	2	1	1 deaf
4/6/13	17	3	3	2	8	1	3	0	0	0
5/6/13	15	2	2	1	3	0	3	4	1	1 Polish
6/6/13	17	5	5	3	3	0	0	3	3	0
7/6/13	20	1	1	9	2	2	1	2	2	1 out of area
11/6/13	21	4	2	7	6	0	1	1	2	0
12/6/13	17	6	5	3	4	0	1	3	0	0
13/6/13	21	5	5	3	5	1	0	4	3	0
14/6/13	20	5	5	3	6	0	2	1	2	1 Spanish
Total	**165**	**40**	**36**	**32**	**39**	**5**	**11**	**20**	**14**	**4**

Total number medical patients = 154

Total number eligible for referral to researcher (excluding those unavailable for questioning) = 36

Percentage eligible for referral = (36/154)*100 = <u>23%</u>

Medical Discharge Prescriptions Processed by Pharmacy on the First Weekday of Each Month between July 2012 and June 2013

Date	Total Discharges	Medical Discharges (Excluding patients discharged from surgical wards, EAU and Observation Ward)
1/7/12	27	17
1/8/12	41	19
1/9/12	35	21
3/10/12	41	24
1/11/12	58	29
1/12/12	41	32
3/1/13	42	20
1/2/13	35	24
1/3/13	51	28
2/4/13	36	27
1/5/13	40	18
1/6/13	47	32
Mean	**41**	**24.25**

Estimated number eligible for referral to researcher = 0.23*24.25 = <u>5.58</u>

Appendix 4: Graphs Showing Relationship between Sample Size and Power to Detect a Specific Effect Size
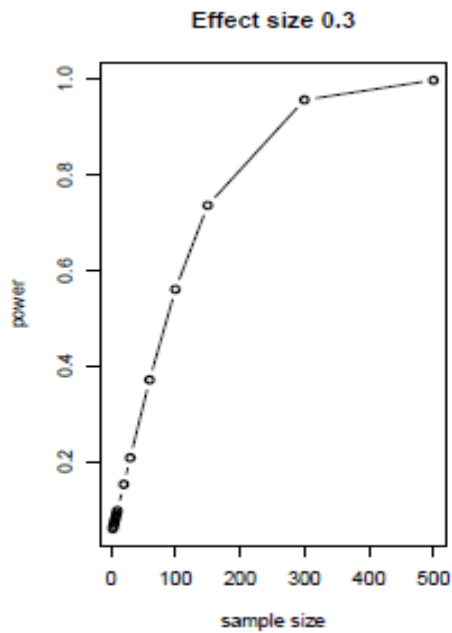

Figure A4.1 Relationship between Sample Size and Power to Detect Effect Size of 0.3 (With thanks to Dr Sven Batke)
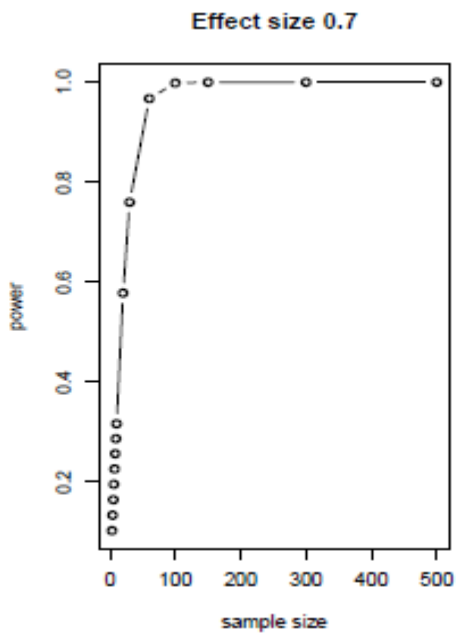

Figure A4.2 Relationship between Sample Size and Power to Detect Effect Size of 0.7 (With thanks to Dr Sven Batke)

1

Appendix 5: Covering Letter and Information Leaflet Sent to Participants' GPs

<div align="right">

Helen Ramsbottom
Clinical Pharmacist and Chief Researcher for Medication Support Study
Southport and Ormskirk Hospitals NHS Trust
Town Lane
Kew
Southport
PR8 6PN
Tel: 01704 704161
Mobile: 07932506802
Fax 01704 704197
Email Helen.ramsbottom@nhs.net

</div>

Dear GP,

Re:……………………………   DOB:………………… NHS No:……………………

The patient identified above has agreed to take part in the **Medicines Support Study**

I am a specialist care of the elderly pharmacist and am also undertaking a PhD with the University of Wolverhampton and Southport and Ormskirk NHS Trust. My research will investigate whether a medicines adherence support service can improve medication adherence and reduce GP visits and hospital re-admissions. The study will involve the pharmacy department at the hospital referring suitable patients for a post discharge Medicines Use Review with their community pharmacist, and comparing their medication-related experiences and outcomes with a similar group of patients who have not been referred. More details about the study can be found attached.

If you have any questions regarding the study, please do not hesitate to contact me using the details above.

Yours sincerely,

Helen Ramsbottom
Clinical Pharmacist and Chief Researcher for Medication Support Study

General Practitioner Information—Medicines Support Study

What is the study?

We are trying to find out if having a post discharge Medicines Use Review (MUR) with a community pharmacist improves patient medication adherence and reduces hospital re-admissions.

Between one-third and half of all medicines for long term conditions are not taken as recommended. Following a medication routine after being in hospital is particularly difficult as nearly two thirds of people have three or more medicines changed during a hospital stay and almost half experience an error with their medication on discharge.

We will be identifying patients who have risk factors for medicines related problems and referring them for a post discharge MUR with their regular community pharmacist. We will follow up these patients and compare them to another group of patients who have not been referred for an MUR.

In the initial feasibility study, we will be setting up a robust referral process from the hospital pharmacy to community pharmacists. We also want to check that the way we plan to collect our results will work. This feasibility study will involve up to 100 patients in total. We then hope to expand the study to conduct a full randomised controlled trial, evaluating a range of outcomes including readmissions, health related quality of life, enablement, medication adherence and the need for post discharge GP visits.

Why has my patient been recruited?

We are recruiting patients aged 65 and older who are either taking multiple medicines or have had medication changes whilst in hospital. The patient named on the accompanying letter has been identified using these criteria and has consented to take part in the study.

What will happen to my patient during the study?

If one of your regular patients is selected to receive an MUR as part of the study, their usual community pharmacist will receive a copy of the discharge medication and a referral form highlighting any changes in medication that have gone on during admission. They will arrange an appointment with the patient within four weeks of discharge in order to carry out the MUR.

During the MUR, the community pharmacist will assess any problems the patient is having with their medication that may limit adherence. These may include forgetfulness, lack of understanding of the purpose or importance of the medication, physical difficulty with taking the medication or side effects. The pharmacist will discuss ways of resolving these issues and ensure the patient understands the purpose of and best way to take each medicine.

Following the MUR, the community pharmacist will return a copy of the action plan produced to the hospital by fax or email. This will help us to improve the medicines service we give to patients whilst they are in hospital. Patients will have agreed to have this information shared with the researcher during the initial consent process.

In order to determine if post discharge MURs improve outcomes, there will also be another group of patients within the study who are not referred for an MUR. These patients will receive standard discharge information including a leaflet explaining the services offered by community pharmacies. Some of these patients may seek an MUR independently and will be treated in the same way as any other post-discharge patient. This will be explored with the patient at follow-up and ensures that no patient will be denied an MUR as part of the study.

We will contact all patients by post at one and six months after discharge and ask some simple questions to evaluate their current medication taking behaviour. Some patients will be interviewed in more depth about their medication-related experiences since returning home. We will ask them about the medicines information given to them by the hospital, any medication review they have had (MUR or otherwise), and any hospital or GP visits.

Will I be expected to do anything extra?
We hope that GP time will actually be saved as part of the study, as medication education following discharge will be provided by community pharmacists, rather than requiring an appointment with the GP. However a community pharmacy MUR is **not** a clinical review and you should continue your usual practice for reviewing the clinical aspects of the patient's post discharge medication.

The community pharmacist will usually only contact you if they have a specific recommendation to make requiring your action. This is in-line with the national service specification for MURs that all community pharmacists follow. The researchers will not contact you with recommendations.

What will happen to the results of the study?
The results will be included in the researcher's PhD thesis. They will also be presented to representatives from the Local Pharmaceutical Committee, Local Professional Network, NHS England and interested community and hospital pharmacists. Summaries of the results will be sent out to all community pharmacists and GPs whose patients have been participants in the study. The results may also be made available to a peer reviewed journal.

No-one will be able to identify you or your patient from the results of the study and all information given will be completely confidential.

Does my patient have to take part?
Your patient has given voluntary, informed consent to take part in the study. They are free to withdraw at any time, without giving a reason. The patient's consent form for the study is attached for your records. If you have any concerns regarding your patient's participation, please contact us using the details below.

Authorisation From Ethics Committee
Ethical approval has been granted by the University of Wolverhampton, by Southport and Ormskirk NHS Trust, and by the Northwest NHS Research Ethics Committee.

Contact for Further Information:
If you have any questions about the study please contact the lead investigator, Helen Ramsbottom, or the university supervisors, who will be pleased to help you:

Helen Ramsbottom	Professor Ray Fitzpatrick/ Dr Paul Rutter
(Supervisors)	
Pharmacy Department	Pharmacy Practice Division
Southport District General Hospital	Department of Pharmacy
Town Lane	School of Applied Sciences
Kew, Southport	University of Wolverhampton
PR8 6PN	Wulfrana Street, WV1 1LY
Tel: 01704 704161 / 07932506802	Tel: 01902 322173
Email: helen.ramsbottom@nhs.net	Email:ray.fitzpatrick@wlv.ac.uk/paul.rutter@wlv.ac.uk

UNIVERSITY OF
WOLVERHAMPTON

Southport & Ormskirk Hospital **NHS**

NHS Trust

Medication Support Study—We Need Your Help!

What is the medication support study?

