FROM HOSPITAL TO HOME: A MIXED METHODS EXPLORATION OF POST-DISCHARGE MEDICINES MANAGEMENT FOR OLDER PEOPLE LIVING WITH LONG-TERM CONDITIONS

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PHD

2020

From hospital to home: a mixed methods exploration of post-discharge medicines management for older people living with long-term conditions

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Submitted for the Degree of

Doctor of Philosophy

School of Pharmacy and Medical Sciences

Faculty of Life Sciences

University of Bradford

2020

"I mean, to be honest, half the things I don’t know what I’m taking them for. I really don’t know, you know...If they gave me poison, I’d take it. I honestly wouldn’t know, no." [Elizabeth, 87]

Abstract

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From hospital to home: A mixed methods exploration of post-discharge medicines management for older people living with long-term conditions

Keywords: Medication management; medication safety; older people; patient safety; hospital discharge; transitions of care; qualitative interviews; systematic review; complex intervention

There are numerous threats to medication safety at care transitions, which are heightened for older people, because they live with multiple long-term conditions as well as polypharmacy, and have frequent hospital admissions. Whilst evidence of the severity and scale of these medicines-related problems exists, there is insufficient detail about the lived experience of post-discharge medicines management, in particular what helps or what hinders, and how better support could be enabled. This thesis, underpinned by the Medicines Research Council framework for complex intervention design, aimed to find acceptable intervention components, which would enhance patient experience.

This research followed a sequential, mixed method design to: establish the evidence base through critical literature review, develop theory using an interview study grounded in behaviour change theory, and finally to model potential intervention components by expert consensus. Interviews revealed that there were gaps in current service provision, which impacted on participants' knowledge of and capabilities with their medicines. Despite these challenges, some participants took actions to safeguard from problems after discharge. The literature review found that effective components of trialled interventions were self-management advice, post-discharge telephone follow-up and medicines reconciliation. Further behaviour change techniques from the literature, alongside expert consensus and theory-driven analysis of interview findings resulted in final selection of eight potential components. Real-world implementation of these must be coupled with key changes to current healthcare practices and policy, including better engagement with

patients and carers, as well as pro-active post-discharge follow-up. Future work must carefully explore how these components can be tested pragmatically.

Acknowledgments

This research would not have been possible without the expert supervision, guidance and advice of Dr Jon Silcock, Dr Beth Fylan, Mrs Heather Smith and Dr Kate Karban. I must also acknowledge the support of my wonderful colleagues within the University of Bradford's Medicines Optimisation Research Group, wider School of Pharmacy and Medical Sciences and Leeds Teaching Hospitals Trust. Research funding for this study has been provided by a generous NIHR Research for Patient Benefit grant (PB-PG-0317-20010).

I would like to thank the patient participants who gave their time to take part in this study and allowed me intimate access to their lives. My heartfelt thanks also go to Connie, Eric, Manoj and Savi; my marvellous PCLSG members. They have unceasingly offered unique insights and perspectives which have positively influenced the research design and conduct. In addition, and more importantly, they have become my critical friends and have made this journey much more enjoyable.

To my family and friends; thank you for maintaining an unfaltering interest in my research. Hannah and Katie – thank you for always caring; for checking in with me and ensuring that I am still ok. I am also especially grateful to my mum for her dedication to the endless synonyms for 'therefore' and 'describes'.

And finally, to my husband David, without whom, I simply would not have been able to undertake and finish this journey. Thank you for your endless supply of love, support, patience and chocolate cake. Fred – you've no idea how lucky you are.

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Glossary of Terms

Adherence
The extent to which patients take their medicines as prescribed by their healthcare professional

APEASE criteria
Evaluative tool developed by Michie et al. (2014) to assess proposed complex interventions

Complex intervention
Interventions that contain several interacting components

Frailty
People who are at highest risk of adverse outcomes such as falls, disability, admission to hospital, or the need for long-term care

HbA1c
A measure of glycated haemoglobin used by healthcare professionals to obtain an overall picture of average blood sugar levels over a time period

Healthcare professional
A qualified individual who is registered with a regulating body and provides a healthcare service to a patient. Also referred to by participants as clinician, chemist, specialist

Medicines management
The processes and behaviours conducted by patients and healthcare professionals that support safe and effective medication use

Medicines use review (MUR)
An adherence-centred service provided by accredited UK community pharmacists to discuss prescribed and non-prescribed medicines, conducted with the patient

Medicines-related problem
An event or circumstance that interferes with the desired outcome relating to medicines

Multi-compartment compliance aid (also called 'Dosette boxes')
A device that contains the individual doses of the daily medicines in separate compartments

Multi-morbidity
The presence of two or more long-term health conditions

New medicines service (NMS)
A service offered in England by community pharmacists to support patients commenced on selected medicines

NVIVO
Qualitative data analysis software

Patient information leaflet (PIL)
A leaflet provided by the manufacturer that is included in every box of medicines offering written information about the medicine

Package of care (POC)
A funded care package arranged for individuals assessed as having a ‘need’. Can be temporary or long-term

PICOS
A tool to develop to develop search terms for a literature review; refers to population, intervention, comparison and outcomes

Polypharmacy
The use of five or more medicines by a person

Post-discharge phase
The time period that immediately follows discharge from hospital, lasting for approximately eight weeks

Primary care network (PCN)
A formal network comprising a range of healthcare staff and services within a geographical area, that provide structure and funding for locally developed, responsive services

Revman
Desktop software for editing systematic literature reviews developed by Cochrane

Structured medicines use reviews (sMUR)
A structured, holistic and personalised review of all the medicines a patient is taking, conducted by a pharmacist employed by a primary care network

List of Abbreviations

AMSTAR Assessment of multiple systematic reviews

APAC Australian Pharmaceutical Advisory Council

ASHP American Society of Hospital Pharmacists

BAME Black and minority ethnic

BCT Behaviour change technique

BCTT Behaviour change technique taxonomy

BRI Bradford Royal Infirmary

CCG Clinical Commissioning Group

CIs Confidence intervals

COMM Continuity of medicines management

CQC Care Quality Commission

cRCT Cluster randomised controlled trial

DHSC Department of Health and Social Care

GP General Practitioner

HCP Healthcare professional

ICS Integrated care systems

ISCOMAT Improving the Safety and Continuity of Medicines at Transitions

LTHT Leeds Teaching Hospitals NHS Trust

MCA Multi-compartment compliance aid

MDT Multi-disciplinary team

MeSH Medical Subject Headings

MR Medicines reconciliation

MRC Medical Research Council

MRH Medication-related harm

MRP Medication-related problem

MUR Medicines use review

NHS National Health Service

NICE National Institute for Health and Care Excellence

NIHR National Institute for Health Research

NMS New medicines service

PCLSG Patient and Carer-led steering group

PCN Primary care network

PIL Patient information leaflet

PINCER Pharmacist-led IT intervention to reduce Clinically Important Medication Errors

POC Package of care

PPIE Patient and public involvement and engagement

PREM Participant reported experience measure

PRISMA Preferred Reporting Items for Systematic Reviews and Meta-analyses

PROM Participant reported outcome measure

PSI Patient safety incident

RCT Randomised controlled trial

RPS Royal Pharmaceutical Society

RR Risk Ratio

SJUH St James' University Hospital

SMR Structured medication review

SOPs Standard Operating Procedures

STP Sustainability and transformation plans

T2DM Type II diabetes mellitus

TCAM Transfer of care around medicines

TDF Theoretical Domains Framework

WHO The World Health Organization

Key outputs arising from this thesis

Peer-reviewed publications

Tomlinson, J., Medlinskiene, K., Cheong, V., Khan, S., Fylan, B. **Patient and public involvement in designing and conducting doctoral research: the whys and the hows**. Res Involv Engagem 2019; 5 (23). https://doi.org/10.1186/s40900-019-0155-1

Tomlinson, J, Cheong, V, Fylan, B, Silcock, J, Smith, H, Karban, K, Blenkinsopp, A. **Successful care transitions for older people: a systematic review and meta-analysis of the effects of interventions that support medication continuity.** Age and Ageing 2020; 49 (4): 558–569. https://doi.org/10.1093/ageing/afaa002

Tomlinson, J, Silcock, J, Smith, H, Karban, K, Fylan, B. **Post-discharge medicines management: The experiences, perceptions and role of older people and their family carers.** Health Expect 2020; 00: 1– 11. https://doi.org/10.1111/hex.13145

Conference presentations

Improving Patient Safety conference, Leeds, 15th October 2019. **Exploring post-discharge medicines management: the older patient's experience**, oral presentation.

Royal Pharmaceutical Society Local branch meeting, Bradford, 28th November 2019. **Patients as partners**, oral presentation.

Prescribing and Research in Medicines Management (PRIMM) conference, Manchester, Friday 17th January 2020. **The assessment of safety incidents reported by recently discharged older adults**, oral presentation.

Prescribing and Research in Medicines Management (PRIMM) conference, Manchester, Friday 17th January 2020. **Post-discharge medication management: the gaps, traps, bridges and props**, poster presentation.

British Geriatrics Society conference, virtual, Thursday 26th November 2020. **Coping with Medicines after Hospital Discharge; The Invisible Work of Older Patients and Their Care-givers**, President's Round video presentation.

Health Services Research in Pharmacy Practice conference, virtual, April 2021 (abstract accepted). **Identifying behaviour change techniques to support medicines management for older people at care transitions.**

Other

Tomlinson, J. **Coping with medicines after hospital discharge: the "belt and braces" approach.** BMJ Opinion (26th November, 2020). Available at: https://blogs.bmj.com/bmj/2020/11/26/coping-with-medicines-after-hospital-discharge-the-belt-and-braces-approach/

Cheong, V., Tomlinson, J., Khan, S., Petty, D. **Medicines-related harm in the elderly post-hospital discharge**. Prescriber (January 2019). Available at: https://www.prescriber.co.uk/wp-content/uploads/sites/23/2019/01/Medicines-harm-EB-edit-lsw.pdf

Leeds Teaching Hospitals Trust Research celebration video. Can be accessed here: https://youtu.be/Jn-VpvA6DxU

Animation video, Patient and Public Involvement: How to find the right people? Available at: https://www.youtube.com/watch?v=_wBvA9SMdxY

Feedback events at Bradford Teaching Hospitals NHS Trust (pharmacy department), Leeds Teaching Hospitals NHS Trust (pharmacy department, elderly medicine team and Discharge Collaboration team).

Chapter 1: Introduction: why focus on supporting post-discharge medication safety?

1.1 Introduction to the researcher and research topic

This doctoral study arose from a partnership between the School of Pharmacy and Medical Sciences, University of Bradford and the Medicines Management and Pharmacy Services Department at Leeds Teaching Hospitals NHS Trust (LTHT). Alongside my research, I practise at St James's University Hospital as an Elderly Care pharmacist and hold a teaching contract with the University. I was initially motivated to apply for this doctoral post after reading the PhD proposal set out by LTHT (**Appendix 1**). It outlined the intention to investigate medication safety for vulnerable older patients after hospital discharge and to develop an intervention to improve service provision. My interest in this topic stems from my previous role as a community pharmacist within which I regularly supported patients after their stay in hospital. I felt frustrated by the lack of communication and co-ordination between the hospital, primary care and community pharmacy; and had to spend vast amounts of time trying to ascertain the correct post-discharge medication regimen. My patients were often unaware of the changes to their medicines and relied wholly on the pharmacy to safely supply their new medicines. This responsibility lay heavily on my shoulders and appeared to cause undue stress and deep anxiety for my patients. My desire to improve service provision for patients, through in-depth inquiry and study, drove me to apply for and successfully obtain this post.

Working within the elderly care team at LTHT has guided me to focus on improving care for older patients living with multi-morbidity and frailty. It is apparent from my clinical experience, scoping of the literature and stakeholder discussions (**Chapter 2**), that these individuals are much more vulnerable to problems as they transition between care settings due to: polypharmacy, high rate of readmission, reduced capacity for self-care, cognitive impairment and reduced resilience (Clegg et al. 2013; Oliver et al. 2014). These problems may result in negative outcomes for the patient such as dissatisfaction, low levels

of adherence to medicines, physical or emotional harm, hospital readmission and a poorer quality of life.

This thesis explores older peoples' experiences with their medicines after a hospital stay and provides insight into the barriers and facilitators to their engagement with post-discharge medicines management. These experiences, combined with evidence from the literature and behaviour change theory, result in the identification of acceptable solutions to better support these older people. It begins with an introduction to the wider context of medicines safety (**Chapter 1**), and the development of the research question, aims and objectives through literature review and stakeholder conversations (**Chapter 2**). The methods, theoretical underpinning and quality criteria are described (**Chapter 3**), followed by an in-depth discussion of each phase of work (**Chapters 4, 5 and 6**). The thesis concludes with a summary of recommendations for practice and further research (**Chapter 7**).

This first chapter explores: the importance of medication safety, situations that are at higher risk of medication error, the rationale for a focus on care transitions and why continuity of medicines management is a positive, helpful concept in the post-discharge phase of the patient pathway.