We are trying to find out if having a medication use review (MUR) with a community pharmacist helps people aged 65 or older to manage their medicines after they have been in hospital.

Why do we need you?

To help us plan and carry out the study in the best possible way, we need the views of patients, their friends, families and carers. This will help make sure we get the answers that really matter to our patients.

What is needed from you

We will be setting up group or one-to-one discussions about the support people are given to manage their medicines and the questions our research is trying to answer. You will be invited to give your opinions on what will happen to patients who participate in the study, as well as some of the paperwork that will be used.

How to get involved

If you are interested in becoming involved, or would like to find out more information, please contact:

Helen Ramsbottom
Pharmacy Department
Southport and District General Hospital
Telephone 01704 704161
Email Helen.ramsbottom@nhs.net

Appendix 7: PPI Group Recruitment Letter Published in SONT Foundation Trust Members Newsletter December 2012

Helen Ramsbottom
Clinical Pharmacist and Chief Researcher for Medication Support Study
Southport and Ormskirk Hospitals NHS Trust
Town Lane
Kew
Southport
PR8 6PN
Tel: 01704 704161
Bleep 3737 via switchboard 01704 547471
Fax 01704 704197
Email Helen.ramsbottom@nhs.net

Dear Foundation Trust Member,

Medication Support Study Patient Involvement

I am one of the clinical pharmacists at Southport and Ormskirk Hospitals NHS Trust and am also working on a PhD with the University of Wolverhampton. I am investigating ways in which pharmacists can help people to get the maximum benefit from their medication.

I am trying to find out if having a Medicines Use Review ('MUR') with a community pharmacist, shortly after being discharged from hospital, helps people to manage their medicines more effectively.

In order to make sure my research provides the best possible information I would like to gain the perspective of patients and members of the public who may use our hospital services. This is likely to involve group or one-to-one discussions about the support people are given to manage their medicines and the questions I am trying to answer through doing my research. You will be invited to give your opinions on what will happen to patients who participate in the study, as well as some of the paperwork that will be used.

If you are interested in becoming involved, or would like to find out more information, please do not hesitate to contact me using the details at the top of this letter.

Yours sincerely,

Helen Ramsbottom
Clinical Pharmacist and Chief Researcher for Medication Support Study

Appendix 8: dMUR Referral Form

UNIVERSITY OF WOLVERHAMPTON

Southport & Ormskirk Hospital NHS
NHS Trust

Community pharmacy referral for post discharge Medicines Use Review

Patient name:		Date discharged:	
NHS number:		Usual community pharmacy:	
Address:		Other relevant patient information:	
Contact telephone number:		GP details:	

To the community pharmacist, the above patient has been recruited into the Medicines Support study. Please review the following changes with the patient as part of a Medicines Use Review.

New or changed medicines and directions include dose and formulation changes	Reasons and suggested follow up
Stopped medicines include rationale and recommendations if needed	

Please find a current medication list for this patient attached to this referral form

Allergies		
Causative medicine	Brief description of reaction	Probability of occurrence

Name of person referring:	Helen Ramsbottom
Job title:	Clinical pharmacist and chief researcher for Medication Support Study
Name and address of organisation:	Southport and Ormskirk Hospitals NHS Trust Town Lane, Kew, Southport, PR8 6PN
Telephone number & bleep:	01704 704161 (Pharmacy Direct Line) or Mobile 07932506802
Email address:	helen.ramsbottom@nhs.net
Fax number:	01704 704197
Signed:	
Please return a copy of issues identified and actions suggested during the MUR(e.g. MUR action plan) to the researcher using the details above	
WE ASK THAT YOU ACKNOWLEDGE RECEIPT OF THIS REFERRAL BY RETURN FAX OR TELEPHONE CALL TO THE NUMBER ABOVE	

UNIVERSITY OF
WOLVERHAMPTON

Southport & Ormskirk Hospital **NHS**

NHS Trust

Study Number:2012/028 SISD
Patient Identification Number for this trial:
Chief Researcher: Helen Ramsbottom

Informed Consent Form (Participant): Medicines Support Study

The Medication Support Study will involve the pharmacy department at Southport District General Hospital identifying people who might benefit from a Medicines Use Review (MUR) with their community pharmacist. Half of these people will be referred for an MUR whilst the other half will not. Everyone who takes part will be asked to answer some questions four weeks and six months after being discharged from hospital. This will usually be by post, but some people will be contacted to arrange a face to face discussion.

If you have read the information about the study and are willing to participate please complete and sign this form. It will then be collected by a member of the pharmacy team. Alternatively, you can give this form to a member of nursing staff and ask them to return it to the pharmacy department.

Please initial each box

I have read and understood parts 1 and 2 of the information sheet dated December 2013 (version 3) for the above study.	
I have had the opportunity to ask questions about the study and have had them answered satisfactorily.	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason, without my medical care or legal rights being affected.	
I understand that the information I give as part of the study may be shared with my regular community pharmacy and the hospital pharmacy. I give permission for this sharing of information.	
I understand that relevant sections of my medical notes will be looked at by the researchers in order to collect background information relevant to my participation in the study, and if I am re-admitted to hospital in order to work out if my re-admission could have been influenced by my medication. I give permission for the researchers to have this access.	
I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the University of Wolverhampton and from the NHS, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
I understand that I may be contacted to arrange a face to face interview with a pharmacist. I agree to the interview being audio recorded, and to anonymous quotes being used in the study report.	
I agree to my GP being informed of my participation in the study.	
I agree to take part in the above study	

Name of participant:	Date:	Signature:
Name of person taking consent:	Date:	Signature:

When complete copy: 1 for participant, 1 for research site file (fax to GP and community pharmacist on discharge), 1 (original) to be kept in medical notes

Appendix 10: Covering Letter and Information Leaflet Sent to Community Pharmacies

Helen Ramsbottom

Clinical Pharmacist and Chief Researcher for Medication Support Study

Southport and Ormskirk Hospitals NHS Trust

Town Lane

Kew

Southport

PR8 6PN

Tel: 01704 704161

Bleep 3737 via switchboard 01704 547471

Fax 01704 704197

Email Helen.ramsbottom@nhs.net

Dear Community Pharmacist,

Medication Support Study

Would you like to receive post discharge MUR referrals for pre-screened patients, along with a copy of their discharge medication and information on changes to medications during admission? All you will have to do is contact the patient to arrange a convenient time for the MUR, and return a copy of your actions to the hospital afterwards.

I am a specialist pharmacist at Southport and Ormskirk Hospitals NHS Trust. I am also undertaking a PhD with the University of Wolverhampton. If you have not signed up already, I would like to invite you to be part of the 'Medication Support Study'.

My research will investigate whether a medicines adherence support service can improve patient medication adherence and reduce GP visits and hospital re-admissions. The initial study will involve the pharmacy department at the hospital referring suitable patients for a post discharge MUR with their community pharmacist, and comparing their medication-related experiences and outcomes with a similar group of patients who have not been referred. More details about the study, and a consent form for you to return if you are willing to take part, can be found attached.

If you have any questions regarding the study, please do not hesitate to contact me using the details above.

Yours sincerely,

Helen Ramsbottom
Clinical Pharmacist and Chief Researcher for Medication Support Study

Community Pharmacy Information—Medicines Support Study

What is the study?

We are trying to find out if having a post discharge Medicines Use Review (MUR) with a community pharmacist improves patient medication adherence and reduces hospital re-admissions.

Between one-third and half of all medicines for long term conditions are not taken as recommended. Following a medication routine after being in hospital is particularly difficult as nearly two thirds of people have three or more medicines changed during a hospital stay and almost half experience an error with their medication on discharge.

We will be identifying patients who have risk factors for medicines related problems and referring them for a post discharge MUR with their regular community pharmacist. We will follow up these patients and compare them to another group of patients who have not been referred for an MUR.

Why should I take part?

Following the changes to the NHS Community Pharmacy Contract in October 2011, half of all MURs conducted have to be targeted towards specific patient groups, one of which is those that have recently been discharged from hospital. By taking part in the study, you will receive referrals from the hospital for patients we have identified as being at risk of medication related problems post discharge. This will help you to identify patients who will benefit from an MUR and provide the basis for its content.

Providing feedback to the hospital will help us to identify ways to improve our own medication support services to patients, which may reduce problems with medication post discharge in the future.

What will happen if I decide to take part?

If one of your regular patients is selected to receive an MUR as part of the study, we will fax you a referral form detailing their discharge medication and any medication related problems identified during admission.

You can then contact the patient to arrange a mutually convenient time for the MUR. According to the national guidance, the MUR should normally take place within **4 weeks** of discharge.

Following the MUR, we would like you to return a copy of the action plan (or feedback on matters identified and actions taken if no action plan is produced) to us by fax or email. This will help us to improve the medicines service we give to patients whilst they are in hospital. Patients will have agreed to have this information shared with the researcher during the initial consent process.

In order to determine if post discharge MURs improve outcomes, there will also be another group of patients within the study who are not referred for an MUR. These patients will receive standard discharge information including a leaflet explaining the services offered by community pharmacies. Some of these patients may seek an MUR independently and should be treated in the same way as any other post-discharge patient. This will be explored with the patient at follow-up and ensures that no patient will be denied an MUR as part of the study.

All patients referred to you for an MUR as part of the study have been fully informed regarding the nature of the study and their consent to take part will have been gained.

We may also ask you to provide feedback on the quality of the referrals you receive from the hospital, to help us review the information we supply on referral and how we identify suitable patients to refer.

What will happen to the data I provide?
Feedback regarding MUR action plans will be used in two ways:
- The number and type of issues addressed during MUR will help to identify recurrent adherence problems faced by patients after discharge. This will inform improvement of the medicines support services provided to patients who are or have recently been in hospital.
- Discussion of their MUR with patients during follow-up interviews will help to find out whether recommendations made by community pharmacists are acted on by patients and whether these improve adherence

What will happen to the results of the study?
The results will be included in the researcher's PhD thesis. They will also be presented to representatives from the Local Pharmaceutical Committee, Local Professional Network, NHS England and interested community and hospital pharmacists. Summaries of the results will be sent out to all community pharmacists and GPs whose patients have been participants in the study. The results may also be made available to a peer reviewed journal.

No-one will be able to identify you from the results of the study and any information you give will be completely confidential.

Do I have to take part?
All community pharmacies in Sefton and West Lancs are being asked to take part in the study. However it is your decision whether you want to be involved. You are free to withdraw at any time, without giving a reason.

Authorisation From Ethics Committee
Ethical approval has been granted by the University of Wolverhampton, the Research and Development Department at Southport and Ormskirk NHS Trust, and the Northwest NHS Research Ethics Committee (pending).

What should I do now if I want to take part?
If you would like to take part in the study, please complete the attached consent form and return it by email or fax to: helen.ramsbottom@nhs.net , or 01704 704197

Contact for Further Information:
If you have any questions about the study before deciding to take part, please contact the lead investigator, Helen Ramsbottom, or the university supervisors, who will be pleased to help you:

Helen Ramsbottom	Professor Ray Fitzpatrick/ Dr Paul Rutter (Supervisors)
Pharmacy Department	Pharmacy Practice Division
Southport District General Hospital	Department of Pharmacy
Town Lane	School of Applied Sciences
Kew, Southport	University of Wolverhampton
PR8 6PN	Wulfrana Street, WV1 1LY
Tel: 01704 704161	Tel: 01902 322173
Email: helen.ramsbottom@nhs.net	Email: ray.fitzpatrick@wlv.ac.uk / paul.rutter@wlv.ac.uk

| UNIVERSITY OF WOLVERHAMPTON | Southport & Ormskirk Hospital **NHS** NHS Trust |

Informed Consent Form (Community Pharmacy): Medicines Support Study

If you have read the information about the study and are willing to participate please complete and sign this form and return it by email or fax to: helen.ramsbottom@nhs.net , or 01704 704197

Please tick each box

I have read and understood the information sheet for the study	
I have had the opportunity to ask questions about the study and have had them answered satisfactorily	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason	
I understand that any information I give as part of the study, including patient details, will be treated with strict confidentiality and that I will be anonymous in any written reports from the research	
I agree to take part in the study	

In addition, we would be grateful if you could provide the following information:

I am able to offer telephone MURs	Yes No
I am able to offer domiciliary MURs	Yes No
I would prefer to receive referrals and other information relating to the study by:	Email: Fax:
My email address / fax number is:	
Name and address of pharmacy:	
Contact number:	

Signed: Date:	Print Name:

Appendix 12: Initial contact slip for potential participants

Dear …………………………………………

One of the hospital's pharmacists is going to see you about a project looking at how we can better support patients with their medication on discharge from hospital. Your consultant…………………………………… knows about this project and is in support.

Signed ……………………………………………………. (Consultant, Ward …………………)

Appendix 13: Participant Information Part 1

UNIVERSITY OF WOLVERHAMPTON

Southport & Ormskirk Hospital **NHS**
NHS Trust

Medicines Support Study: Participant Information Part 1

What is the study?
Between one-third and half of all medicines for long term conditions are not taken as recommended. Following a medication routine after being in hospital is particularly difficult as nearly two thirds of people have three or more medicines changed during a hospital stay and almost half experience an error with their medication on discharge.

We are trying to find out if having a Medicines Use Review ('MUR') with a community pharmacist helps people aged 65 or older to manage their medicines after being in hospital.
An MUR provides an opportunity for people to find out more about the medicines they are taking and pick up and tackle any problems they are having with their medicines.

The research we are inviting you to take part in is called a feasibility study. The results will be used to help improve the medicines service people receive when they are discharged from hospital. They will also be used to help us plan a larger study to look at the benefits of the service in more detail.
This part of the study will involve about one hundred patients in total.

Do I have to take part?
It is your decision whether you want to be involved in the study. If you decide to take part, you are free to withdraw at any time, without giving a reason. Any information you have given us can be destroyed if you wish. You can still ask your community pharmacist for help with your medicines even if you are not taking part in the study.

What will happen if I decide to take part?
People who agree to take part in the study will be divided randomly into two groups (meaning you have an equal chance of being in either group). This is called a randomised controlled trial (RCT). RCTs are used in research when we want to compare different ways of treating people, to see if one is any better than the other.

People in the first group will be referred to their usual community pharmacist for an MUR. People in the second group will not be referred. They will be called the control group.

If you are referred for an MUR, we will send the community pharmacist details of any medicines that have changed during your hospital stay along with a full list of your discharge medication and the ward you were on, to help them prepare for your MUR. No details of the reason for your admission will be sent.

People in the MUR group will be contacted at home by their community pharmacist to arrange a convenient time for them to attend the pharmacy for their MUR. The MUR will take place within 4 weeks of you being discharged from hospital. You will be informed before your discharge if you are going to be referred for an MUR. Otherwise you will be discharged as normal and your community pharmacy will not contact you to arrange an MUR. If this happens to you and you would like more information about your medicines, you can still ask for help from your community pharmacist.

During an MUR, your community pharmacist may produce an 'action plan' of the advice they give you. As part of the study, the hospital will also receive a copy. This will help us to improve the medicines service we give to patients whilst they are in hospital.

One month after your discharge, whether you received an MUR or not, you will receive some questions in the post. You will be asked around 20 questions, about how you are taking your medicines and your general state of wellbeing. This will take about 10 minutes. We will provide a stamped addressed envelope for you to post your answers back. A similar questionnaire will be sent six months after your discharge.

Some people from the MUR group and the control group will be telephoned just before their first questionnaire to arrange a home visit by a pharmacist.   If you are visited at home, you will be asked in more detail about the medicines information given to you by the hospital, your MUR if you had one, and any other help you have had with your medicines since being discharged. This should not take longer than 30 minutes. These discussions will be audio recorded but will be anonymous (no-one will know who you are afterwards). The discussions will help us to find out how much benefit people get from having an MUR, so that we can decide whether or not to refer more patients for an MUR in the future.

We will also look at the hospital's patient tracking system to see if you have been back into hospital in the first six months after agreeing to take part in the study. If you have been back into hospital we will look at your records to see if your admission could have been related to problems with your medication. This will help us to find out if people who have had an MUR are more or less likely to be taken back into hospital than people who have not.

If this information has interested you and you are considering participation, please let your doctor, nurse or ward pharmacist know. The research pharmacist or pharmacy technician will visit you later today or tomorrow to provide you with some more detailed information and answer any questions you have about the study.

Appendix 14: Sticker Applied to Case notes of Eligible Patients

This patient has been identified as eligible for the Medicines Support Study

REC Ref: 13/NW/0779

Local Ref: 2012/028 SISD

Initial information has been given to the patient

Signed: ……………………………………

Position……………………………………

UNIVERSITY OF WOLVERHAMPTON   Southport & Ormskirk Hospital **NHS**
NHS Trust

Medicines Support Study: Participant Information Part 2

What happens if I don't want to carry on with the study?
You can withdraw from the study at any time, without giving a reason. We will still use information collected from you up to your withdrawal.

What if there is a problem?
Any complaint about the way you have been dealt with during the study will be addressed. If you have a concern about any aspect of the study, you should ask to speak to the researchers who will do their best to answer your questions. Contact details are at the end of this leaflet. If you remain unhappy and wish to complain formally, you can do this in writing or by email to Southport & Ormskirk NHS Trust. Leaflets explaining our complaints policy are available across the hospital, and via the Trust website: www.southportandormskirk.nhs.uk/PALS/

Will my taking part in the study be kept confidential?
No-one will be able to identify you from the results of the study and the information collected about you will be completely confidential.

Interview recordings will be transferred into writing as soon after the interview as possible, and then the original recording will be destroyed. Direct quotes from the discussions may be used in the report of the study, but again no-one will know that it is you who said those words.

All the information you give will be stored on a computer network that only the chief researcher will be able to access. As soon as the researcher's PhD is complete (Spring 2017), all records that could identify you will be securely destroyed.

Will my GP know that I am taking part in the study?
If you decide to take part in the study, we will send your GP a letter to let them know.

What will happen to the results of the study?
We should have all the results of the study by Autumn/Winter 2015. The results will be presented to the people looking after the hospital and community pharmacies in the area. A meeting for patient support groups, patients and carers will also be organised, which you will be welcome to attend. The results may also be made available for an approved medical or scientific journal. They will be published on the Southport and Ormskirk NHS Trust website, and maybe also in a local newspaper. The data will also form part of a PhD study conducted by the chief researcher, Helen Ramsbottom.

A copy of the results will be sent to you, your community pharmacist and your GP.

Who is organising and funding the research?
The research is being organised by a pharmacist from Southport & Ormskirk NHS Trust, in association with the University of Wolverhampton. The consultants Dr Horsley and Dr McDonald are also supporting the research. We are hoping to get some funding from the National Institute for Health Research but this is not certain yet. No-one will be paid for including you in the study.

Who has reviewed the study?
All research in the NHS is scrutinised by an independent group of people, called a research ethics committee, to protect your interests. This study has been reviewed and given a favourable opinion by the University of Wolverhampton, Southport and Ormskirk NHS Trust, and by the NHS Northwest Research Ethics Committee.

What should I do now if I want to take part?
If you would like to take part in the study, please complete the consent form and return it to a member of the research team, your ward pharmacist or pharmacy technician. Or you can give the consent form to a member of nursing staff and ask them to return it to the pharmacy department.