1.2 Medication safety: setting the scene

Medicines are the most frequently used intervention in the National Health Service (NHS) (Department of Health 2004). Approximately 1,108 million prescriptions are dispensed annually in England (NHS Digital 2017), so it is unsurprising that errors can and do occur. Errors are the product of system weaknesses and medication safety is often compromised in the context of complex combinations of processes, technology and human interactions (World Health Organization 2019).

Medication errors, defined as "*errors in the process of prescribing, preparing, dispensing, administering, monitoring or providing advice on medicines*" (NHS England 2014a), have the potential to cause significant harm to patients. Whilst it is estimated that 237 million medication errors occur in England per year, 72% (n=171 million) have little or no potential to cause patient harm

(Elliott et al. 2020). However, those that do cause harm may result in ill-effects, hospitalisation or even death.

Threats to medication safety occur throughout the healthcare system (Elliott et al. 2020). It is estimated that 2-3% of primary care encounters and 10% of hospital encounters result in medication error (Sheikh et al. 2019). The factors influencing medication safety can be categorised as healthcare professional-(HCP), patient- or work environment- related (Medicines Complete 2019). Professional factors include the level of training, clinical knowledge, fatigue, communication and knowledge of the patient (World Health Organization 2016). Older multi-morbid patients who take multiple medicines and have more than one HCP involved in their care are at a significantly greater risk of experiencing harm (Assiri et al. 2018). Work-related factors include available resources, time and distractions (Medicines Complete 2019).

1.3 A call to action

Alongside the potential to cause significant harm, medication errors are estimated to cost $42 billion globally each year (Aitken and Gorokhovich 2012). Improving medication safety by implementing activities to avoid, prevent or correct adverse events that may result from the use of medicines (Council of Europe: Committee of Experts on Management of Safety and Quality in Health Care 2005) is an international priority (Stelfox et al. 2006). In recognition of the seriousness of the medication safety problem, The World Health Organization (WHO) has tasked all countries to halve avoidable medication-related harm by 2022 (Donaldson et al. 2017; World Health Organization 2017). Improving safety and reducing the incidence of medication errors is also in the NHS Outcomes Framework (Department of Health 2010), acting as a catalyst to focus research on identifying problematic high-risk areas (Garfield et al. 2009; Avery et al. 2012a; Panagioti et al. 2015; Assiri et al. 2018).

A consensus exercise by medication safety experts, in response to the WHO's global target, identified six research priorities (Sheikh et al. 2019):

- technology to increase medication safety
- guidelines and standard operating procedures (SOPs) for high-risk patients, medicines and contexts
- developing prediction tools for high-risk patients and situations
- interventions to increase patient medication literacy
- focused training for HCPs
- developing pictograms for improving medication safety.

These research priorities appear to focus on improving organisational processes with little or no attention given to doing things with patients. Whilst this consensus exercise gathered the opinions of 42 international experts, it failed to seek the patient voice and elicit what was most important to them.

Flawed or dysfunctional healthcare systems, processes and procedures are also a significant threat to medication safety (World Health Organization 2017). The WHO has identified three key areas of focus for improvement: polypharmacy, high-risk clinical situations and transitions of care (Donaldson et al. 2017; World Health Organization 2017). These key areas involve complex clinical situations or medication regimens that are most likely to lead to significant medication errors when there are flawed systems in place (World Health Organization 2017).

Providing patient care across transitions is a notoriously risky situation due to: the involvement of multiple providers, a failure of systems to ensure that effective communication takes place, or incomplete execution of post-discharge plans (Coleman 2003; Avery et al. 2012a). These and other gaps created within the system can lead to a lack of continuity of care, which then results in worse patient outcomes (Cornwell et al. 2012). In their landmark paper, Coleman et al. (2003) defined a novel research agenda to improve patient safety at transitions of care. They outlined a need to: identify how to encourage patient and family carer engagement, foster collaboration at an organisational level, explore which patients are at the highest risk, and

investigate communication technology systems to improve transfer of information.

Seventeen years later, and despite continued research in this field, we are still grappling with these same issues. Factors which may be contributing to this dilemma include the growing complexity of medicines regimens, care in general, or increased healthcare demand, which have made the problems trickier to solve. Furthermore, due to organisational complexity, solving one aspect of the problem can often reveal or create further issues (Wu 2019). This is evident in the difficulty encountered when implementing system-wide technology solutions within the NHS (Syal 2013).

1.4 The problem with transitions in care

A 'transition of care' is a broad term describing the transfer of a patient's care from one healthcare professional and/or setting to another (Oboh 2016). It is further defined by the American Geriatrics Society (Coleman and Boult 2003) as: *"a set of actions designed to ensure the coordination and continuity of health care as patients transfer between different locations or different levels of care within the same location."* Transitions can include movement in to and out of hospital, nursing facilities and the home. It is widely known that these transitions pose risks to patient safety and increase the chance of harm (Coleman 2003; Kripalani et al. 2007a; Kripalani et al. 2014; World Health Organization 2016).

These transitions of care involve multiple health and social care professionals, often working in complex fragmented systems. Deficits in care and hazards across teams or organisations are frequently compounded by multiple systems and settings (Dixon-Woods 2019). An estimated 60% of all medication errors occur during transitions of care (Johnson et al. 2015). Hospital admission and discharge are thought to be particularly challenging and problematic care transitions (Garfield et al. 2009; Tarrant et al. 2014). For example, 11-59% of medication discrepancies, defined as differences among documented medicines across different sites of care (Neumiller et al. 2017), that occur at hospital admission and discharge are considered to have the potential to cause harm (World Health Organization 2016). One-half of

medication error at transitions is thought to be as a result of poor cross-sector communication (Barnsteiner 2005). Furthermore, during inpatient hospital stays, HCPs are constantly present, but when patients are discharged, research demonstrates that they can often feel alone and unsure of what to do (Knight et al. 2013; Andreasen et al. 2015). This can result in post-hospital syndrome, where without appropriate support patients often relapse and deteriorate further or are readmitted to hospital (Krumholz 2013). This is costly for the NHS and the hospital; it also reduces the patient's quality of life. More recently, this post-hospital syndrome has been hypothesised to be the result of allostatic overload, or repetitive stress exposure, during the hospital stay (Goldwater et al. 2018). Unnecessary social and environmental stressors can compound this elevated vulnerability after a hospital stay, especially in older people living with multi-morbidity and frailty. Hence, how adverse outcomes from post-hospital syndrome can be mitigated, especially through improved medication safety as well as stress reduction through better medicines management, is important.

1.5 Patients at significant risk of medication errors at transitions

Young children and the elderly are more susceptible to adverse outcomes from medication error in general, as are those patients with complex co-morbidities including liver or kidney disease (World Health Organization 2017). Patients taking high-risk medicines, e.g. warfarin, are also at risk of significant negative consequences should errors occur (World Health Organization 2019). In a scoping review (Oliver et al. 2014), vulnerable groups (such as those patients who live with multiple health conditions and polypharmacy) were found to suffer from more challenging problems associated with transitions of care. The medicines-related challenges faced by these higher-risk patients and the causal factors will form the basis of a literature review in **Chapter 2**.

1.6 Local, national and international policy driving improvement of care transitions

Hospital discharge, as one of the riskier error-producing processes, has been prioritised and widely studied (Midlöv et al. 2005; Osorio et al. 2014; Waring et al. 2014; Williams et al. 2015). For example, between October 2012 and September 2013 an NHS England Patient Safety Alert reported 10,000 safety incidents related to hospital discharge (NHS England 2014b). Communication between providers was identified as a key area of risk and accounted for approximately 33% of the incidents (NHS England 2014b). Discharge without adequate communication and information not being acted on in a timely manner were found to be underlying factors (Williams et al. 2015). This and related research has driven an international, national and local demand for better quality transitions and safer patient handover. Key organisations' roles at each of these levels are shown in **Figure 1**.

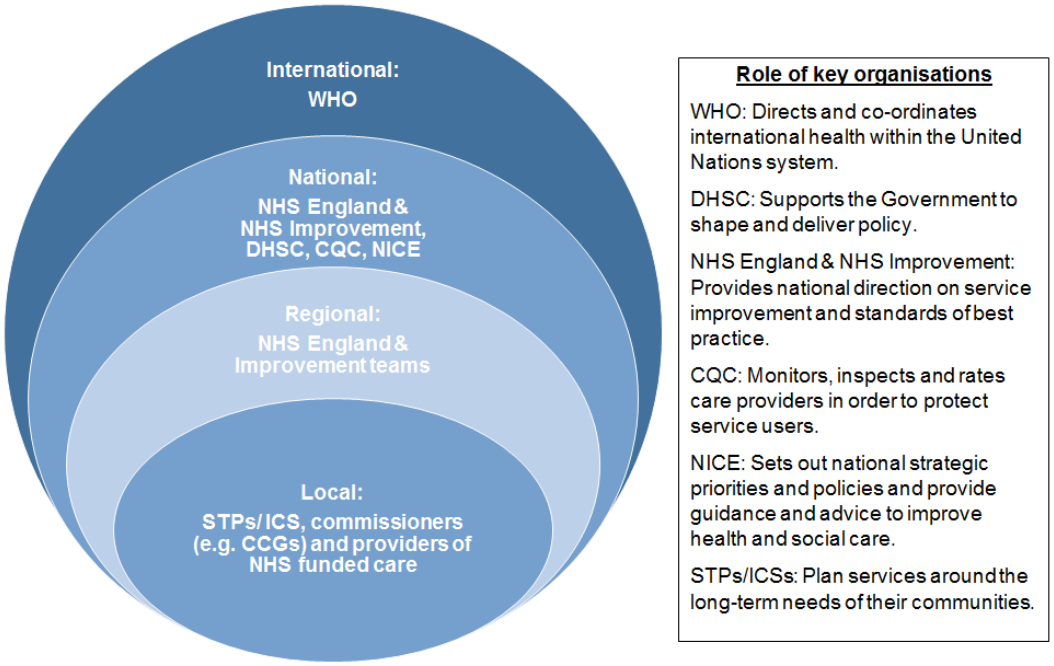


Figure 1: Key healthcare organisations involved in medication safety

1.6.1 Local

Sustainability and Transformation Plans (STPs), sometimes evolving into Integrated Care Systems, have been developed by local authorities in conjunction with stakeholders. These set out health and social care agendas reflecting the needs of local populations. Much emphasis has been placed on the development of integrated services and the need to work together to reduce variation and share best practice within the West Yorkshire and Harrogate area of England, which forms one STP 'footprint' (NHS England 2016). More collaboration between health and social care, together with a need to develop new models of care to support self-management have also been highlighted as priorities in Leeds and Bradford localities.

1.6.2 National

A special enquiry commissioned into hospital discharge by Healthwatch England, identified that patients frequently experience delay, lack of co-ordination, discrimination and do not feel involved in decisions about their care (Healthwatch England 2015). The NHS Long Term Plan (2019) recognises the artificial divide between primary and secondary care created by NHS staff and organisational systems. With concerns over increasing inequalities and pressures from the ageing population, it is acknowledged that greater integration and co-ordination of health and social care is required (Department of Health 2001; NHS England South 2014; Oliver et al. 2014). Therefore, there is urgent need to review and redesign NHS care pathways in order to ensure the best use of staff and resources to maximise patient outcomes and benefit. New service models that offer patients better support and co-ordinated care, at the right time and in the optimal care setting are sought (NHS 2019).

The Department of Health and Social Care's working group for reducing medication-related harm further suggested strategies within four domains to encompass The WHO's priorities for action (Department of Health and Social Care 2018) (**Table 1**).

Table 1: Strategies suggested by the DHSC's working group for reducing mediation-related harm (Department of Health and Social Care 2018). Reproduced from 'The Report of the Short Life Working Group on reducing medication-related harm' © Crown copyright 2016.

Domain	Suggested strategies
Patients and the public	Encouraging shared decision making Improve information for patients and carers
Medicines	Producing patient-friendly labelling and packaging Drug differentiation (reducing 'look alike sound alike' errors)
Healthcare professionals	Improve shared care Education in safe and effective medicines use Reducing inappropriate polypharmacy
Systems and practices of medicines	Hospital E-prescribing deployment Roll out of PINCER (Avery et al. 2012b)

Furthermore, the NHS has made significant commitment to improving the overall patient safety culture and systems (NHS England and NHS Improvement 2019) by developing their Medicines Safety Improvement Programme. This programme aims to illustrate best practice in transitions of care and develop local quality improvement approaches (Cattell 2019).

In 2015, the National Institute for Health and Care Excellence (NICE), in collaboration with the Social Care Institute for Excellence published guidance to support patient transition between the inpatient hospital setting and community or care home settings (National Institute for Health and Care Excellence 2015b). Proactive information sharing, liaison between care providers and encouragement of self-care were all highlighted as important holistic factors for safer hospital discharge. The implementation of new technologies and communication systems to aid the sharing of information has been widespread (Chen et al. 2010; Gurwitz et al. 2014; Nazar et al. 2016). Promoting patient self-care, "*a process through which people take responsibility for their own health, understanding how to promote it and what can damage it*", is known to be an important factor in the management of chronic illnesses (Ausili et al. 2014). Whilst research has sought to explore

self-care (or self-management activities and behaviours) that support the management of long-term conditions (Artinian et al. 2002; Bourbeau et al. 2004; Kennedy et al. 2007), self-care as a strategy to enhance care transitions appears less well studied (Kripalani et al. 2007a).