Contact for Further Information:
If you have any questions about taking part in this study, please ask your ward pharmacist or pharmacy technician on their next visit. If you would like to speak to the chief investigator, one of the consultants or the university supervisors, please inform your ward pharmacist or pharmacy technician, or use the contact information below:

Helen Ramsbottom
Pharmacy Department
Southport & Ormskirk NHS Trust
Town Lane
Kew, Southport
PR8 6PN
Tel: 01704 704161/07932506802
Email: helen.ramsbottom@nhs.net

Dr John Horsley / Dr Patrick McDonald
Southport & Ormskirk NHS Trust
Town Lane
Kew, Southport
PR8 6PN
Tel (secretary): 01704 705181

Professor Ray Fitzpatrick/ Dr Paul Rutter (Supervisors)
Pharmacy Practice Division
Department of Pharmacy
School of Applied Sciences
University of Wolverhampton
Wulfrana Street, WV1 1LY
Tel: 01902 322173
Email: ray.fitzpatrick@wlv.ac.uk / paul.rutter@wlv.ac.uk

Further general information about taking part in research can be found at:
http://www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

Appendix 16: Sticker Applied to Case Notes of Recruited Participants

This patient has been recruited into the Medicines Support Study

REC Ref: 13/NW/0779

Local Ref: 2012/028 SISD

 Signed: …………………………….

 Position………………………………

Appendix 17: Participant Baseline Demographics Data Capture Form

UNIVERSITY OF
WOLVERHAMPTON

Southport & Ormskirk Hospital **NHS**
NHS Trust

Medicines Support Study Data Capture Form: Baseline Characteristics

Participant ID:……………………………………

Characteristic	Value
Age	
Female	
Living alone	
No. meds	
Consultant speciality	
Medication complexity index	
Cognitive impairment	
No. co-morbidities	
Admission within last 30 days	
No. admissions in last 12 months	
Length of baseline admission (days)	

Southport & Ormskirk Hospital **NHS**
NHS Trust

UNIVERSITY OF
WOLVERHAMPTON

Medicines Support Study

Participant Diary

Name:………………………………………….

Date:……………………………………….....

If you need any help or would like to ask a question about the study, please contact:

Helen Ramsbottom
Pharmacy Department
Southport and District General
Hospital
Telephone 01704 704161

Please use this booklet to record every time you see your GP, pharmacist or go to the hospital. If you do not want to include the reason for the visit, just write the date and who you saw.

Date	What type of visit was it? E.g. GP appointment, hospital admission	What was the reason for the visit? (You do not have to complete this section if you do not want to)

Appendix 19: Follow-up Questionnaire 1 – Control Group

UNIVERSITY OF
WOLVERHAMPTON

Southport & Ormskirk Hospital **NHS**
NHS Trust

Follow-up Questionnaire — Medicines Support Study

If you would prefer not to answer a particular question, you do not need to

1. Are you still managing your medication on your own at home?

Yes ☐ Continue to question 2

No ☐ Who helps
you?...

If you answered No, you do not need to continue with this questionnaire. Please return it in the stamped addressed envelope provided.

2. Has anyone reviewed your medication since you came out of hospital?

Yes ☐ Who was this?..
 Did you request the review? Yes ☐
 No, they offered ☐
No ☐ Continue to question 3

3. Do you sometimes forget to take your medication?
 Yes ☐ No ☐

4. Over the past two weeks, were there any days when you did not take all of your medication?
 Yes ☐ No ☐

5. Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?
 Yes ☐ No ☐

6. When you travel or leave home, do you sometimes forget to bring along your medications?
 Yes ☐ No ☐

7. Did you take all of your medication yesterday?
 Yes ☐ No ☐

8. When you feel like your health is good, do you sometimes stop taking your medicine?

      Yes   ☐   No   ☐

      Please turn over

9. Taking medication every day is a real inconvenience for some people. Do you ever feel inconvenienced about sticking to your daily medication routine?

      Yes   ☐   No   ☐

10. How often do you have difficulty remembering to take all your medication?
Circle one answer

Never/rarely	4
Occasionally	3
Sometimes	2
Often	1
Every day	0

For each of the following questions, please tick the one box that best describes your answer.

11. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

12. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
	▼	▼	▼

a <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf .... ☐ 1 .... ☐
    2 .... ☐ 3

b Climbing <u>several</u> flights of stairs .... ☐ 1 .... ☐
    2 .... ☐ 3

13. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Were limited in the <u>kind</u> of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

14. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did work or other activities <u>less carefully than usual</u>	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

15. During the <u>past 4 weeks</u>, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Please turn over

3

16. These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt downhearted and low?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

17. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thankyou for completing this questionnaire! Please return it in the stamped addressed envelope provided

UNIVERSITY OF WOLVERHAMPTON

Southport & Ormskirk Hospital NHS
NHS Trust

Follow-up Questionnaire — Medicines Support Study

If you would prefer not to answer a particular question, you do not need to

1. Are you still managing your medication on your own at home?

Yes ☐ Continue to question 2

No ☐ Who helps
you?..

If you answered No, you do not need to continue with this questionnaire. Please return it in the stamped addressed envelope provided.

2. Have you had your medicines use review (MUR) with your community pharmacist?

Yes ☐ Continue to question 3

No ☐ Why
not?..

3. Has anyone **else**, other than your community pharmacist, reviewed your medication since you came out of hospital?

Yes ☐ Who was
this?..
   Did you request the review? Yes ☐
   No, they offered ☐
No ☐ Continue to question 4

4. Do you sometimes forget to take your medication?
   Yes ☐ No ☐

5. Over the past two weeks, were there any days when you did not take all of your medication?
   Yes ☐ No ☐

6. Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?
   Yes ☐ No ☐

Please turn over

7. When you travel or leave home, do you sometimes forget to bring along your medications?

Yes ☐ No ☐

8. Did you take all of your medication yesterday?

Yes ☐ No ☐

9. When you feel like your health is good, do you sometimes stop taking your medicine?

Yes ☐ No ☐

10. Taking medication every day is a real inconvenience for some people. Do you ever feel inconvenienced about sticking to your daily medication routine?

Yes ☐ No ☐

11. How often do you have difficulty remembering to take all your medication?
Circle one answer

Never/rarely	4
Occasionally	3
Sometimes	2
Often	1
Every day	0

For each of the following questions, please tick the one box that best describes your answer.

12. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

13. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
b Climbing <u>several</u> flights of stairs	☐ 1	☐ 2	☐ 3

14. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Were limited in the <u>kind</u> of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

15. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did work or other activities <u>less carefully than usual</u>	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Please turn over

16. During the <u>past 4 weeks</u>, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3

17. These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt downhearted and low?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

18. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

19. As a result of your visit to the pharmacist for your Medicines Use Review (MUR), if you had one, do you feel you are…

	Much better	Better	Same or less	Not applicable
Able to **cope** with your **medication** regimen	○	○	○	○
Able to **understand** your medical **conditions**	○	○	○	○
Able to **understand** your **medications**	○	○	○	○
Able to keep yourself healthy	○	○	○	○

	Much more	More	Same or less	Not applicable
Confident about managing your **medication**	○	○	○	○
Able to **help yourself**	○	○	○	○

Thankyou completing this questionnaire! Please return it in the stamped addressed envelope provided.

UNIVERSITY OF
WOLVERHAMPTON

Southport & Ormskirk Hospital **NHS**
NHS Trust

Follow-up Questionnaire — Medicines Support Study

If you would prefer not to answer a particular question, you do not need to

1. Are you still managing your medication on your own at home?

Yes   ☐   Continue to question 2

No   ☐   Who helps you?..

If you answered No, you do not need to continue with this questionnaire. Please return it in the stamped addressed envelope provided.

2. Has anyone reviewed your medication since you last heard from us?

Yes   ☐   Who was this?..

Did you request the review?   Yes   ☐   No, they offered   ☐

No   ☐   Continue to question 3

Not sure   ☐   Continue to question 3

3. Do you sometimes forget to take your medication?
        Yes   ☐   No   ☐

4. Over the past two weeks, were there any days when you did not take all of your medication?
        Yes   ☐   No   ☐

5. Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?
        Yes   ☐   No   ☐

6.   When you travel or leave home, do you sometimes forget to bring along your medications?
        Yes   ☐   No   ☐

7.   Did you take all of your medication yesterday?
        Yes   ☐   No   ☐

8.   When you feel like your health is good, do you sometimes stop taking your medicine?
        Yes   ☐   No   ☐
        Please turn over

9.   Taking medication every day is a real inconvenience for some people. Do you ever feel inconvenienced about sticking to your daily medication routine?

1

Yes ☐ No ☐

10. How often do you have difficulty remembering to take all your medication?
Circle one answer

Never/rarely	4
Occasionally	3
Sometimes	2
Often	1
Every day	0

11. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
○	○	○	○	○

12. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	○	○	○
b Climbing <u>several</u> flights of stairs	○	○	○

13. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a <u>Accomplished less</u> than you would like	○	○	○	○	○
b Were limited in the <u>kind</u> of work or other activities	○	○	○	○	○

14.   During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a <u>Accomplished less</u> than you would like	○	○	○	○	○
b Did work or activities <u>less carefully than usual</u>	○	○	○	○	○

15.   During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
○	○	○	○	○

16.   These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling.
How much of the time during the <u>past 4 weeks</u>...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Have you felt calm and peaceful?	○	○	○	○	○
b Did you have a lot of energy?	○	○	○	○	○
c Have you felt downhearted and depressed?	○	○	○	○	○

17.   During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
○	○	○	○	○

Thankyou for completing this questionnaire! Please return it in the stamped addressed envelope provided.

Appendix 22: Covering Letter Sent Out With Follow-up Questionnaire 1

Southport & Ormskirk Hospital NHS *NHS Trust*

UNIVERSITY OF WOLVERHAMPTON

Southport and Formby District General
Hospital
Town Lane
Kew
Southport
PR8 6PN

Date

First name Last Name
Address Line 1
Town Post code

Dear Mr/Mrs Last Name,

When you were in hospital a few weeks ago you agreed to take part in our 'Medicines Support Study'. You will remember that we are trying to find out if having a Medicines Use Review ('MUR') with a community pharmacist helps people to manage their medicines after being in hospital. People who agreed to participate in the research were randomly assigned to one of two groups. One group were referred to their regular community pharmacist for an MUR after they had been discharged. The other group were discharged as normal.