1.6.3 International

The WHO has committed to tackling the challenges of patient safety and to identifying practical interventions to address them (**Section 1.3**). A list of potentially beneficial interventions has been proposed, with a focus on reducing the risks associated with transitions of care (World Health Organization 2016). These come with the caveat that a 'one-size fits-all' strategy is inappropriate, and a range of tools are likely to be needed. Unfortunately, these interventions are widely generic, such as "increasing the involvement of primary care physicians" and could, therefore, be difficult to operationalise in practice.

Table 2: American Geriatrics Society Health Care Systems Committee position statements (Coleman and Boult 2003). Reproduced with kind permission.

Position 1. Clinical professionals must prepare patients and their caregivers to receive care in the next setting and actively involve them in decisions related to the formulation and execution of the transitional care plan.
Position 2. Bidirectional communication between clinical professionals is essential to ensuring high-quality transitional care.
Position 3. Policies should be developed that promote high-quality transitional care.
Position 4. Education in transitional care should be provided to all healthcare professionals involved in the transfer of patients across settings.
Position 5. Research should be conducted to improve the process of transitional care.

The American Geriatrics Society Health Care Systems Committee has also developed five position statements (Coleman and Boult 2003) to guide HCPs, governing bodies and researchers working in this field of care transitions (**Table 2**). Transfer of information, patient engagement and multidisciplinary

team involvement also feature within The Joint Commission's seven foundations for safe, quality transitions in care for all American settings (The Joint Commission 2013). Early identification of high-risk patients, leadership support and medicines management are emphasised. Once again, in-depth detail of exactly how these are to be achieved in practice is lacking.

1.7 The ideal transition of care

To complement these key policy documents, researchers have tried to establish more clearly those actions which are fundamental to a high-quality and safe transition. The Ideal Transitions Bridge (Burke et al. 2013) (**Figure 2**) is a framework synthesised from ten core components, validated by literature review (Burke et al. 2014), that support effective hospital discharge. Burke et al. (2013) explain that the more components of the bridge that are achieved per patient, the better and more successful the transition is thought to be. In addition, they determine who has the responsibility for each component, illustrated by the location of the component on the bridge. Medication safety is named as one of these ten core components and is often cited in literature surrounding transitions as a fundamental process to minimise harm (Coleman 2003; Laugaland et al. 2012; Pollack et al. 2016). It appears closer to the hospital column of the bridge, highlighting that this is where they believe that key responsibility lies.

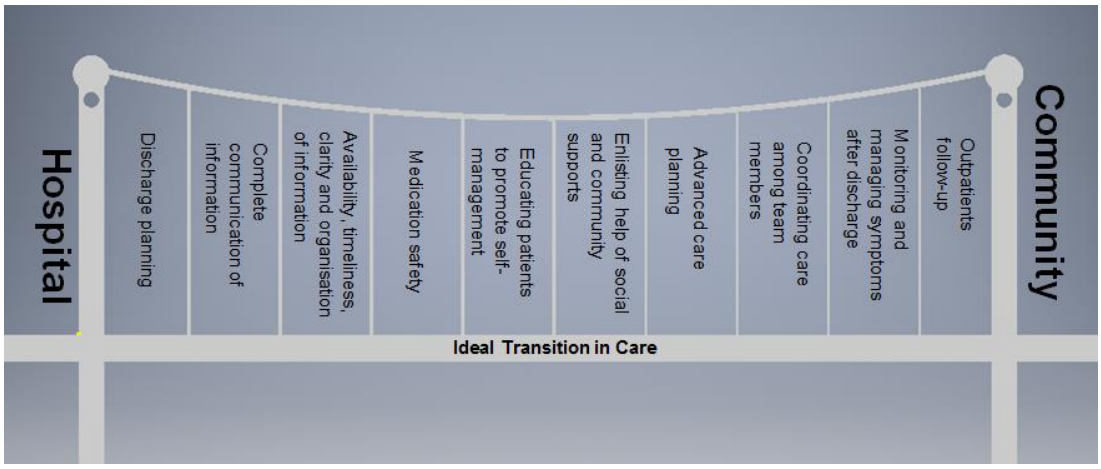


Figure 2: The Ideal Transition in Care Framework, reproduced from Burke et al. (2013)

1.8 The concept of continuity of care in medication management

To mitigate the risk of medication error and to optimise medication safety for patients after hospital discharge, continuity of care in medicines management is recommended (American Society of Health System Pharmacists Continuity of Care Task Force 2005; Australian Pharmaceutical Advisory Council 2005; Beadles et al. 2014). Continuity of care has been defined in general terms as:

"*The degree to which a series of discrete health care events is experienced as coherent and connected and consistent with the patient's needs and personal context* " (Haggerty et al. 2013).

Haggerty et al. (2013) defined this as relying on three essential elements: interpersonal, management and informational continuity (**Figure 3**). Whilst this model is applicable to all aspects of care continuity, Beadles et al. (2014) adapted it further and introduced the concept of continuity of medication management (COMM), increasing the relevance of the model to those HCPs prescribing medicines for chronic conditions. This model focuses on the number of prescriptions issued and the number of prescribers rather than the

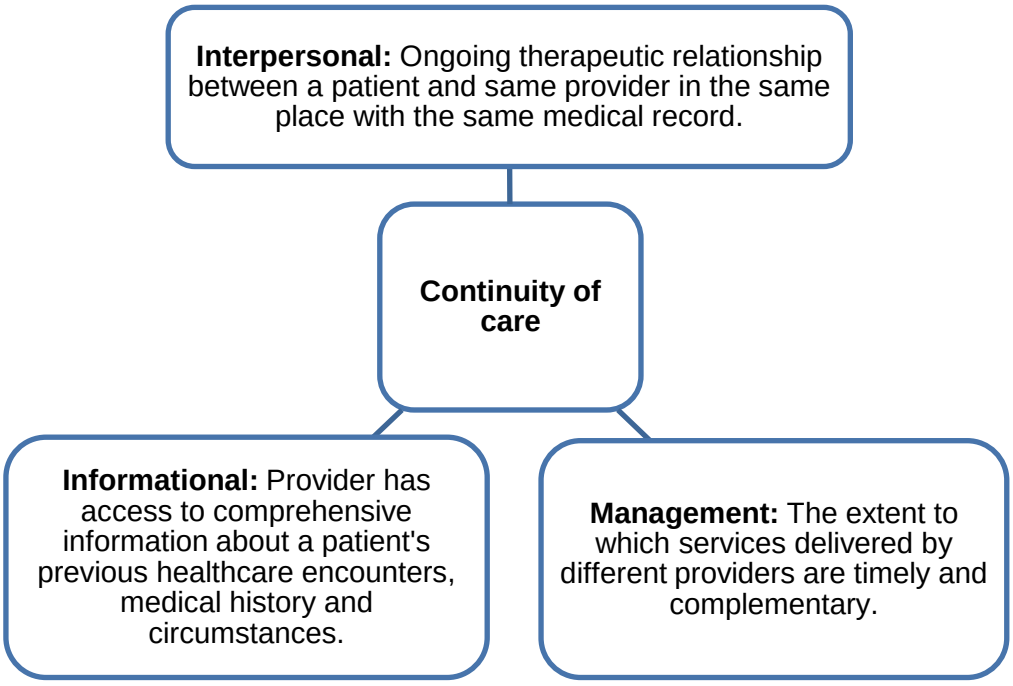


Figure 3: Conceptual model of Continuity of Care, themes from Haggerty et al. (2013)

traditional continuity of care concept of provider encounters. Whilst fewer prescribers may reduce the potential for medication error and be associated with higher quality care, it does not encompass non-medicines management, obtaining supply from an alternative appropriate setting, nor necessary monitoring. Whilst widely utilised by researchers and organisations, a definitive definition of COMM and the appropriate process measures are absent.

Layson-Wolf and Morgan (2008) identified that the community pharmacist is often not provided with any information about the patient's post-discharge medicines. This is predominantly because medicines reconciliation (MR) traditionally relies on hospital communication being sent directly to the GP. For COMM, or post-discharge medicines management to occur, Layson-Wolf and Morgan (2008) suggested that community pharmacists must also be provided with information about changes to medicines and follow-up care plans.

For COMM to function in practice, the Royal Pharmaceutical Society (RPS) defined four core principles for HCPs (Royal Pharmaceutical Society 2012) (**Table 3**). Likewise, The Australian Pharmaceutical Advisory Council's Guiding Principles for COMM (2005) similarly focus on obtaining accurate medicines information and communicating this onward to the next setting. Both sets of principles outline the responsibility and accountability of the HCP and Health Service Managers. They seemingly emphasise doing things *to* or *for* the patient and not *with* them. What these principles appear to lack is recognition of the patient's own responsibility and role within their post-discharge medicines management, including how they can be encouraged to be active partners or 'agents' in their own care (Stone 1997).

Table 3: Royal Pharmaceutical Society's core principles of COMM for healthcare professionals (2012). Reproduced from 'Keeping patients safe when they transfer between care providers – getting the medicines right' © 2012 Royal Pharmaceutical Society

1. Healthcare professionals transferring a patient between settings should ensure that all necessary information about the patient's medicines is accurately recorded and transferred with the patient, and that responsibility for ongoing prescribing is clear.
2. When taking over the care of a patient, the healthcare professional responsible should check that information about the patient's medicines has been accurately received, recorded and acted upon.
3. Patients (or their parents, 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.
4. Information about patients' medicines should be communicated in a way which is timely, clear, unambiguous and legible; ideally generated and/or transferred electronically.

1.9 Chapter summary

It is widely recognised that researchers, organisations and HCPs must focus their efforts to reduce avoidable medication errors, especially for patients undergoing transitions of care. Continuity of care as a means of avoiding patient harm becomes increasingly important as people age, have multiple conditions or complex healthcare issues, and become socially vulnerable (Cornwell et al. 2012).

Medication safety, and in particular COMM or post-discharge medicines management, has been highlighted as a key component of effective care transitions. However, how this becomes a viable fit for healthcare practice must be further explored. In **Chapter 2**, the current evidence surrounding medication safety following the hospital to home transition will be reviewed.

Chapter 2: Developing the research question; a literature review and stakeholder consultation

Chapter 1 presented the context for this doctoral study investigating medication safety at the point of hospital discharge and LTHT's desire for the development of an effective, evidence-based intervention. Furthermore, it highlighted the marked lack of progress made in improving patient safety at transitions of care, whilst also indicating a renewed worldwide effort to reduce medication errors. **Chapter 2** will scope the literature related to medication safety following hospital discharge and the recommended strategies used to support medication safety at care transitions. Alongside the literature search, key stakeholder discussions are presented, which provided a more knowledgeable insight and promoted a deeper understanding of the local context.

2.1 Aim of Chapter 2

Designing research questions is an important first step in research development as it gives clear focus and purpose. **Chapter 1** outlined the background to the topic of interest and highlighted the current issues surrounding medicines continuity at transitions of care. In order to clearly define the research problem that this study addresses, it was necessary to conduct a literature review to provide a specific focus and identify any current and significant gaps. To guide and enhance the literature review, and, more importantly to help develop meaningful research questions, it was also necessary to explore local service provision and public opinion around the theme of post-discharge medicines-related care.

The purpose of this literature review was to clearly synthesise the extent of current evidence surrounding:

- the prevalence of medication errors and the associated problems following hospital discharge;
- the types of problems patients face and where they occur;

- the causal factors and patient groups at the highest risk;
- the interventions presently employed to reduce medication-related harm at care transitions.

The stakeholder conversations grounded me in current practice, whilst at the same time ensured that the research topic resonated equally with members of the public and healthcare staff.

2.2 Literature review strategy

A scoping review strategy was adopted to guide this search as the breadth of relevant, available literature was unknown. It was also felt that this would provide a suitable starting point to identify firstly, the nature, and secondly, the extent of current research (Grant and Booth 2009). In addition, this particular strategy is useful in providing direction for research priorities, a map of the literature on a particular issue and in identifying key concepts (Colquhoun et al. 2014).

The review followed the framework of Arksey and O'Malley (2005), namely: identify the area(s) of research, identify relevant studies, select studies, collate, summarise and synthesise the data, and report the findings.

A database search, guided by the aims of the review (**Section 2.1**), was conducted using Medline, Embase and CINAHL, combining relevant Medical Subject Heading (MeSH) terms and free-text keywords related to "medication safety" and "care transitions". Reference lists from the policy documents discussed in **Chapter 1** were also interrogated and further literature was sourced from the references in resultant relevant papers (known as snowballing). The steps of the scoping review were carried out iteratively, whilst being continually shaped by a variety of stakeholder conversations and their reflections on current healthcare practice.

Studies were synthesised narratively and the findings related to each aim of the review are presented in turn. Quality assessment of the literature within this scoping review was considered unnecessary because the aims of the review could be met without this step (Peterson et al. 2017). A summary of the

stakeholder conversations is then reported and the chapter concludes with a summary of the gaps in evidence, which this study will seek to fill.

2.3 The frequency and nature of medication errors and problems following hospital discharge

Transitions of care frequently result in medication errors, such as a discrepancy between the planned or recommended post-transition prescription and what the patient is actually prescribed (Boockvar et al. 2004; Forster et al. 2004; Midlöv et al. 2005; Frydenberg and Brekke 2012; Redmond et al. 2019), with an estimated variation between 14.1% to 94% of patients affected (Paulino et al. 2004; Coleman et al. 2005; Corbett et al. 2010; Garcia-Caballos et al. 2010). These wide-ranging estimates stem from the difference in definitions of the terms ‘discrepancy’ and ‘error’ used between studies, which makes them challenging to compare.

Studies have shown that where discrepancies do occur, patients are likely to experience more than one discrepancy (Midlöv et al. 2005; Boockvar et al. 2009; Corbett et al. 2010), a situation which often has the potential to cause harm (Frydenberg and Brekke 2012). In one study of 43 patients, for example, a total of 124 potential adverse drug effects (average 2.9 events per patient) from discrepancies in their post-discharge medicines were experienced (Armor et al. 2014). Omitted medicines and incorrect dosages are the most frequently reported error after hospital discharge (Cornu et al. 2012; Knight et al. 2013; Ahmad et al. 2014; Osorio et al. 2014).

Alongside these discrepancies and errors (**Figure 4**), problems such as difficulty obtaining or taking medicines, accessing follow-up tests and adequate monitoring or having unanswered questions were all common after discharge (Coleman 2003; Paulino et al. 2004; Arora et al. 2010). These medication-related problems (MRPs) often result in feelings of anxiety and confusion from both patients and family carers, which may lead to incorrect medicines use (Knight et al. 2013), yet these types of psychological harm have not often been measured nor reported in research. As **Figure 4** illustrates, MRPs encompass everything that can go wrong with medicines use, and are

significantly broader than traditional definitions of ‘error’, or ‘discrepancy’. Whilst the vast majority of MRPs do not cause any consequences, (below the line depicted on **Figure 4**), those that do can have clinical, psychological and/or financial impacts.

MRPs have the potential to cause medication-related clinical harm (MRH), increasing the risk of readmission and resulting in a worse quality of life for the patient (Knight et al. 2013; Ahmad et al. 2014). For example, in one study of 375 older patients (Coleman et al. 2005) a total of 53 patients (14.1%) experienced discrepancies with their medicines. Of these, 14.3% patients (n=7.6) were readmitted to hospital within 30 days of discharge, compared to 6.1% of patients (n=3.2) who had no problems (p=0.04). Another recent study observing post-discharge MRH found that 37% of older patients (n=413/1280) experienced MRPs, which the study authors estimated to cost the NHS £396million annually (2018 prices), and 52% (n=214) were found to be preventable (Parekh et al. 2018a). Similar estimates were found by Riordan et al. (2016), where 43% of their participants (n=36/83) experienced a post-discharge error with 86% (n=31/36) at risk of moderate harm. Of greater consideration, on investigation, 58 errors (88%) were found to occur at discharge and then persist for 14 days into the post-discharge phase (Riordan et al. 2016).

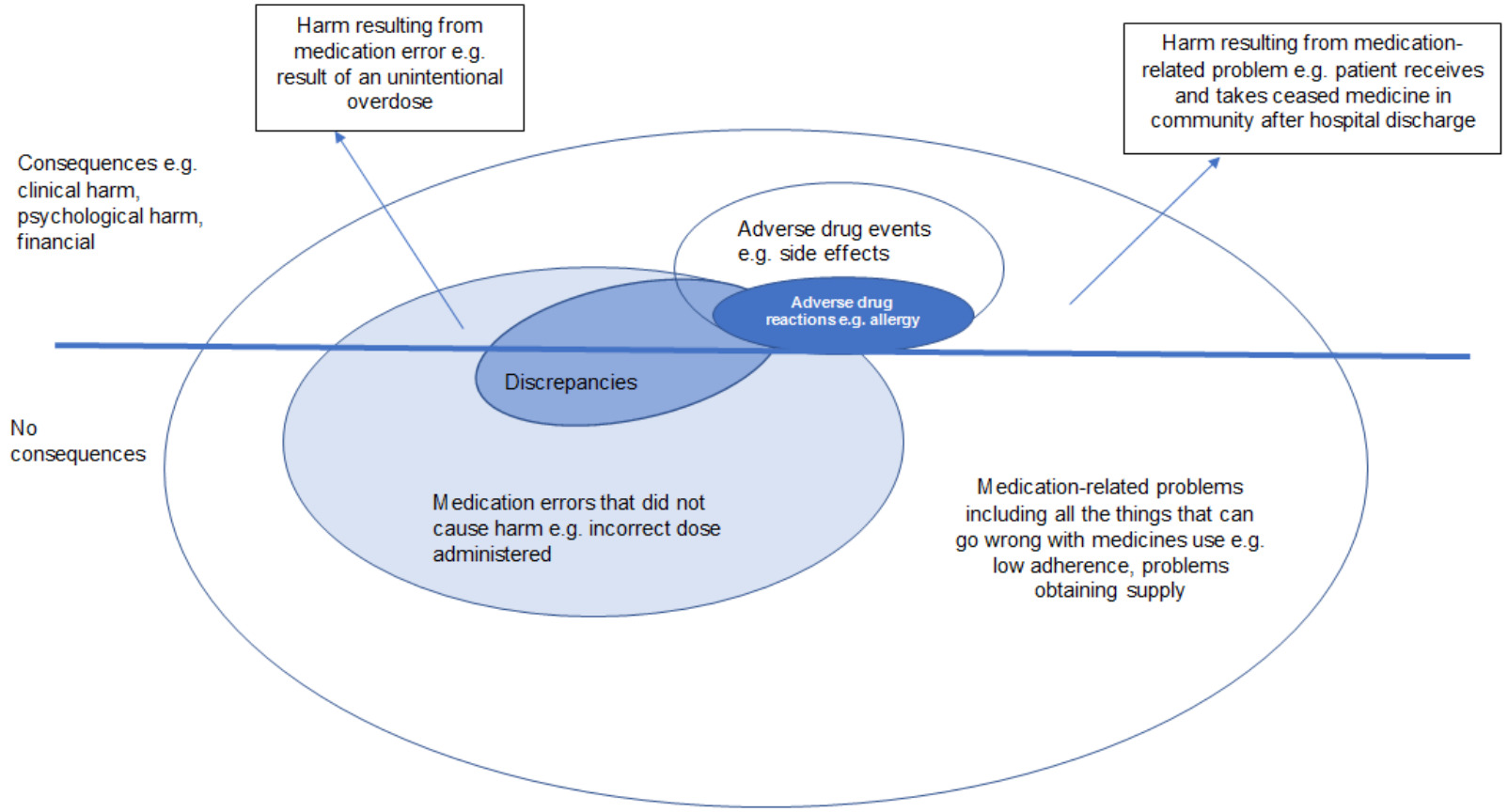


Figure 4: Illustration of MRPs, errors and ADEs and their relationship with MRH

In order to overcome MRPs, priority has been given to improving MR processes at admission and discharge (Burke et al. 2013; World Health Organization 2016). MR is a process whereby the best possible medication history is obtained for all the medicines that the patient was taking before admission and compares it with that of the inpatient regimen. Any discrepancies are highlighted and resolved, ensuring safer and appropriate continuation (National Prescribing Centre 2008). When patients are discharged, their medicines may have undergone several changes, and more importantly, careful reconciliation is required in primary care to ensure that post-discharge prescribing matches those specific changes made in hospital. Whilst this is an important process and valuable initiatives have demonstrated effectiveness at reducing discrepancies (Kwan et al. 2013; Mekonnen et al. 2016; McNab et al. 2018), many MRPs (which are broader in concept than those traditionally classed as 'errors', shown in **Figure 4**) continue to be problematic for patients. Problems such as patients continuing to use pre-admission medicines instead of new treatments (Paulino et al. 2004; Eassey et al. 2016) increase the potential for harm and indicate that activities beyond MR are required.

Much of the research effort has focused on reducing medication error, but studies have shown that a larger proportion of patients report difficulties with adherence to post-discharge medicines regimens, due to confusion and uncertainty (Ensing et al. 2017), rather than experience an error (10.9% vs 3.4% respectively) (Parekh et al. 2018a). In addition, Armor et al. (2014) estimated that medicines non-adherence and underuse were responsible for up to 18% of cases (n=23/124) of potential adverse drug events. Therefore, a wider investigation of the post-discharge medicines experience is necessary for this current study, encompassing all aspects of post-discharge medicines management, rather than a focus on simply 'error' or 'discrepancy'.

2.4 Where do medicines-related problems occur in the post-discharge pathway?

In a national report (Care Quality Commission 2009), the Care Quality Commission outlined the ideal patient pathway for medicines management from the point of hospital admission through to discharge and follow-up (**Figure 5**). MRPs are thought to occur at various points in this pathway. However, they are found to be most prevalent at the key stages of post-discharge prescribing, monitoring and administration (Paulino et al. 2004; Forster et al. 2005; Kanaan et al. 2013; Williams et al. 2015; Spencer et al. 2018).

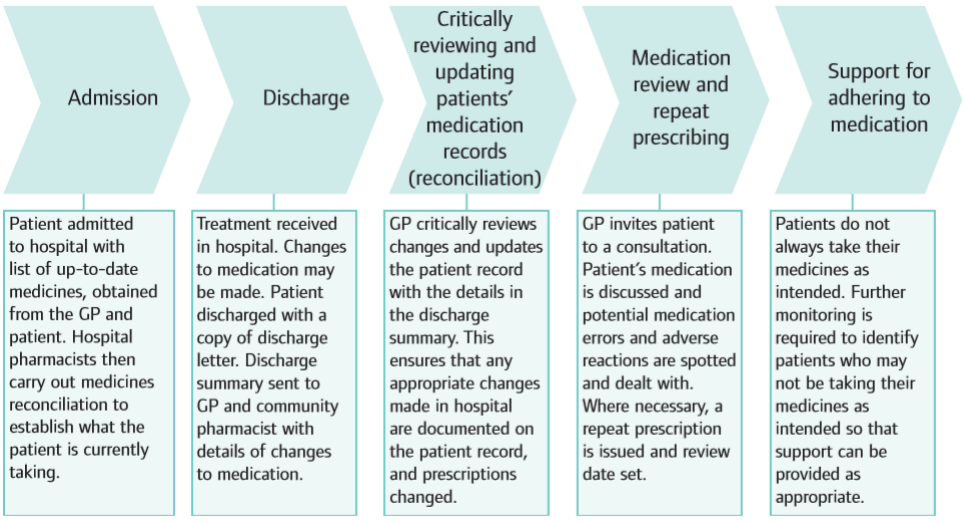


Figure 5: The ideal patient pathway for medication management. Reproduced from 'Managing patients' medicines after discharge from hospital' © Care Quality Commission 2009

2.4.1 Prescribing

Changes to medicines are frequent during hospitalisation (Mixon et al. 2015); therefore reconciliation and prompt review are needed in primary care following discharge. In a recent study, documented medication changes in discharge summaries were not implemented by primary care in 17% of cases (Spencer et al. 2018). The risk of failure to make changes was highest with

newly started medicines. Paulino et al. (2004) also found that dosage, drug duplication, interactions and prescribing errors accounted for 24% of post-discharge MRPs. More recent studies have found that the most common discrepancies were the prescribing of discontinued medicines, incorrect dosages and wrong dosing frequencies (Downes et al. 2015).

2.4.2 Administration

Several studies have demonstrated that unintentional non-adherence is a contributing factor to MRPs and leads to MRH following hospital discharge (Coleman et al. 2005; Downes et al. 2015; Eassey et al. 2016). Unintentional non-adherence occurs when "*the patient wants to follow the agreed treatment but is prevented from doing so by barriers that are beyond their control*" (National Institute for Health and Care Excellence 2009). Examples of these barriers include, the patient not realising that they were supposed to take a new medicine (Downes et al. 2015), not being aware of their medicine's side effects (Forster et al. 2005), or patients feeling they lacked knowledge about their medicines (Paulino et al. 2004). In an observational study of 202 patients transitioning from hospital to residential care, 75 medication doses for 37 patients (18.3%) were missed or significantly delayed in the 24 hours post-discharge (Elliott et al. 2012). In addition, approximately 20% of patients experienced an administration error within 24 hours of discharge.

2.4.3 Monitoring

In a study of discharge summaries for 300 patients, monitoring tests were incomplete in 26% of cases and action was not taken for 27% of follow-up tasks (Spencer et al. 2018). Additionally, in a prospective sample of 400 discharged patients, Forster et al. (2005) found that 11% of them experienced an adverse drug event, of which 27% were thought to be preventable and 33% could be ameliorated. The most common reason for this was the failure to implement appropriate and effective drug monitoring. For example, the study reports that a patient was discharged with potassium supplements and spironolactone but had had no electrolyte monitoring arranged for them. Consequently, this patient was readmitted with dangerously elevated potassium levels within two weeks of discharge (Forster et al. 2005). More to

the point, it is often unclear which sector or healthcare professional is responsible for post-discharge monitoring. As a result this can lead to either a lack of, or quite inappropriate, action (Williams et al. 2015).