Enclosed with this letter is the first of two follow-up questionnaires you agreed to complete as part of the study. We ask that you complete the questionnaire as honestly as possible and return it to us in the stamped addressed envelope provided.

Please **do** complete the questionnaire even if you have not had a medicines review since leaving hospital as it will still help us to hear from you.

We will send you the second (and final) questionnaire in five months' time. After this your part in the study will be over.

If you have any questions relating to the questionnaire or the study in general, please do not hesitate to contact me on 01704 704161 or 07932506802. Thank you very much for being a participant in our study!

Yours Sincerely,

Helen Ramsbottom
Pharmacist, Southport & Ormskirk NHS Trust
Chief Researcher, Medicines Support Study

Appendix 23: Covering Letter Sent Out With Follow-up Questionnaire 2

Southport & Ormskirk Hospital *NHS*
NHS Trust

UNIVERSITY OF
WOLVERHAMPTON

Southport and Formby District General
Hospital
Town Lane
Kew
Southport
PR8 6PN

Date

First name Last Name
Address Line 1
Town Post code

Dear Mr/Mrs Last Name,

When you were in hospital 6 months ago you agreed to take part in our 'Medicines Support Study'. You will remember that we are trying to find out if having a Medicines Use Review ('MUR') with a community pharmacist helps people to manage their medicines after being in hospital. People who agreed to participate in the research were randomly assigned to one of two groups. One group were referred to their regular community pharmacist for an MUR after they had been discharged. The other group were discharged as normal.
Enclosed with this letter is the second follow-up questionnaire you agreed to complete as part of the study. We ask that you complete the questionnaire as honestly as possible and return it to us in the stamped addressed envelope provided.

After this your part in the study is over. If you have any questions relating to the questionnaire or the study in general, please do not hesitate to contact me on 01704 704161 or 07932506802. Thank you very much for being a participant in our study!

Yours Sincerely,

Helen Ramsbottom
Pharmacist, Southport & Ormskirk NHS Trust
Chief Researcher, Medicines Support Study

Appendix 24: Reminder Letter: Follow-up Questionnaire 1

Southport & Ormskirk Hospital NHS
NHS Trust
UNIVERSITY OF WOLVERHAMPTON

Southport and Formby District General
Hospital
Town Lane
Kew
Southport
PR8 6PN

Date

First name Last Name
Address Line 1
Town Post code

Dear Mr/Mrs Last Name,

When you were in hospital a few weeks ago you agreed to take part in our 'Medicines Support Study'. You will remember that we are trying to find out if having a Medicines Use Review ('MUR') with a community pharmacist helps people to manage their medicines after being in hospital.

Two weeks ago we sent you the first of two follow-up questionnaires you agreed to complete as part of the study. We have not yet received your completed questionnaire. If you have returned your questionnaire to us within the last five days, you do not need to do anything else and can ignore this letter. If you have **not** yet completed your questionnaire, it would be very helpful to us if you could do this now. Enclosed with this letter is a second copy of the questionnaire in case you do not have the first. We ask that you complete the questionnaire as honestly as possible and return it to us in the stamped addressed envelope provided.

Please **do** complete the questionnaire even if you have not had a medicines review since leaving hospital as it will still help us to hear from you.

We will send you the second (and final) questionnaire in four and a half months time. After this your part in the study will be over.

If you have any questions relating to the questionnaire or the study in general, please do not hesitate to contact me on 01704 704161or 07932506802. Thank you very much for being a participant in our study!

Yours Sincerely,

Helen Ramsbottom
Pharmacist, Southport & Ormskirk NHS Trust
Chief Researcher, Medicines Support Study

Appendix 25: Reminder Letter: Follow-up Questionnaire 2

Southport & Ormskirk Hospital NHS
NHS Trust

UNIVERSITY OF WOLVERHAMPTON

Southport and Formby District General Hospital
Town Lane
Kew
Southport
PR8 6PN

Date

First name Last Name
Address Line 1
Town Post code

Dear Mr/Mrs Last Name,

When you were in hospital just over 6 months ago you agreed to take part in our 'Medicines Support Study'. You will remember that we are trying to find out if having a Medicines Use Review ('MUR') with a community pharmacist helps people to manage their medicines after being in hospital. People who agreed to participate in the research were randomly assigned to one of two groups. One group were referred to their regular community pharmacist for an MUR after they had been discharged. The other group were discharged as normal.

Two weeks ago we sent you the second of the two follow-up questionnaires you agreed to complete as part of the study. We have not yet received your completed questionnaire. If you have returned your questionnaire to us within the last five days, you do not need to do anything else and can ignore this letter. If you have **not** yet completed your questionnaire, it would be very helpful to us if you could do this now. Enclosed with this letter is a second copy of the questionnaire in case you do not have the first. We ask that you complete the questionnaire as honestly as possible and return it to us in the stamped addressed envelope provided.

After this your part in the study is over. If you have any questions relating to the questionnaire or the study in general, please do not hesitate to contact me on 01704 704161 or 07932506802. Thank you very much for being a participant in our study!

Yours Sincerely,

Helen Ramsbottom
Pharmacist, Southport & Ormskirk NHS Trust
Chief Researcher, Medicines Support Study

1

<u>**Appendix 26: Follow up interview – Control Group**</u>

Introduction: When you were in hospital a few weeks ago you agreed to take part in a research study called the Medicines Support Study. Today I'd like to ask you a few questions to see how things are going with you and your medication. Is that OK?

1) **Thinking back to when you first came out of hospital, how did you feel about the information you were given to help you manage your medicines?**

Prompts: Did you feel that you had enough information to take your medicines as the doctors intended?

If yes: Why was that?

       Who gave you the information?

       What information did they give you? (e.g. that a medicine had been stopped or had its dose changed, name of new medicines, what they were for, how to take them, side effects)

       How did they give it to you? (Was it written, through talking to you or both?)

       When were you given the information?

If no: What do you think could have been improved?

2) **Are you still managing your medication on your own at home (** *Prompt*: **or does someone else help you)?**

     Yes   No

If yes *continue*

If no: Who is helping you? What do they do to help you with your medicines?

3) **Has anyone been through your medication with you since you came out of hospital?**

     Yes   No

If yes: Tell me about that

Prompts: Who was this?

Did you ask them to look at your medication or did they offer?

When did you have this review?

What advice did (they) give to help you take your medication?

Have you changed anything about the way you take your medicines because of what (they) said?

If yes, what are you doing differently now?

If only some actions have been implemented, try to ascertain the reasons for this.

    a) Did you find the review useful?

    Yes   No

    Why / why not?

4) Have you been to see your GP since coming out of hospital?
(Participant diary can be used as a prompt)

    Yes   No

If yes: Will you tell me about that?

Prompts   How many times have you been?

                When was/were the visit(s)?

                If you don't mind telling me, what was the reason for each visit?

5) Have you been back into hospital since you agreed to take part in the study? *(Participant diary can be used as a prompt)*

    Yes   No

If yes: Tell me about that

Prompts: How many times?

When was/were the visit(s)?

If you don't mind telling me, what was the reason for each visit?

6) Is there anything else about your medication that you'd like to talk about?

Do you have any other questions for me?

Thank-you very much for taking part in our study. *Terminate interview*

Appendix 27: Follow up interview – Intervention Group

Introduction When you were in hospital a few weeks ago you agreed to take part in a research study called the Medicines Support Study. We referred you to your usual community pharmacy for a review of how you were managing your medication after being in hospital. Today I'd like to ask you a few questions to see how things are going with you and your medication. Is that OK?

1) **Thinking back to when you first came out of hospital, how did you feel about the information you were given to help you manage your medicines?**

Prompts: Did you feel that you had enough information to take your medicines as the doctors intended?

If yes: Why was that?

   Who gave you the information?

   What information did they give you? (e.g. that a medicine had been stopped or had its dose changed, name of new medicines, what they were for, how to take them, side effects)

   How did they give it to you? (Was it written, through talking to you or both?)

   When were you given the information?

If no: What do you think could have been improved?

2) **Are you still managing your medication on your own at home (*Prompt*: or does someone else help you)?**

   Yes   No

If yes *continue*

If no: Who is helping you? What do they do to help you with your medicines? Why did you decide you needed help?

3) **Have you had your medicines review with your community pharmacist?**

   Yes   No

This information should be available to the researcher prior to interview through liaison with the community pharmacist. Prompts can be given to participant as below:

If No: Is there a reason for that*?*

If the participant wishes to withdraw from the study, explore reasons. If participant still does not wish to take part, thank them for their time and terminate interview. If participant now decides to take up offer of MUR, terminate interview and liaise with community pharmacist to arrange MUR.

If the participant has been unable to access the community pharmacy: Would you be interested in having a pharmacist come to your home or telephone you to talk about your medicines if this was available?

Then thank them for their time and terminate interview.

If yes, ask the participant to fetch their copy of the MUR action plan. If the patient does not have an action plan, document this. The researcher should also have a copy that has been returned by the community pharmacist.

b) What advice did the pharmacist give to help you with your medicines?

c) Have you changed anything about the way you take your medicines because of what the pharmacist said?

If yes, what are you doing differently now?

If only some actions have been implemented, try to ascertain the reasons for this.

d) Did you find the review useful?

Yes   No

Why / why not?

4) Since your talk with the pharmacist, how have you found managing your medicines?

Prompt: *Easier? The same? More difficult?*

Why do you think this is?

5) Has anyone else been through your medication with you since you came out of hospital?

Yes   No

If yes: Tell me about that

Prompts: Who was this?

Did you ask them to look at your medication or did they offer?

When did you have this review?

What advice did (they) give to help you take your medication?

Have you changed anything about the way you take your medicines because of what (they) said?

If yes, what are you doing differently now?

If only some actions have been implemented, try to ascertain the reasons for this.

    e) Did you find the review useful?

       Yes   No

       Why / why not?

6) Have you been to see your GP since coming out of hospital?
(Participant diary can be used as a prompt)

       Yes   No

   If yes: Will you tell me about that?

Prompts   How many times have you been?

                When was/were the visit(s)? Before or after your medicines review with the community pharmacist?