2.5 Why do medicines-related problems occur?

Studies have investigated the underlying causal factors which increase the risk of experiencing MRPs and MRH following hospital discharge. In an American study, 50.8% of contributing factors were categorised as patient-associated (for example unintentional non-adherence, financial barriers and supply issues) and 49.2% were system-associated (such as poor quality discharge instructions, conflicting information from different sources and duplicate prescribing) (Coleman et al. 2005).

2.5.1 System-associated factors

Poor quality discharge communication is often cited as an error producing factor (Coleman et al. 2005; Avery et al. 2012a; Williams et al. 2015; Shah et al. 2016). Legibility, erroneous content, layout and the ambiguous wording of discharge letters are all thought to increase the risk of MRPs during post-discharge prescribing. A review of 71 discharge summaries found that 79.7% contained one or more medicine or dose discrepancies compared with the patients' discharge prescriptions (median: 2 discrepancies per patient; range: 0–16) (Elliott et al. 2012). Only 50.3% of changes to regular medicines and 24% of changes to 'when required' medicines were communicated in the discharge summary. This further illustrates why MR has been found to be challenging in primary care as it can be unclear whether medicines has been discontinued intentionally, particularly when the rationale for change is not clearly documented (Avery et al. 2012a; Shah et al. 2016).

In a retrospective case note review identifying risk factors for readmissions, Witherington et al. (2008) found that sixty-seven (62%) patients either had no discharge letter or were readmitted before the letter was even typed in the hospital. This untimely transfer of information prohibits the safe and effective prescribing of the correct medicines in the next setting. Clarification of information between primary and secondary care colleagues is made more

challenging due to the lack of or incomprehensible authorship of documentation, lack of contact details (Witherington et al. 2008), and changing shift patterns for junior medical staff in hospitals (Williams et al. 2015).

Many of these studies were conducted before electronic discharge forms were routinely used. Modern technology has had a moderately positive impact on the quality of information transferred. This was clearly demonstrated in a large audit where an electronic discharge summary template greatly increased its quality (Hammad et al. 2014). E-mailed and faxed discharge summaries were more frequently received within seven days, whereas posted and hand delivered (by patient) summaries were less frequently received (Chen et al. 2010).

When good quality documentation is available, at least one change is actioned incorrectly for 6% of patients in primary care (Shah et al. 2016). It is General Practitioners (GPs) who predominantly report conducting post-discharge MR, however studies show a proportion are completed by other team members; from pharmacists to reception staff (Care Quality Commission 2009; Shah et al. 2016). Staff without appropriate clinical training may incorrectly reconcile the patient's medicines or may not action appropriate monitoring and follow-up, in particular without explicit instruction in the discharge information.

2.5.2 Patient-associated factors

As patients age, they are more likely to experience multi-morbidity and polypharmacy (Lenaghan 2019; Whitty et al. 2020). Older patients are also susceptible to multiple hospital admissions and, therefore, frequent care transitions, putting them at higher risk of MRPs and MRH (Stevenson et al. 2019). Additionally, hospital admission is expected to result in multiple changes to a patient's medicine, making discrepancies and errors much more likely (Redmond et al. 2016). In an observational study of 300 patients (Himmel et al. 2004) only 13 patients experienced no change in their medicines during admission. More than 60% (n=184) of patients had three or more changes to their drug regimen. A further large cohort study (n=26,256) demonstrated that older people are more likely to experience increased odds of unintentional medicines discontinuity in the six months following hospital discharge

The number of MRPs has been shown to increase with polypharmacy (Coleman et al. 2005; Ahmad et al. 2014) and certain chronic conditions such as type II diabetes mellitus (T2DM) (Aminzadeh and Dalziel 2002; Ahmad et al. 2014) or congestive heart failure (Coleman et al. 2005). Biochemical factors, such as low sodium levels, have also been shown to predict MRH (Parekh et al. 2020). Physiological changes associated with ageing and the increased risks posed by polypharmacy reinforce the need for individualised treatment plans, careful medicines optimisation and post-discharge follow-up (Spinewine et al. 2007; Kalyani et al. 2017; Wastesson et al. 2018). These factors are particularly relevant to older patients living with long-term conditions.

Frailty, now itself seen as a long-term condition, is multi-factorial and reduces an older person's resilience to small injury or incidents, such as an infection or hospital stay (Clegg et al. 2013). Frailty advances deterioration in quality of life, worsens health outcomes and is associated with an increased cost to the economy (Ament et al. 2014; Age UK 2015; Andreasen et al. 2015). It is likely that frailty affects a patient's capacity to self-care as well as the ability to manage their medicines (Ipsos Mori for Age UK 2014) and may also be an additional risk factor for MRPs. It is estimated that 36% of patients living with frailty experience MRH, compared to 25% of non-frail patients (Stevenson et al. 2019).

The category or class of medication used has also been shown to significantly impact on MRH. Anticoagulants (Forster et al. 2005; Kanaan et al. 2013), analgesics (Forster et al. 2005; Midlöv et al. 2005; Kanaan et al. 2013), hypnotics (Midlöv et al. 2005; Parekh et al. 2018a), cardiovascular medications (Boockvar et al. 2004; Midlöv et al. 2005; Ellitt et al. 2010; Kanaan et al. 2013) and anti-diabetic medications (Ahmad et al. 2014; Azzi et al. 2014) are linked to post-discharge MRPs.

Finally, health literacy and the level of cognitive impairment are strongly linked to experiencing post-discharge MRH (Nicholls et al. 2017). In an Australian cross-sectional survey of 506 participants (median age 64 years), participants were more likely to experience MRH if they reported problems understanding

written information, they needed help reading written medical information or were less confident in completing medical forms (Eassey et al. 2016). The odds of reporting a problem were higher for participants who were: reporting less control over their medicines; who described not having an active role with their medicines; who reported not playing an active role during their follow-up; and who reported missing doses (Eassey et al. 2016). Lenaghan (2019) further illustrated that older patients often lack the assertiveness to challenge and chase medicines-related decisions, thereby increasing their risk of MRH. In addition, Ensing et al. (2017) identified that patients' lack of knowledge about post-discharge medicine was alarmingly high; 60% of patients required further medication information and 37.2% required education about medicines management to prevent MRH occurring. Providing further reinforcement and repetition of key messages seems, therefore, to be considered a significant action to promote safer medicines management throughout the post-discharge phase (Ensing et al. 2017).

2.6 Patient and healthcare professionals' perceptions of medicines management across transitions

Continuity of medicines at transitions, including the scale and location of MRPs, has been extensively investigated using quantitative observational methods as demonstrated in **Sections 2.1** and **2.2**. Far fewer in number are those qualitative studies that describe and explore the experiences and behaviours of HCPs, patients and family carers in relation to post-discharge medicines management. Where qualitative studies have been conducted, barriers to medicine management are all too frequently highlighted, with less attention given to enablers or examples of best practice (Care Quality Commission 2009; Avery et al. 2012a; Manias et al. 2015a).

2.6.1 Healthcare professionals

Challenges to post-discharge prescribing have been identified by means of in-depth interview. Poor quality MR during inpatient stay (Avery et al. 2012a; Manias et al. 2015a), lack of interdisciplinary communication (Manias et al. 2015a; Redmond et al. 2016) and ambiguous wording on discharge documentation (Avery et al. 2012a) were identified by healthcare professionals

as barriers to post-discharge medicines management. One GP from the PRACTICE (prevalence and causes of prescribing errors in general practice) study described how mismatched information caused great confusion following hospital discharge (Avery et al. 2012a: 104):

"I think when they've been in and out of hospital is a real time of uncertainty because they've had things stopped and started, you've not got or had anything come through, you don't know, sometimes they've stopped things deliberately, sometimes they just haven't realised they're on it, (…)"

Poor communication and documentation of medication changes during inpatient stay were also found to cause delay and significantly increase the risk of MRPs at hospital discharge (Manias et al. 2015a: 76):

"We have someone who came in on oral hypoglycaemics and insulin, which are not charted at the moment on the drug chart and this patient is being discharged, so I have no idea whether or not they were stopped on purpose. I [the pharmacist] have to go through three weeks' worth of notes to find out or find a cover doctor who doesn't know the patient."

Other HCPs in the primary care setting disclosed that they felt 'de-skilled' compared to hospital practitioners and would ultimately prescribe what was requested on the hospital documentation, even if this were shrouded in uncertainty (Avery et al. 2012a).

2.6.2 Patients and family carers

Poor communication of medication changes during the inpatient stay was frequently considered to affect medicines management following discharge (Fylan et al. 2018; Parekh et al. 2018b). Inadequate explanations to patients and their family carers led to medication omissions, incorrect dosages, anxiety,

frustration and confusion (Arora et al. 2010; Knight et al. 2013). Manias et al. (2015a: 75) also identified that patients and family carers do not tend to seek clarification about medicines changes due to insufficient knowledge, lack of opportunities to participate, forgetfulness and lack of insight into possible repercussions. This family carer explained:

"The difficult thing about having information explained to you, is that it all makes sense. And then the minute they walk away you think, 'I forgot to ask them about the new medications.'"

Patients were also uncertain about information transfer procedures, which led to further confusion after hospital discharge. Some patients believed that good quality communication had taken place between the hospital and primary care provider, which led to further negative emotions if they experienced MRPs (Arora et al. 2010).

Other studies have highlighted the significant effort that patients exert during medicines management in the home (Cheraghi-Sohi et al. 2015; Lang et al. 2015; Fylan et al. 2018; Schafheutle et al. 2018). Cheraghi-Sohi et al. (2015) termed this 'medicines work' and found that for patients with long-term conditions and their support network of family, friends and healthcare team, this work could be categorised as: articulation (planning and co-ordination of medicines), surveillance (checking medicines and monitoring progress), emotional (providing reassurance), and informational (clarifying and checking information).

In more recent literature, this work that patients perform has been linked to resilience factors, which scaffold (O'Hara et al. 2019) and prop (Fylan et al. 2019a) the healthcare system in order to promote safety. Patients have been shown to proactively contribute to safety within primary (Rhodes et al. 2016; Phipps et al. 2018) and secondary care (O'Hara et al. 2019). Fylan et al. (2019a) demonstrated that cardiology patients employed post-discharge medicines management resilience strategies, including anticipating problems, identifying errors and taking corrective action. The strategies used by older people and their family carers to support post-discharge medicines

management are largely unknown. Further to this, it is unclear how a transition of care affects medicines work in this population.

2.7 Interventions to reduce medicines related problems

To improve medication safety and reduce MRPs at transitions, various organisations have developed good practice guidance and policies to be used by HCPs identified by this current scoping review (Royal Pharmaceutical Society 2012; National Institute for Health and Care Excellence 2015b; World Health Organization 2016). Much of the focus of these documents, to date, has been on better quality of information transfer between settings, whilst also prioritising improvements in MR. This has driven a large-scale audit of current service provision (Shah et al. 2016) and the development of unique initiatives (Naylor et al. 1999; Jack et al. 2009; Odeh et al. 2020). Many interventions appear to target discrete MRPs (such as medicines discrepancies) and fail to take the patient's broader life context into consideration (Nicosia et al. 2020). Often MRPs are the result of numerous factors and not just a breakdown in processes. Therefore, any medication safety recommendation should be consciously underpinned by patient experience.

2.7.1 Interventions to improve information transfer between settings

Communication failures are thought to be one of the key factors in post-discharge MRH (Barnsteiner 2005). There has been a drive to improve communication not only within and between care settings but also with patients (Claeys et al. 2013; Nicholls et al. 2017).

To improve the quality of hospital discharge communication and to ensure safer post-discharge prescribing, the former National Prescribing Centre recommended a minimum dataset (**Table 4**) that should be transferred to primary care following discharge (National Prescribing Centre 2008). An audit of 3444 discharge summaries demonstrated that the mean adherence to the minimum dataset was 71.7% (Hammad et al. 2014). Whilst medication information was complete in 67.2% (95% CI 66.3, 68.2) of cases, therapy change information was only present in 48.9% of them (95% CI 47.5, 50.3).

Allergy status, co-morbidities, medication history and rationale for therapy change were the most frequent omissions. Despite increased awareness of the importance of quality discharge communication, this audit demonstrated that key data were still not recorded.

The RPS (Royal Pharmaceutical Society 2012) has prompted service commissioners to review their existing contracts and to incorporate improved transfer of information interventions. This, along with other key policy documents has encouraged the development of local initiatives, such as LTHT's 'Connect with Pharmacy' (Sabir et al. 2019) and the East Lancashire Teaching Hospitals Trust 'Refer 2 Pharmacy' interventions (Gray 2015). As a result of these novel interventions, the hospital pharmacy transfers high-risk patients' discharge information to their chosen community pharmacy. Whilst these early adopters of this change to practice have seen benefits (Nazar et al. 2016; Sabir et al. 2019) such as a reduction in readmission rates and fewer medication errors, the initiatives varied widely between areas and there was no consistency between services.