                If you don't mind telling me, what was the reason for each visit?

7) Have you been back into hospital since you agreed to take part in the study? *(Participant diary can be used as a prompt)*

       Yes   No

   If yes*:*   Tell me about that

Prompts: How many times?

When was/were the visit(s)? Before or after your medicines review with the community pharmacist?

If you don't mind telling me, what was the reason for each visit?

8) Is there anything else about your medication that you'd like to talk about?

I would like to leave this questionnaire with you. Fill it in as soon as you are ready and return it to us using the stamped addressed envelope inside.

Do you have any other questions for me?

Thank-you very much for taking part in our study. *Terminate interview*

UNIVERSITY OF WOLVERHAMPTON

Southport & Ormskirk Hospital *NHS*
NHS Trust

Transfer of Care Focus Group - Information

What is a focus group?
A focus group is an in-depth, open-ended group discussion that explores a specific set of issues on a pre-defined topic. The group is conducted under the guidance of a facilitator.

What is the purpose of this focus group?
Between one-third and half of all medicines for long term conditions are not taken as recommended. Following a medication routine after being in hospital is particularly difficult as nearly two thirds of people have three or more medicines changed during a hospital stay and almost half experience an error with their medication on discharge.

We are currently investigating the feasibility of setting up a referral process from hospital to community pharmacy for post discharge Medicines Use Reviews (MURs). A key objective of this is the identification of patients who may benefit from the service, whilst they are still in hospital. The aim of the transfer of care focus group is to explore the views of hospital pharmacists and technicians on issues such as:

- The benefits and drawbacks of post-discharge MURs
- How able you feel to identify and refer suitable patients
- What would need to happen to take the service forward
- What else could be done to improve medicines management on transfer of care

Why should I take part?
The Department of Health states that referral of suitable patients for post discharge MURs should be an integral part of the medicines pathway. However no additional resources have been made available to hospitals to identify patients who may benefit from such a service, nor have any formal mechanisms for referral been established. The MUR service as a whole has attracted criticism, with some claiming it is being used more for profit than for patient benefit. Focus groups with community pharmacists on the subject of transfer of care have been published but the views and experiences of hospital pharmacists seem to have been less widely studied.

This session allows you to express in your own words what you think of the current transfer of care service provided at Southport And Ormskirk NHS Trust, exchange opinions and ideas for improvement with your colleges and hear other people's experiences and suggestions. This technique can be used to solve problems and improve services, with the overall objective of improving patient care.

What will happen if I decide to take part?
Participation in the focus group is entirely voluntary. You will be asked to sign a consent form before the session begins. The session will last about 45 minutes and will be facilitated by Helen Ramsbottom, clinical pharmacist and lead researcher on the study. The topics mentioned above will be introduced by the facilitator and you will be encouraged to express your opinions and discuss them with the other participants in the session. Personal experiences, suggestions and insights are welcome! You are encouraged to respond to or challenge the views of other participants but we ask that you do so in a professional and respectful manner.

The session will be audio-recorded, and quotes may be used in the written report. However no-one will be able to identify you from the report and all quotes will be anonymous. If at any point

during the discussion you would like a break or wish to leave the group, you may do so without providing a reason. If you do not want your data to be used, just tell the facilitator afterwards.

What will happen to the data I provide?
The recording of the session will be transcribed and analysed and the information used to improve the medicines support patients get on transfer of care. The results will be included in the researcher's PhD thesis and may also be made available to a peer reviewed journal.

Contact for Further Information:

If you have any questions about the study before deciding to take part, please contact the lead investigator, Helen Ramsbottom, or the university supervisors, who will be pleased to help you:

Helen Ramsbottom   Professor Ray Fitzpatrick/ Dr Paul Rutter
(Supervisors)
Pharmacy Department   Pharmacy Practice Division
Southport District General Hospital   Department of Pharmacy
Town Lane   School of Applied Sciences
Kew, Southport   University of Wolverhampton
PR8 6PN   Wulfrana Street, WV1 1LY
Tel: 01704 704161/07932506802   Tel: 01902 322173
Email: helen.ramsbottom@nhs.net   Email: ray.fitzpatrick@wlv.ac.uk / paul.rutter@wlv.ac.uk

Appendix 29: Hospital Pharmacist Focus Group Consent Form

UNIVERSITY OF WOLVERHAMPTON   **Southport & Ormskirk Hospital** **NHS**
NHS Trust

Study Number:2012/028 SISD
Chief Researcher: Helen Ramsbottom

Informed Consent Form: Transfer of Care Focus Group 31st July 2014

If you have read the information about the session and are willing to participate please complete and sign this form, and return it to Helen Ramsbottom, focus group facilitator and lead researcher.

Please initial each box

I have read and understood parts the information sheet dated July 2014 (version 1) for the Transfer of Care Focus Group.	
I have had the opportunity to ask questions about the study and have had them answered satisfactorily.	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason.	
I agree to the interview being audio recorded, and to anonymous quotes being used in the study report.	
I agree to take part in the focus group	

Name of participant:	Date:	Signature:
Name of person taking consent:	Date:	Signature:

When complete copy: 1 for participant, 1 (original) to be kept in study file

Appendix 30: Hospital Pharmacist Focus Group Topic Guide

Transfer of Medicines Related care from hospital back into primary care

What problems have you experienced with transfer of medicines related care from hospital back into community?

> *Prompt: Could be before/after discharge or when patients are readmitted*
> *Communication with GP / community pharmacy / patient /carer*

Post Discharge MURs – Opinions of Hospital Pharmacy Staff

What do you think are the benefits or drawbacks of post-discharge MURs?

> *Prompt: For patient/community pharmacy/GP*

Is it a good idea for hospital pharmacy staff to refer patients for post-discharge MURs? Why / why not?

Barriers to Implementation of Service

What factors make it harder to identify suitable patients to refer for a post discharge MUR?

> *Prompt: Time/acute illness*

Enablers for Implementation of Service

What makes or could make it easier to identify patients or get them referred?

What do you think needs to happen to make referrals commonplace? (If this is considered appropriate)

> *Prompt: Manpower? / SOPs? /IT?*

Appendix 31: Hospital Pharmacist Questionnaire

UNIVERSITY OF WOLVERHAMPTON   **Southport & Ormskirk Hospital** **NHS**
                                                                    NHS Trust

Hospital Pharmacy - Post Discharge Medicines Use Review (DMUR) Questionnaire

Your Views About the DMUR Referral Service

I would like to ask for your help in my evaluation of the feasibility of a post discharge MUR referral service from hospital to community pharmacy. The results of the questionnaire are confidential and will be used to help interpret the data collected during my feasibility study, which, if successful, could become a model for other hospitals to implement. I am interested in your opinion of the service, particularly of your own involvement. The questionnaire should take 10-15 minutes to complete. When you have completed the questionnaire, please return it to me (Helen Ramsbottom) by placing it in my tray in the fishbowl.

1. What is your current AfC banding at the hospital pharmacy?
a. Band 6 ◯
b. Band 7 ◯
c. Band 8a ◯
d. Band 8b or above ◯

2. What best describes your patient facing role?
a. Non-specialist /rotational ◯
b. Specialist ◯
c. Other (please specify)………………………………………………………………………………………………

3. Approximately how many patients did you identify for a possible post discharge Medicines Use Review (DMUR) in a typical month?
a. 0 ◯
b. 1-5 ◯
c. 6-10 ◯
d. 11-15 ◯
e. 16-20 ◯
f. >20 ◯

If you did not identify any patients, please can you tell us why?

…….

………..

4. For what reasons did you refer patients to the DMUR service? (Please tick all that apply)
a. Risk of poor adherence ◯

1

b. High risk drug prescribed ○
c. Specific patient groups (e.g. cardiac) ○
d. Pre-admission medication stopped in hospital ○
e. New medication started in hospital ○
f. Change of dose of medicine/s ○
g. Patient request for information on medicines ○
h. Other (please specify)

………

5. Each of the issues below may represent a **barrier** to hospital pharmacy's involvement in referring patients for DMURs. For each, please tick the box that most closely represents your view

Key:
1 = Not a barrier
2 = Occasional barrier
3 = A barrier about half of the time
4 = Major barrier
5 = Always a barrier

		1	2	3	4	5
a.	Difficulty identifying suitable patients	○	○	○	○	○
b.	Remembering to try to identify patients to refer	○	○	○	○	○
c.	Patient refusal to participate	○	○	○	○	○
d.	Time pressures	○	○	○	○	○
e.	Patient stay in hospital too short to identify them as suitable	○	○	○	○	○
f.	Difficulty in identifying patients' usual community pharmacy	○	○	○	○	○
g.	Having to complete a referral form	○	○	○	○	○
h.	Lack of recognition for extra work	○	○	○	○	○
i.	Lack of IT infrastructure for communicating information to community pharmacy	○	○	○	○	○

6. Please state any other barriers you can think of that affected the delivery of the DMUR referral service

……

……

……

7. The list below contains some **solutions** to address the potential barriers to the delivery of a DMUR referral service. For each, please tick the box that most closely represents your view

Key

1 = Would not improve delivery

2 = Slight improvement

3 = Substantial improvement

4 = Major improvement

		1	2	3	4
a.	Send discharge information electronically to community pharmacy	◯	◯	◯	◯
b.	Improve documentation of changes to medication on discharge summaries	◯	◯	◯	◯
c.	Greater promotion of DMURs to patients while in hospital	◯	◯	◯	◯
d.	Greater promotion to patients in the community pharmacy	◯	◯	◯	◯
e.	Better communication of concept of DMUR referral to hospital pharmacy staff	◯	◯	◯	◯
f.	Greater promotion of DMURs to ward staff	◯	◯	◯	◯
g.	Investment in staff to free up time for pharmacists to do MUR referrals	◯	◯	◯	◯
h.	Focus on specific patient groups initially	◯	◯	◯	◯
i.	Feedback to hospital pharmacy about actions arising from DMURs in community	◯	◯	◯	◯
j.	Compulsory patient registration with a named community pharmacy	◯	◯	◯	◯

8. Please state any other solutions you can think of

……

……

……

……......