Table 4: The National Prescribing Centre's minimum dataset of information recommended in primary care following discharge from hospital (2008). Reproduced from 'Medicines Reconciliation: A guide to implementation'.

1. Complete and accurate patient details, i.e. full name, date of birth, weight if under 16 years, NHS/unit number, consultant, ward, date of admission, date of discharge.
2. The diagnosis of the presenting condition plus co-morbidities
3. Procedures carried out
4. A list of all medicine prescribed for the patient on discharge from hospital (and not just those dispensed at the time of discharge)
5. Dose, frequency, formulation and route of all the medicines listed
6. Medicine stopped and started, with reasons
7. Length of courses where appropriate (e.g. antibiotics)
8. Details of increasing, or decreasing dose regimens (e.g. insulin, warfarin, oral corticosteroids)
9. Known allergies, hypersensitivities and previous drug interactions
10. Any additional patient information provided such as corticosteroid record cards, anticoagulant books
11. This information should be clear, unambiguous and legible and should be available to the GP as soon as possible. Ideally, this should be within two working days of the patient's discharge

Due to such positive outcomes, demonstrated by these local initiatives, 'Transition of Care around Medicines' (TCAM) was one of the national programmes for regional Academic Health Science Networks. Throughout 2018-2020, Academic Health Science Networks have supported TCAM implementation and roll-out across England (The AHSN Network 2019). TCAM initiatives ensure that hospitalised patients, who are assessed as needing additional support with their medicines, are electronically referred to their community pharmacy on discharge. Although these initiatives are

currently being established and appraised at scale, initial findings have demonstrated that TCAM supports community pharmacists in reducing post-discharge medicines errors (Nazar et al. 2016). The specific effects TCAM has had on the patient (for example, medicines knowledge, adherence, satisfaction with medicines, and experience of MRP) have yet to be evaluated.

Building on this TCAM work, a new Discharge Medicines Service is proposed by the UK Government. This service will be delivered by community pharmacies and is likely to include: information transfer regarding medicines changes between the hospital and community pharmacy, MR and patient education (Pharmaceutical Services Negotiating Committee 2020a). How this service is to be operationalised is currently (Autumn 2020) in the early stages of development.

2.7.2 Medicines reconciliation

Along with APAC's Guiding Principles (Australian Pharmaceutical Advisory Council 2005) and the Joint Commission in America (The Joint Commission 2013), The WHO has advocated a focus on MR as a way to improve systems which prevent adverse drug events (World Health Organization 2019). The Institute for Healthcare Improvement created toolkits, provided guidance and defined clearer target measures so that MR could be tested in various settings (Institute for Healthcare Improvement 2018). In March 2015, NICE produced new guidance that prioritised the need for effective MR (National Institute for Health and Care Excellence 2015a). This guidance recommended that MR is carried out by a trained and competent health professional within 24 hours of hospital admission and also again one-week post-discharge; and that pharmacists with relevant clinical knowledge and skill should be involved when making strategic decisions about medicines use (National Institute for Health and Care Excellence 2015a). This prompted widespread review of practice within principle organisations (Shah et al. 2016).

Many studies have demonstrated positive outcomes when MR is utilised during hospital admission and prior to discharge (Kwan et al. 2013; Mekonnen et al. 2016; Cadman et al. 2017). A more recent major study of 1648 American patients showed that MR at admission and discharge was associated with an

overall reduction in medication discrepancies, but not those potentially harmful discrepancies (IRR 0.97 CI 0.86 to 10.8; p=0.53) (Schnipper et al. 2018).

Despite worldwide effort, MR which was conducted post-discharge has not been shown to improve healthcare utilisation or to reduce primary care workload in a recent meta-analysis of 14 studies (McNab et al. 2018). Furthermore, whilst MR offers the potential to detect errors and prevent MRPs, the evidence of its impact on clinical outcomes appears scant (Lehnbom et al. 2014). Studies have revealed that whilst MR alone does not reduce the rate of hospital readmission, it may do so when combined with other inventions in a bundle (Kwan et al. 2013; Ensing et al. 2017; Etchells and Fernandes 2018). This leads to the suggestion that interventions with multiple components of medicines-related activities, such as active patient engagement (Etchells and Fernandes 2018) and medicines review (Nicholls et al. 2017) alongside MR, could enhance post-discharge medicines management.

2.7.3 Other interventions to reduce MRPs

As highlighted in **Sections 2.1** and **2.3.2**, many MRPs are caused by both the patient and their family carers' poor understanding of the post-discharge regimen. Reviews of interventions (Garcia-Caballos et al. 2010; Laugaland et al. 2012) have highlighted that those which include patient education and post-discharge follow-up are more likely to result in fewer MRPs and improve patient safety.

Despite this, the literature evidences the fact that patients and their family carers are often not involved in the discharge process (Cain et al. 2012) and patients themselves reported a lack of verbal instruction from HCPs about their medication changes (Moore et al. 2003; Manias et al. 2015a; Wright et al. 2017). Whilst home follow-up has been shown to reduce the rate of hospital readmission (Misky et al. 2010), it is unclear how best to do this, at which time points are most effective and ultimately what the aim should be.

Moreover, it is becoming apparent that patients and their family carers can also engage in activities that are geared to scaffolding and supporting the healthcare system, whilst preventing MRH from occurring (Fylan et al. 2018;

O'Hara et al. 2019). In some studies, patients have acted as conduits for information or proactively asked questions about their medicines which enhanced safety (Arora et al. 2010; Manias et al. 2015a). A patient's ability to perform these tasks and to self-manage their health conditions have been linked to their ability to solve problems, self-confidence, experience, knowledge and access to resources (Driscoll 2000; Pollack et al. 2016). Encouraging and enabling patients and their family carers to take an active role in their own post-discharge medicines management appears to be an under-researched area. The safety strategies that older patients use in order to protect themselves from MRPs warrant further investigation.

2.7.4 The role of community pharmacy in post-discharge medicines management

It has been reported that patients value the accessibility of advice and post-discharge support available from their community pharmacy team (Parekh et al. 2018b). Previous work has documented that the involvement of community pharmacy in post-discharge medicines management resulted in a reduction in 90-day hospital readmission rates ($p<0.001$) (Mantzourani et al. 2020). Since 2012, community pharmacy, in response to not only an increasing number of hospital readmissions, but also to the unmet post-discharge medicines needs of patients, has been able to deliver post-discharge medication reviews for patients who have had medication changes during an admission (Pharmaceutical Services Negotiating Committee 2020b). This medicines review, conducted by the pharmacist, can reduce the occurrence of potentially harmful MRPs and provide an opportunity for patient education (Ahmad et al. 2012). Whilst this service has been available for some time, the uptake has been shown to be exceptionally poor. The particular barriers highlighted include: no discharge documentation received by the pharmacy, lack of time to deliver this service, non-uptake by patients and a perceived lack of skill to deliver such a review by pharmacists (Bhatti et al. 2013; Hodson et al. 2014; Ramsbottom et al. 2016; Rutter et al. 2016). Patients who are at the highest-risk of MRPs (for instance, those older patients living with polypharmacy, multi-morbidity and frailty as highlighted in **Section 2.3.2**) would benefit from this

service the most. However, they are often housebound and, therefore, logistically challenging to engage with (Bhatti et al. 2013). Many pharmacists reported this as a barrier to delivering their service as they felt unable to organise the necessary authorisations and allocate enough time to deliver MURs in the home (Rutter et al. 2016). The evidence of clinical effectiveness of MURs has been slow to develop (Stewart et al. 2020) and their cost-effectiveness is highly contested (Centre for Policy of Ageing 2014). Therefore, following the publication of the NHS Long Term Plan (2019), the decision was made to decommission the current MUR service within the Community Pharmacy Contractual Framework (NHS England 2019). The MUR service has been replaced by a Structured Medication Review service, performed by clinical pharmacists working within Primary Care Networks (NHS England 2019). This will effectively remove the MUR service from community pharmacy by the end of 2020.

2.8 Scoping in the field and stakeholder conversations

To position this doctoral study within the local context, an understanding of how service provision operated, the breadth of what was available and how this was perceived by patients and their family carers was significant. Scoping work was undertaken during the early stages of study design, involving Patient and Public Involvement and Engagement (PPIE) activities, in-depth conversations with service commissioners and observations of practice with various discharge services: AgeUK Hospital to Home, the Neighbourhood Community Pharmacy Technician Team, Bradford Royal Infirmary's (BRI) virtual ward, LTHT early discharge assessment team and ward discharge co-ordinators. This ensured that the development of the research questions was founded on local knowledge, practice and current thinking and also informed the iterative searching of the literature.

2.8.1 PPIE work

To fully achieve its benefit, research must be grounded by patients' experiences. Often target populations are not consulted about the issues under investigation nor during intervention design, which could potentially result in unsuccessful and wasteful research (Chalmers and Glasziou 2009;

Ocloo and Matthews 2016). Specialist organisations such as INVOLVE in the UK and the Patient-Centered Outcomes Research Institute based in the United States of America advocate and actively promote public involvement in research. This has led to a reported increase in the use of PPIE within research (Domecq et al. 2014). Unfortunately, this involvement can be tokenistic and lacks meaningful impact (Ocloo and Matthews 2016).

Patients and their informal carers were identified as key stakeholders in this current study. Valuable consultation and collaboration activities were planned and carried out, guiding the research design. Two established PPIE groups (University of Bradford's School of Health PPIE panel and Leeds and York Partnership NHS Foundation Trust PPIE panel) were approached to discuss how members of the public could best contribute to the proposed study. During these early consultations, members stated that the topic resonated with them and they positively endorsed the proposal as they each described their own experiences of post-discharge MRPs. They also considered the meaningful ways in which members of the public could become engaged with the research, for example by writing a plain English summary and creating a participant information sheet.

Following these valuable early discussions, it was decided to form a PPIE steering group, which would continue to provide advice on research design and remain involved throughout the study. To facilitate recruitment into the group, reimbursement was offered for each individual's time (£12.50 per hour) and travel expenses (funded by a £480 grant awarded by the NIHR Research Design Service for Yorkshire and Humber).

Four individuals were recruited to form the Patient and Carer-Led Steering Group (PCLSG). Three of the group were aged over 65 and one was a family carer, supporting an older relative. Two PCLSG members had a dual role – that of a patient and as an informal carer. All members had previously taken part in a research project as participants. This maximised the outcomes from two initial workshops that aimed at scoping the proposed research question, including the most appropriate methods. This work provided the foundation for

a further successful NIHR Research for Patient Benefit grant application (PB-PG-0317-20010).

2.8.2 Overview of initial consultation workshops

Both workshops involved short presentations concerning the topic background, group discussions and facilitated activities:

- Workshop one (19th June 2017) focused on exploring the group's experiences of medicines-related care after discharge, developing a timeline of post-discharge events, formulating the research questions and refining the aim.

- Workshop two (17th July 2017) focused on developing the research methods, recruitment ideas and drawing together the preliminary considerations for the participant diary.

During these early meetings, members identified that post-discharge medication-related care appeared inconsistent and variable, amplified by the group's different experiences in Bradford and Leeds. A post-discharge word cloud was created from discussions about the topic, and words such as "frustrated", "uncertainty" and "lost" were frequently associated with medicines, leading to "anxiety and worry" (**Figure 6**). The group voiced that follow-on medication-related care seemed reactive, only being triggered when problems were highlighted to a healthcare professional or more worryingly, at crisis point of hospital readmission. This was felt by the PCLSG to be highly inefficient and unnecessarily costly to the NHS.

Reflecting on these discussions, I began to realise that the scope of my study was far wider than simply medication error and it was clear that much more could be done to effectively support patients with their post-discharge medicines management. It appeared that frustrations and stresses surrounding medicines supplies and unanswered questions added a needless burden, and this drove the medicines management focus of the research, rather than a 'safety' or 'error' focus as originally outlined by LTHT.

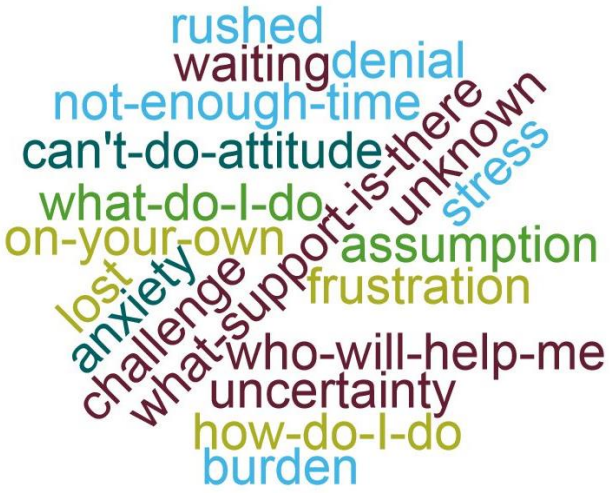


Figure 6: Word cloud created from discussions with PCLSG members

Construction of the post-discharge timeline highlighted key milestones in a patient journey and this prompted initial considerations of when best to interview patients. In discussion with the PCLSG, interview milestones were agreed: two-weeks, two-months and six-months post-discharge. At two-weeks, it was felt that the patient should be beyond the critical point of their recovery allowing them to effectively reflect on their experiences. By this point in time, they should also have received their first supply of medicines after their hospital stay. At two-months, the primary care provider should have made necessary medication changes, carried out monitoring and reviewed the patient's treatment. Finally, at six-months, the patient's treatment should be optimised to safely meet their needs and conditions.

2.8.3 Observation of discharge services

Shadowing of discharge service staff and observations of practice undertaken in both Leeds and Bradford has led to a greater awareness of the numerous packages of care (POC) available to patients after hospital discharge. Organised POCs may pre-date admission, such as, a homecare service to encourage medication adherence; or may arise during admission, for example, a district nurse service to administer injectable medicines. Often these POCs are funded short-term (up to 12 weeks) by Health or Social Care Authorities to support recuperation in the home and aim to build self-care

capacity, thereby reducing future hospital readmission. Both geographical areas of Leeds and Bradford offer extensive POCs (**Figure 7**). However, discussions with NHS staff, service providers and patients suggest that sometimes patients may cover up the extent of their medication-related needs, inhibiting the set-up of appropriate post-discharge services. A further point is that services may take several weeks to have availability and capacity (leading to prolonged admission) or, may not be as responsive as required. This can lead to patients succumbing inadvertently to failure, where either an inappropriate service is assigned, or the patient receives no POC at all.

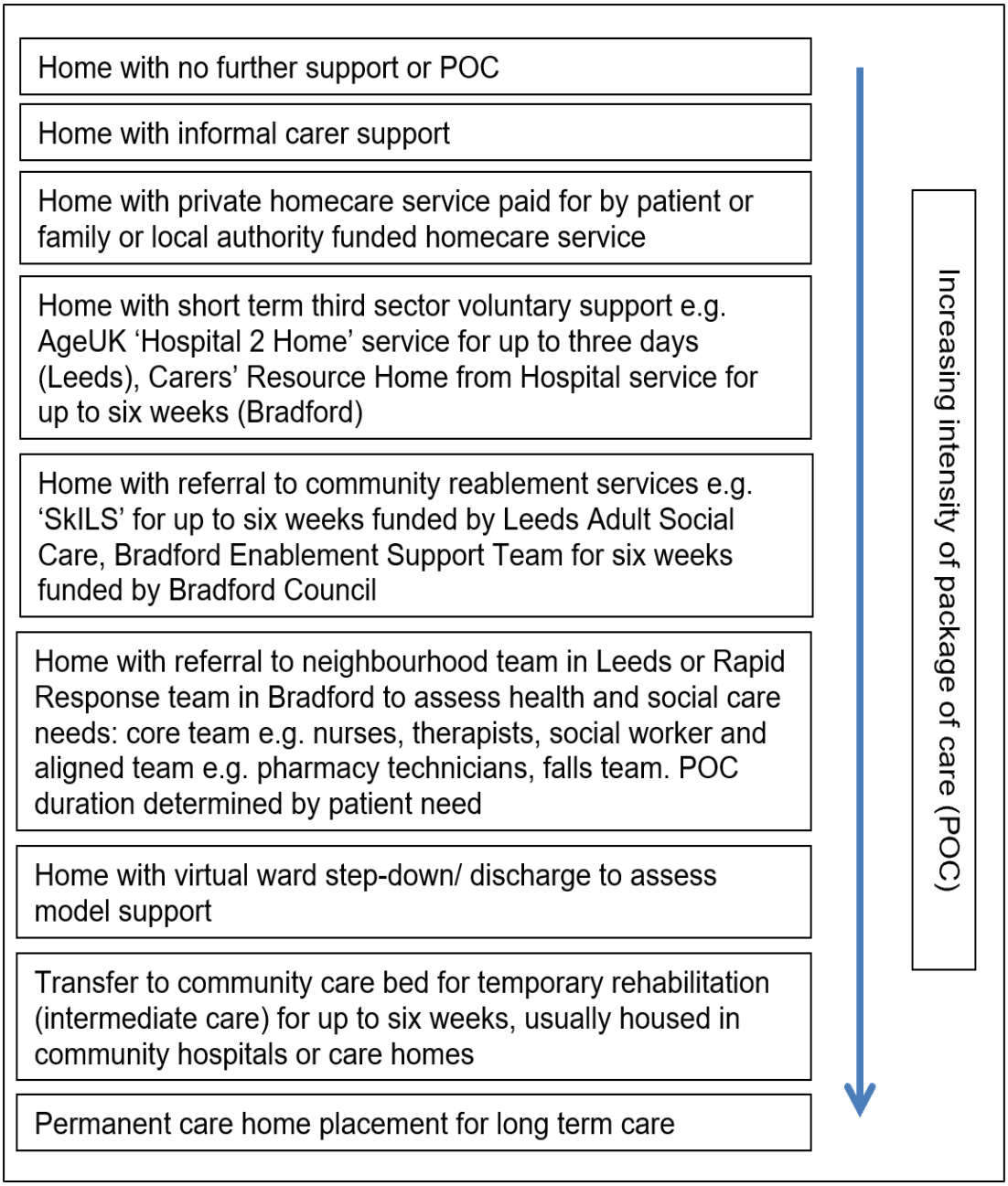


Figure 7: Packages of care (POC) available within Bradford and Leeds after discharge from hospital

2.9 Summary of scoping work into problem statements

This scoping review aimed to provide an overview of the breadth and nature of available literature on the research topic. Engaging with patient and public groups, review of the literature, and observations in the field have identified that MRPs are a common and problematic cause of MRH, resulting not only in costly healthcare utilisation, but also in undue stress and anxiety for patients.

Reducing MRH at care transitions is an international priority (World Health Organization 2017) and much effort has been placed on improving both MR and communication between settings with the intention of reducing medication errors. The wider literature and conversations with patients and their family carers suggest that medication error was only one aspect of post-discharge medicines management and other areas, such as poor medication adherence, are responsible for a greater proportion of MRPs (Parekh et al. 2018a). Patient education and post-discharge follow-up are shown to be beneficial in reducing MRPs (Garcia-Caballos et al. 2010). However, how current interventions effectively support post-discharge medicines management, particularly for older patients, remains unknown.

The literature review and scoping work have resulted in the development of the following problem statements reflecting current issues and gaps that have informed the aims and objectives (**Section 2.9** and **2.10)**:

- Post-discharge medication-related pathways for older patients living with frailty and long-term conditions are highly complex, fragmented and uncertain. Studies outlined in **Sections 2.1** and **2.2** have identified the scale and nature of the MRPs that patients face. However, a lesser amount of literature explored the patient experience.

- The perceived level of follow-on support provided by primary care following discharge, including how effectively medicines management is achieved, is under researched.

- Patients and their family carers are being increasingly recognised for their ability to reach into and support the healthcare system to prevent errors. The strategies that older patients use for effective post-discharge management require further investigation.

- Interventions have mainly focused on improving information transfer between settings and minimising medication discrepancies for all patients. A wider evaluation of interventions that support post-discharge medicines management for older people is necessary.

- Patients and their family carers have not been effectively engaged to understand how pathways can be re-designed to improve medication-related care and to ensure that they receive the medicines they need, once they have returned home following a hospital stay.

2.10 Research questions arising from these statements

i) How is post-discharge medicines-related care experienced by older patients living with frailty and long-term conditions?

ii) How might an intervention be designed to reduce MRPs and support post-discharge medicines management for this patient group?

2.11 Research aim

To design an intervention that aims to reduce MRPs and promote post-discharge medicines management for older patients living with frailty and long-term conditions.

2.12 Research objectives

1. To explore patients' and family carers' perceptions of post-discharge medicines management for older people living with frailty and long-term conditions (using T2DM as an example; see **Section 3.7** for rationale).

2. To examine the behaviours and support mechanisms that allow these patients and/or their family carers to manage their medicines safely post-discharge.

3. To describe and evaluate examples of interventions designed to support post-discharge medicines management.

4. To use a best-evidence synthesis, combined with patient experience, to suggest intervention components that will support post-discharge medicines management.

This chapter has presented a scoping review of the literature and local context in which this research takes place. **Chapter 3** will describe the proposed methods that will be employed to address these objectives.

Chapter 3: Methodology and methods

This chapter describes the philosophical stance, methods and quality criteria for this translational research study. The literature review (**Chapter 2**) identified how patients' experiences of post-discharge medicines management and the strategies that they use to ensure medicines safety are largely unknown. The methods in this next chapter were selected firstly, to explore published interventions that support post-discharge medicines management, and secondly, the patient's own lived experience. Findings were then synthesised to offer not only valuable but also constructive insights into the design of a truly patient-centred intervention (**Chapter 6**).

3.1 Philosophical approach

When designing research, it is important that the choice of methods aligns with the researcher's underpinning philosophical assumptions. These assumptions, originally based on an objectivist-subjectivist continuum (Crotty 1998), reflect the researcher's stance on the nature and purpose of knowledge (epistemology) and the nature of social reality (Cunliffe 2011). Winit-Watjana (2016) suggests that there are four philosophical realms to consider: ontology, epistemology, axiology and logic of enquiry.

3.1.1 Ontology and epistemology

Objectivist approaches, traditionally found within pharmaceutical research or clinical experiments, assume that a reality exists independently of consciousness and experience (Crotty 1998) and that research is able to observe and measure the objective truth. By contrast, subjectivist approaches assume that reality is a projection of the human mind and that research explores individual understandings and experiences (Cunliffe 2011). A researcher's philosophical view will, therefore, influence the theoretical perspective, methodology and methods, and needs to be outlined at the point of study design (**Figure 8**).

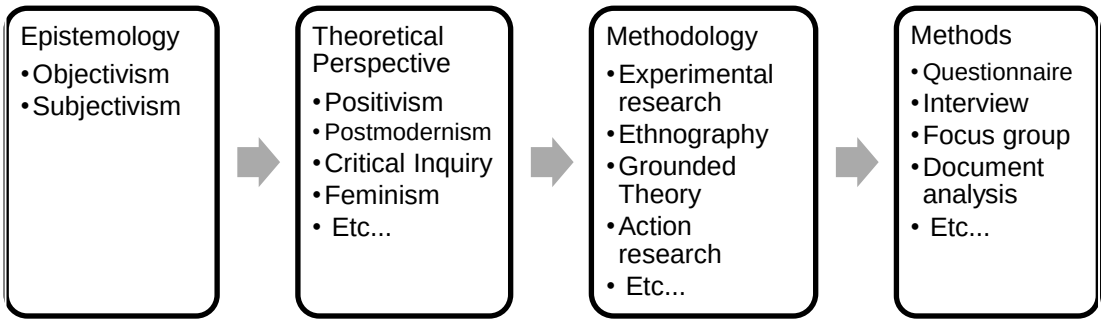


Figure 8: The philosophical approach to research design, adapted from Crotty (1998)

Health services researchers have argued that due to the social nature of health and the complexity of health care systems, different theoretical perspectives and philosophical assumptions must be adopted (Long et al. 2018). Pragmatism, "*the assumption that 'perfect' knowledge is not possible, nor required, and that knowledge is only meaningful when coupled with action*", emerged in the late 1800s (Long et al. 2018). Pragmatism is concerned with solutions to real-world problems and allows researchers to adopt theories and methods which best answer their research questions (Creswell 2013). This study, therefore, adopts a pragmatic world view aiming to translate this novel research directly into health and social care practice.

3.1.2 Axiology

Axiology identifies personal values and ethics and their role with knowledge (Winit-Watjana 2016). Objectivist research is designed to report reality and the researcher is deemed to have no effect on the outcome. On the other hand, subjectivist research accepts the influence of the researcher's values and acknowledges that the self cannot be fully separated from the research process (Silverman 2000). Thus, these personal values and ethics can affect the conduct of the study. Unconscious biases, beliefs and preconceptions need to be carefully considered in light of how they may affect the data collection, subsequent analysis and interpretation.

Researchers who assume a positivist lens, often adopt the stance of 'detached observer' as they believe this is a requirement to produce reliable knowledge (Blaikie 2010). Other stances, such as that of an 'empathetic observer' and

'dialogic facilitator' have been described within this literature, where the researcher is far less detached and neutral (Blaikie 2010). Considering my professional background (outlined in **Section 1.1**) and my personal values, I did not believe detachment was possible during data collection and analysis. Hence, I considered my role to be more of a 'faithful reporter', described by Blaikie (2010) as "allowing the research participants to speak for themselves". Being a practising pharmacist, I am aware that I have preconceptions about medicines management and healthy ageing that may have impacted on this research and, therefore, must be made clear.

This personal reflexivity (Walsh 2003) can be challenging for new researchers and has led to the development of a framework that supports reflexivity in health research (Rae and Green 2016). This model was used to provoke deep reflection about perceptions of the world, including how this might affect research design, data collection or analysis, whilst it supported a more comprehensive consideration of all potential influencing factors. The completed matrix, which outlines my '*a priori'* assumptions, can be seen in **Appendix 2**. The matrix was given careful consideration throughout all research activity.