9. The list below contains some statements about DMUR referrals. Please indicate your level of agreement/disagreement for each of the statements using the scale below:

Key

1 = Strongly disagree
2 = Disagree
3 = neither disagree nor agree
4 = Agree
5 = Strongly agree

	1	2	3	4	5
a. DMUR referrals will help patients to manage their medicines better after being in hospital	○	○	○	○	○
b. DMURs will allow adherence problems and medication errors to be identified and resolved sooner	○	○	○	○	○
c. Time spent on the MUR referral process takes hospital pharmacists away from other patients	○	○	○	○	○
d. The lack of reimbursement for hospital pharmacy puts me off providing the service	○	○	○	○	○
e. DMUR referrals help foster better working relationships with community pharmacies	○	○	○	○	○
f. The service is not yet ingrained in the daily work of a ward pharmacist	○	○	○	○	○
g. The patient's priority is to get home from hospital; so it is hard to engage them in the DMUR scheme	○	○	○	○	○

10. Please summarise your opinion of the pilot DMUR referral service at Southport and Ormskirk NHS Trust below

………

………

………

Thank you for completing this questionnaire. Please return it to Helen Ramsbottom, Pharmacy department, Southport District General Hospital

Appendix 32: Community Pharmacist Questionnaire

UNIVERSITY OF WOLVERHAMPTON **Southport & Ormskirk Hospital** **NHS**
NHS Trust

Community Pharmacy - Post Discharge Medicines Use Review (DMUR) Questionnaire

Thank you for taking part in our study of a DMUR referral service. To help us understand our results, we would be very grateful if you would take a few minutes to answer the questions below. Completed forms should be returned using the details below.

Question 1: Concerns the referrals sent to you by the hospital:

  a. They contained all the information I needed to conduct the MUR   ◯

  b. More information would have been useful regarding: (tick as many as apply)
   i) The discharge medication regimen   ◯
   ii) Reasons for changes made to pre-admission medication   ◯
   iii) Indications for new medications started   ◯
   iv) Adherence support needs of the patient post discharge   ◯
   v) Patient contact details   ◯
   vi) Other (please specify below)
   ………

  c. I do not remember receiving any referrals (go straight to Question 4) ◯

Question 2: Concerns the suitability of the patients

  a. All patients referred to me were suitable for an MUR   ◯

  b. One or more patients were unable to engage fully in the MUR because: (tick as many as apply)
   i) They were unable to attend in person   ◯
   ii) They were no longer self-administering their medication   ◯
   iii) They no longer wished to receive an MUR   ◯
   ii) They were already fully informed regarding their medicines   ◯
   v) I was unable to contact them using the details available   ◯
   vi) They did not attend their arranged MUR   ◯
   vi) Other (please specify below)
   ………

Question 3: How long, on average, did it take to conduct a DMUR as part of the study?

    a.   Less than 20 minutes   ◯

    b.   20 – 39 minutes   ◯

    c.   40 - 59 minutes   ◯

    d.   60 minutes or more   ◯

Question 4: Have you done any DMURs since 6th April 2014 that were **not** a part of this study?

    a.   No   ◯

    b.   Yes, 1- 5   ◯

    c.   Yes, 6-10   ◯

    d.   Yes, 11-15   ◯

    e.   Yes, 16-20   ◯

    f.   Yes, more than 20 ◯

If you have done any DMURs that were **not** a part of the study, please write a few words below about how you identified the patients involved.

……

……

……

Question 5: The list below contains some statements about DMUR referrals in general. Please indicate your level of agreement/disagreement for each of the statements using the scale below:

Key

1 = Strongly disagree
2 = Disagree
3 = Neither disagree nor agree
4 = Agree
5 = Strongly agree

	1	2	3	4	5
a. DMUR referrals will help patients to manage their medicines better after being in hospital	◯	◯	◯	◯	◯
b. DMUR referrals will allow adherence problems to be identified and resolved sooner	◯	◯	◯	◯	◯
c. DMUR referrals will allow medication errors to be identified and resolved sooner	◯	◯	◯	◯	◯
d. DMUR referrals help foster better working relationships with hospital pharmacists	◯	◯	◯	◯	◯
e. DMURs are more complex than other types of MUR	◯	◯	◯	◯	◯
f. It is hard to engage patients in DMURs	◯	◯	◯	◯	◯

Please add any other comments regarding the referral process or post-discharge MURs in general

……

……

……

Thank you very much for completing this questionnaire. Please return it to:

Helen Ramsbottom
Pharmacy Department
Southport District General Hospital
Town Lane
Kew, Southport
PR8 6PN
Tel: 01704 704161
Fax: 01704 704197
Email: helen.ramsbottom@nhs.net

Appendix 33: Criteria Used During Case note Analysis of Readmissions

Criteria used for assessing causality of suspected medication-related problems (61,62)

1) Known adverse drug reaction, toxic reaction, response to omission of treatment or inadequate treatment
2) Reasonable temporal relationship between commencement or cessation/omission of treatment and onset of problem
3) Risk of further problems likely to be reduced by dose reduction or increase, discontinuation, closer monitoring or commencement of treatment
4) Not explained by any other known condition of predisposition to the patient, or This condition/predisposition is likely to be exacerbated by the presence/absence of the drug
5) For drug toxicity *(1 out of):*
   - Symptoms reappeared upon re-exposure
   - Laboratory tests showed toxic drug levels or drug-induced metabolic disturbances that explained the symptom
   - Symptoms resolved on dose reduction or discontinuation of the drug

   For drug omission:

   - Symptoms resolved upon re-introduction of the drug or dose increase

If **five** criteria fulfilled, then **definite**.

If **four** criteria fulfilled, then **probable**.

If **three** criteria fulfilled, then **possible**.

If two or fewer criteria fulfilled, then either not drug-related or unevaluable.

Criteria used for classification of medication-related problems (61,215)

Class	Definition
1	Inappropriate prescribing
2	Inappropriate delivery (drug unavailable when needed, incorrect formulation, failure to administer, dispensing error)
3	Non-compliance by patient
4	Patient idiosyncrasy (response to drug, mistake or accident)
5	Inappropriate monitoring
6	Potentially preventable with interventions which are not standard care at present

Criteria used for assessing preventability of medication-related problems
(61,215)

1) Drug-related morbidity (DRM) preceded by a recognisable drug therapy problem (DRP)
2) Given the DRP, the DRM would have been reasonably foreseeable
3) The cause of DRM would have been identifiable with reasonable probability (above criteria probable or definite for causality)
4) The cause of the DRM could have been reasonably controllable within the context and objectives of therapy

Criteria used for assessing the contribution of medication-related problem to hospital admission (61,62)

Score	Category	Definition
3	Dominant	The suspected symptoms were the main reason for admission, and no other symptoms contributed significantly
2	Partly contributing	The suspected symptoms played a substantial role in admission, but other factors also contributed significantly
1	Less important	The suspected symptoms played a minor or uncertain role, and the patient would probably have been admitted without them
0	Not contributing	Other symptoms/circumstances were the reason for hospitalisation

Appendix 34: Significance Scoring of Community Pharmacist Interventions during Post Discharge Medicines Use Reviews: Round 1

Below is a list of 30 interventions made during post discharge Medicines Use Reviews (dMURs) by community pharmacists. For the purposes of this exercise, an intervention is classed as any action taken or piece of advice given to the patient during the dMUR, as reported by the community pharmacists who undertook the dMURs.

For each of the interventions described, please assign the score which you believe most closely represents the **most likely** outcome for the patient (**not** the best or worst case scenario). Space is provided for any comments you wish to add regarding the reasons for your choice, or any other information you feel is relevant to the interpretation of the significance of the intervention.

Note: An intervention scoring '3' is one where a recommendation was made by the pharmacist to the patient's GP but not actioned by the GP, and therefore did not make any difference to the patient's care, whatever its potential significance may have been

Intervention type	Score
Intervention which is detrimental to the patient's well-being	1
Intervention is of no significance to patient care	2
Intervention is significant but does not lead to an improvement in patient care	3
Intervention is significant and results in an improvement in the standard of care	4
Intervention is very significant and prevents a major organ failure or adverse event of similar importance (e.g. hospitalisation for worsening clinical condition)	5
Intervention is potentially life-saving	6

List of Interventions

1. Patient discharged after acute coronary syndrome struggling to remember to take medicines as prescribed. Community pharmacist organised blister packs

   Score:………………………….

   Extra comments:

2. Patient having difficulty with co-ordination of metered dose inhaler device. Patient not keen on breath actuated device so community pharmacist requested spacer from GP *(Unknown if spacer was actually provided)*

   Score:…………………………….

   Extra comments:

3. Patient discharged with atrial fibrillation newly prescribed antiarrythmics and warfarin. Struggling to remember if she has taken all medication so community pharmacist provided medicine administration record (MAR) sheet

   Score:…………………………….

   Extra comments:

4. Community pharmacist explained to patient the system for obtaining future prescriptions following discharge after a stroke

   Score:…………………………….

   Extra comments:

5. Patient had been buying antihistamine to help with skin itching. Community pharmacist suggested GP add this to repeat prescription *(Actioned by GP)*

   Score:…………………………….

   Extra comments:

6. Clopidogrel prescribed during admission for acute coronary syndrome for a patient already taking warfarin. Patient unsure of indication, and whether clopidogrel will be long term. Community pharmacist liased with hospital pharmacy to find answer *(Clopidogrel to be discontinued after 12 months)*

Score:…………………………….

Extra comments:

7. Community pharmacist discussed indication for new medication (betahistine) and how to obtain further supplies.

   Score:…………………………….

   Extra comments:

8. Community pharmacist provided information on newly initiated furosemide - indication (heart failure) and how to take to manage side effects, for example can take at lunchtime instead of in morning if need to go out in morning, rather than skipping dose altogether to avoid polyuria (previous poor compliance)

   Score:…………………………….

   Extra comments:

9. Community pharmacist explained indication for new medicine (finasteride 5mg od).

   Score:…………………………….

   Extra comments:

10. Patient prescribed iron supplements during admission and noticed dark stools following discharge. Community pharmacist reassured patient that darkened stools whilst taking iron supplements is normal

    Score:…………………………….

    Extra comments:

11. Community pharmacist reinforced counselling on apixaban (replacement for warfarin) as patient unsure of reason for switch and why blood tests no longer required

   Score:……………………………

   Extra comments:

12. Healthy living advice given re diet and physical activity to patient with angina

   Score:………………………….

   Extra comments:

13. Patient is a current smoker despite diagnosis of COPD. Community pharmacist provided smoking cessation advice *(unknown if acted on)*

   Score:………………………….

   Extra comments:

14. Patient unsure of how to take some medicines and reasons for taking (patient has angina, diabetes and chronic kidney disease stage 3B). Community pharmacist reinforced times of day to take them and indications

   Score:………………………….

   Extra comments:

15. Patient taking simvastatin in the morning. Community pharmacist explained rationale for evening dosing and patient changed time of dose

   Score:………………………….

   Extra comments:

16. Lansoprazole removed from blister pack following discussion with patient to facilitate administration on empty stomach

    Score:………………………………

    Extra comments:

17. Aspirin not being dispersed as blister packed and patient could not identify it. Removed from blister pack by community pharmacy to aid identification

    Score:………………………………

    Extra comments:

18. Patient with osteoporosis not always taking Cacit due to forgetfulness. Community pharmacist discussed with patient and son, who will now help her remember to take it

    Score:………………………………

    Extra comments:

19. Patient **not** taking senna regularly but still 'very constipated'. Pharmacist advised to try taking regularly

    Score:………………………………

    Extra comments:

20. Patient had restarted isosorbide mononitrate which had been stopped during admission due to low blood pressure. This medicine was also still on repeat prescription. Pharmacist liaised with GP and isosorbide was discontinued.

    Score:………………………………

    Extra comments:

21. Gabapentin still on current record at pharmacy. Community pharmacist ascertained that this had been discontinued and records updated to prevent re-ordering

Score:………………………………

Extra comments:

22. Colecalciferol increased during admission. Community pharmacist updated their records accordingly

Score:………………………………

Extra comments:

23. Bisoprolol stopped in hospital but no indication as to why. Re-issued by GP. Community pharmacist liaised with GP surgery to clarify situation. (Bisoprolol to continue)

Score:………………………………

Extra comments:

24. Patient presented prescription for pre-admission medication which was identified by community pharmacist due to information provided with dMUR referral from hospital pharmacy. Prescription referred back to GP surgery. (Diuretic had been changed from bendrofluazide to furosemide, perindopril dose increased and warfarin and bisoprolol started)

Score:………………………………

Extra comments:

25. Community pharmacist asked GP to consider whether patient appropriate for steroid inhaler due to recent discharge following exacerbation of COPD requiring antibiotics and steroids. (Patient had been on no regular inhalers

prior to admission although reported having been on inhaled steroids in the past. She had been discharged on salbutamol and tiotropium)

Score:…………………………….

Extra comments:

26. Patient started on warfarin during recent admission. Community pharmacist noticed INR had risen from 1.5 to 2.5 in 7 days with no dose change and patient had later seen blood after going to toilet.   Pharmacist arranged INR clinic appointment the next day.

Score:…………………………….

Extra comments:

27. Pharmacist advised patient to consult GP if dizziness symptoms return, for review of blood pressure medicines (postural drop in blood pressure had been evident during admission)

Score:…………………………….

Extra comments:

28. Blood pressure medicines reduced in hospital. Community pharmacist re-checked blood pressure and it was 80/44mmHg. Pharmacist told patient to see GP.

Score:…………………………….

Extra comments:

29. Amlodipine stopped in hospital as perindopril had been started and blood pressure controlled by this. Patient started taking amlodipine again post-discharge. Pharmacist referred patient to GP.

Score:………………………………….

Extra comments:

30. Patient taking metformin and Novomix 30 insulin for diabetes was altering dose of metformin depending on blood sugars. Pharmacist advised this is not the correct way to manage their readings and advised patient to ring diabetes nurse for review.

Score:………………………………….

Extra comments:

Thank-you for completing this review of dMUR interventions. Please email the completed document to helen.ramsbottom@nhs.net or post to Helen Ramsbottom, Pharmacy Department, Southport and Ormskirk NHS Trust, Town Lane, Kew, Southport PR8 6PN

We will be back in touch in the next 2-3 weeks with some feedback on the results of this round of scoring and instructions for the next stage of the analysis

Appendix 35: Coding Framework Used During Analysis of Qualitative Participant Interviews

1. Information / Advice re medication given in hospital
    a. Amount
    b. Nature
    c. Medium (e.g. written/verbal)
    d. Person(s) giving
    e. Timing
    f. Perceived utility
    g. Participant (pt) recall of advice
    h. General attitude of pt towards advice given and reasons for holding this view
    i. Offered by staff or requested by pt/family
    j. Person receiving (pt / family)
    k. Information deficits from hospital as perceived by pt
        i. Nature of deficit
        ii. Attitude towards this (e.g. in relation to expectations/perceived need)
        iii. Action taken (if any) since discharge to resolve deficit
    l. Reasons for different perceptions
        i. Prior level of knowledge
        ii. (Perceived) simplicity of changes
        iii. Nature of change e.g. greater information need perceived for addition of new medicines than over discontinuation of pre-admission meds

2. Transfer of care issues surrounding medicines
    a. Nature of problem
    b. Cause
    c. Preventability

3. Contact with healthcare professionals (HCP) since discharge
    a. Initiation (pt/HCP)
    b. Location
    c. HCP involved
    d. Timing
    e. Reason (e.g. test/procedure, general review)
    f. Patient attitude (e.g. appointment fatigue)

4. Medication support (other than dMUR) since discharge
    a. Medication review by HCP
    b. Advice re specific medicines (e.g. anticoagulant clinic)
    c. GP surgery medicines management staff
    d. Family
    e. Other contact with community pharmacy

5. Barriers to medication adherence
    a. Memory
    b. Manual dexterity
    c. Misunderstanding of complex dosing instructions
    d. Side effects
    e. Eyesight
    f. Pre-existing beliefs

6. Medicines management systems at home
    a. Nature
    b. Initiation (e.g. by pt/family)

7. Discharge Medicines Use Review (dMUR)
    a. Intervention group
        i. Completion (and reasons for non-completion)
        ii. Attendees (e.g. pt alone, pt and relative/carer)
        iii. Action plan
        iv. Method of organisation (e.g. arranged via telephone / 'opportunistic' when pt in pharmacy)
        v. Content of consultation
        vi. Duration?
        vii. Supporting materials (e.g. written advice, compliance aids)
        viii. Pt / carer recall of consultation
        ix. Changes to medication/health related behaviour following dMUR
        x. Perceived utility to pt / carer
        xi. Factors influencing utility (e.g. level of information obtained from hospital)
        xii. Utility to community pharmacist e.g. information supplied by pt may be useful in updating PMR and reducing later prescribing / dispensing errors
        xiii. General attitude and reasons
        xiv. Changes to medication post discharge: timing in relation to dMUR (may cause confusion?)

    b. Control group
        i. Perception of whether dMUR would have been useful

    c. Both groups
        i. Barriers to dMUR

8. General attitudes towards community pharmacy
    a. Positive/negative
    b. Reasons for holding this view

      c. Knowledge of role of community pharmacist
      d. Reasons for using community pharmacy

9. Residual information needs surrounding medication
      a. dMUR completers vs non-completers/controls
      b. Nature
            i. Specific to medication changes in hospital
           ii. Relating to pre-existing medication
          iii. Relating to subsequent medication changes
          iv. OTC medications

Methodological Themes

1. Difficulty in discussing particular topics
      a. Topic (e.g. medicines information given by hospital)
      b. How demonstrated
            i. Brief answers
           ii. Pauses
      c. Underlying reasons

2. Digression of interviewer into HCP role
      a. Trigger/prompt
            i. In response to direct question or issue raised by patient
      b. Nature
            i. Supporting information re medicines
           ii. Management of side effects
      c. Participant subgroups where digression occurred (ie MUR vs non-MUR completers vs control group pts)
      d. Possible effect on outcomes

3. Difficulty of participants with completing questionnaire
      a. Comprehension in pts with mild cognitive impairment
      b. Eyesight (font size too small)

Appendix 36: Coding Index for Hospital Pharmacist Focus Group

1. Problems with current procedure for transfer of medicines related care

   a. Poor documentation of medicines changes on current discharge prescriptions
   Exacerbated by limitations of the e-prescribing system
   Leading to ambiguity over whether medicines have changes/what the changes are

   b. Timeliness of information transfer to primary care records

2. Positive attitudes to / benefits of post discharge medicines use review (DMUR) referral

   a. General
   b. Picking up on side effects
   c. Promoting concordance in medicine taking
   d. Reinforcement of advice given in hospital
   e. Allow community pharmacists to pro-actively work with GPs to ensure changes are actioned, particularly for patients using monitored dosage systems (MDS)

3. Barriers to DMUR referral service

   a. Lack of familiarity with community pharmacy services/potential
   b. Time taken to refer patients
   c. Funding
   d. Patient engagement/suitability
   e. Establishing a patient's regular chemist
   f. Lack of integration of DMUR referrals with current practice in hospital pharmacy
   g. Rapid turnover of patients
   h. Negative attitudes towards extra work required to make DMUR referrals
   i. Consent/information governance issues
   j. Perceived barriers from community pharmacy

4. Solutions for DMUR referral service

   a. Better use of IT
   b. Integration of referral process into established activities of hospital pharmacy

5. Priority/Target groups for referral for DMUR

   a. Patients prescribed new medicines / high risk medicines
   b. Cardiac patients
   c. Pros and cons of targeting particular patient groups to refer