3.1.3 Logic of inquiry

Research reasoning has historically been either deductive (developing and testing theory using the data), inductive (theory generation to explain this data) or abductive (where both are used for hypothesis generation) (Gray 2004; Lipscomb 2012). The logic of inquiry is determined by the key research questions and their aim. Within deductive and inductive reasoning answers can be found within the data, and scrutiny will allow understanding to be extracted (Lipscomb 2012).

Johnstone (2004) argues that pragmatists make the most efficient use of both inductive and deductive reasoning, to understand social phenomena. This study therefore makes use of both types of reasoning where it is appropriate to do so.

3.2 Theoretical perspective

Theoretical perspectives, also known as paradigms, are interpretative frameworks used within research that lie behind a researcher's philosophy (Creswell 2013). The theoretical perspectives, such as positivism, critical realism and constructivism, help researchers to outline the assumptions which they bring to the study that may be reflected in the methodology, based on the four realms explored in **Section 3.1** (Crotty 1998).

Positivists, for example, believe there is an objective reality, where patterns can be predicted using theory (Winit-Watjana 2016). Thus, the researcher has no influence on the results and only deductive reasoning is used within the method. Gray (2004) argues that this, "disengages the researcher from the people and field they are researching" and cannot, therefore, gain insight into people's construction of 'reality'. Constructivists, by comparison, believe that there are multiple realities, created by subjective interpretation. The type of research conducted by constructivists is often inductive, commencing with firstly data collection before continuing to generate a theory. One critique of this interpretivism is that for some types of research e.g. policy research, multiple realities have very little value (Murphy et al. 1998).

The choice of theoretical perspective is related to the nature of the research, its aims, and its objectives. For example, in this study, it may not be possible to explore older patients' post-discharge medicines management through positivism alone since unobservable processes and patient causal factors exist. It is also challenging to study through constructivism as I cannot reject causality, nor can I deny that knowledge is not real. Therefore, alternative theoretical perspective(s) must be pragmatically adopted depending on the work being conducted.

Critical realism, one form of realism, is a lens that embraces the strengths of both positivist and constructivist perspectives, whilst trying to avoid their weaknesses (Bhaskar 2008). It has been employed by researchers to search for causation and to explain social events, whilst also allowing recommendations to be developed to address social problems (Fletcher 2017). Instead of focusing on a standard approach of structure-process-

outcomes, critical realism believes that consequences arise due to “interactions between social structures, mechanisms and human agency” (McEvoy and Richards 2006). These mechanisms provide researchers with an explanation of how and why events occur in the social world (Williams et al. 2017). Consideration is given to the contextual factors that interact with these mechanisms and how people also interact with them to offer a deeper explanation of how the outcome is caused (McEvoy and Richards 2006).

I chose, therefore, to adopt a predominantly critical realist lens throughout the work because this study seeks to understand how post-discharge medicines management works in the real world; namely what helps and what hinders patients, together with how an intervention can be designed to better support them. Understanding the causal processes that affect post-discharge medicines management is important for successful intervention design. Where it was not possible to maintain this lens, due to the nature of the research or type of data, I have defaulted to using positivism as the most appropriate approach.

3.3 Study design

Research design ultimately depends on a researcher’s questions, aims and philosophy (Silverman 2000). Designs align with quantitative or qualitative paradigms or elements of each that are combined as a ‘mixed method’. Lincoln and Guba (1985) argue that quantitative and qualitative methods are fundamentally different and mixing methods is inappropriate. However choosing the research methodology is a pragmatic decision (Murphy et al. 1998), and methods are chosen so that answers to the research questions are provided most efficiently and effectively. Therefore, to meet the research objectives, pragmatists may choose to use slightly different methods and assumptions in each aspect of the study.

Quantitative research involves, for example, statistics and surveys, and can be used to calculate relationships between variables. Bowling (1997) highlights that quantitative work is more commonly used when the issue under investigation is known about, is less ambiguous and can be measured. Quantitative methodologies may, however, disregard observation of behaviour

in everyday situations (Silverman 2000) and are sometimes considered inadequate when the research involves people (Murphy et al. 1998). Qualitative research, by comparison, utilises methods which provide deeper understanding about the topic of interest. It is used when exploring new topics or for obtaining rich and detailed data on complex issues (Bowling 1997).

This research aims to explore patients' experiences of post-discharge medicines management and to seek current best-evidence, in order to inform intervention design. The design, therefore, involves methods predominantly aligned to the qualitative paradigm. However, it does draw from quantitative methodologies where appropriate e.g. for meta-analysis of intervention effectiveness. This research seeks to understand how an intervention might be developed. Existing methodologies, discussed in the following section, guide the study design.

3.3.1 Methodology of intervention design

Complex interventions are those described as having: numerous interacting components targeting various behaviours, multiple target groups or organisational levels, variable outcomes and/or a degree of flexibility within the intervention (Craig et al. 2008). Complex interventions that aim to alter behaviour have historically been poorly designed because they are underpinned by personal experience, favoured theory or cursory analysis (Michie et al. 2014), rather than scientific evidence. To aid the development of interventions aimed to change behaviour, attempts have been made to make the process more systematic.

The intervention mapping strategy (Bartholomew et al. 1998), for example, has been adopted in various projects (Heath et al. 2015; Garba and Gadanya 2017). This methodology was first used in health promotion and ensures that interventions are grounded in theory (Bartholomew et al. 1998). The use of theory is important because it provides researchers with an understanding of the factors that might influence behaviour change and it also identifies possible behaviour change techniques that directly target these factors (Michie and Abraham 2004; French et al. 2012). Intervention mapping has come under scrutiny, however, as it is not comprehensive enough to consider all the

possible intervention options and does not clearly link to models of behaviour change.

In 2000, and later updated in 2006 and 2019, the Medical Research Council (MRC) developed a framework to guide the development and evaluation of complex interventions in response to these challenges. Best practice, as highlighted by this guidance, is to "*develop interventions systematically, using the best available evidence and appropriate theory*" (Craig et al. 2019).

3.3.2 Theory of behaviour change

Kok et al. (2016) describe how effective behaviour change interventions:
1. Target key determinants that predict the behaviour that needs to change
2. Use techniques that are able to change the key determinants
3. Fit the target population, culture and context.

Multiple psychological theories and models exist in the field of health behaviour and justifying which one should guide the research is difficult. Selecting one theory may exclude areas of potential importance and many overlap or are redundant (Michie and Abraham 2004). To mitigate this and to simplify the process for non-experts, Michie et al. (2005) developed the Theoretical Domains Framework (TDF). Developed by consensus study, the TDF is a validated list of 14 (originally 12) theoretical constructs relevant to behaviour change determinants, identified from 33 theories (Michie et al. 2005) (**Table 5**). Each domain is associated with component constructs that aid the researcher to consider the cognitive, affective, social and environmental influences on behaviour (Atkins et al. 2017).

The TDF has been used to guide the development and implementation of interventions to change the behaviour of both healthcare professionals and patients (Sinnott et al. 2015; Patton et al. 2018). Whilst it provides a useful basis for intervention design, it does not offer guidance on how to operationalise the components (Michie et al. 2008). Therefore, Michie et al. (2013) conducted further consensus research that has resulted in the Behaviour Change Technique Taxonomy (BCTT); an "exhaustive list of behaviour change techniques (BCTs)" linked to each theoretical construct of

the TDF (Michie et al. 2013). This taxonomy identifies 93 discrete BCTs, which are further categorised into 16 clusters according to similarity of active ingredient or characteristic (Michie et al. 2013). This taxonomy, along with expert mapping exercises (Michie et al. 2008; Cane et al. 2015) enables researchers to link key determinants of behaviour, transparently and systematically, with theoretical constructs and the appropriate techniques that are likely to be effective.

Table 5: The domains of the TDF V1 and V2

Domains (n=12) of the TDF V1	**Domains (n=14) of the TDF V2**
Knowledge	Knowledge
Skills	Skills
Social/ professional role and identity	Social/ professional role and identity
Beliefs about capabilities	Beliefs about capabilities
Beliefs about consequences	Optimism
Motivation and goals	Beliefs about consequences
Memory, attention, and decision processes	Reinforcement
Environmental context and resources	Intentions
Social influences	Goals
Emotion	Memory, attention, and decision processes
Behavioural regulation	Environmental context and resources
Nature of behaviours	Social influences
	Emotions
	Behavioural regulation

3.3.3 Developing a theory-informed intervention

Implementing new practices through behaviour change interventions requires an understanding of the contextual influences affecting the specific behaviour (Atkins et al. 2017). Basing intervention design on an understanding of the behavioural change process is, thus, more likely to result in an effective intervention (Craig et al. 2008).

The MRC recommends that researchers should: identify the existing evidence about similar interventions, develop a theoretical rationale for the likely process of behaviour change targeted by the proposed intervention and ensure adequate feasibility testing before full scale evaluation (Craig et al. 2019). As described within this guidance, prior to design, careful exploration of the rationale, context and appropriate target behaviours for change via the complex intervention, must take place.

Similarly, French et al. (2012) emphasise that identification of the key determinants of behaviour is crucial when developing a theory-informed intervention. The next step involves using a theoretical framework to identify the barriers and enablers to behaviour change. To overcome the challenges identified with the intervention mapping approach (Bartholomew et al. 1998) (**Section 3.3.1**), it is recommended that intervention components be systematically selected based on their ability to overcome these barriers and enablers to behaviour change (French et al. 2012).

These processes of intervention design have been used successfully to develop interventions which support the management of patients with multi-morbidity (Sinnott et al. 2015), more evidence based practice in primary care (Lawton et al. 2016) and greater medication adherence (Patton et al. 2018; Easthall et al. 2019). They commonly used three systematic steps to do this: literature review, primary research, and intervention modelling (Cadogan et al. 2015; Sinnott et al. 2015; Patton et al. 2018). How these key processes inform the design of this three-phase study, namely literature review, primary research and intervention modelling can be seen in **Table 6**.

Table 6: Linkage of theory-informed intervention development process to the MRC guidance and proposed methods

Stage of MRC guidance	Step to develop theory-informed intervention	Stage of study
Identify existing evidence		**Phase 1:** Conduct literature review evaluating effectiveness of interventions that support continuity of medicines management at discharge.
Identify and develop theory	Who needs to do what differently? Using a theoretical framework, which barriers and enablers need to be addressed?	**Phase 2:** Conduct primary research with patients and family carers to explore post-discharge medicines management behaviours, what helps and hinders.
Model the complex intervention	Which intervention components could overcome the modifiable barriers and enhance the enablers? How can behaviour change be measured and understood?	**Phase 3:** Intervention modelling exercises combined with expert consensus to identify key BCT components, how they might be delivered and measured in practice.

As outlined in **Section 3.1**, each phase of work will require a pragmatic choice of methods and theoretical assumption, based on the research objectives. These will be explored in further detail within Sections **3.5** (Phase 1), **3.6** (Phase 2) and **3.7** (Phase 3) and are outlined in **Table 7**.

3.3.4 Trustworthiness and quality criteria

Trustworthiness of a research study is important when evaluating its quality (Lincoln and Guba 1985; Mays and Pope 2000) and the criteria by which it is judged, depends on the underpinning theoretical assumptions and design. This is important, particularly within qualitative research, which is seen as a minor methodology in some areas (Silverman 2000). Researchers must work hard to justify the quality of their research as it relies on interpretation.

Quantitative researchers focus on reliability, objectivity, and validity. The trustworthiness and quality of a qualitative study, however, is dependent on its credibility, dependability, transferability and confirmability (Lincoln and Guba 1985; Anney 2014). Relevant strategies will be used throughout, where possible, to ensure rigour in the findings. These will be dependent on the nature of the research being conducted and will be discussed in greater detail in **Sections 3.5.5, 3.6.9** and **3.7.5**.

Table 7: Mapping of study phase with methods and theoretical assumptions

<table>
<tr><th>Study phase & objectives</th><th>Method</th><th>Theoretical basis</th><th>Logic of inquiry</th><th>Data sources</th><th>Data analysis</th></tr>
<tr><td rowspan="2">Phase 1:

To describe and evaluate examples of interventions designed to support post-discharge medicines management</td><td>Systematic review</td><td>Positivism</td><td>Deductive</td><td rowspan="2">Database citations</td><td>Meta-analysis</td></tr>
<tr><td>Secondary analysis</td><td rowspan="4">Critical realism

Behaviour change theory</td><td>Deductive</td><td>Theory-based analysis using BCTT and TDF mapping techniques</td></tr>
<tr><td rowspan="2">Phase 2:

To explore patients’ and family carers’ perceptions of post-discharge medicines management for older people living with frailty and long-term conditions

To examine the behaviours and support mechanisms which allow these patients and/or their family carers to manage their medicines safely post-discharge</td><td rowspan="2">Qualitative patient and care-giver interviews</td><td>Inductive</td><td rowspan="2">Patient and family carer interviews

Diary entries

Primary care medical records</td><td>Framework analysis</td></tr>
<tr><td>Deductive</td><td>Mapping of barriers and facilitators using TDF</td></tr>
<tr><td>Phase 3:

To use a best-evidence synthesis, combined with patient experience to create an intervention that will support post-discharge medicines management</td><td>Intervention modelling

Consensus exercises</td><td>Deductive</td><td>Survey

Synthesis workshop</td><td></td></tr>
</table>

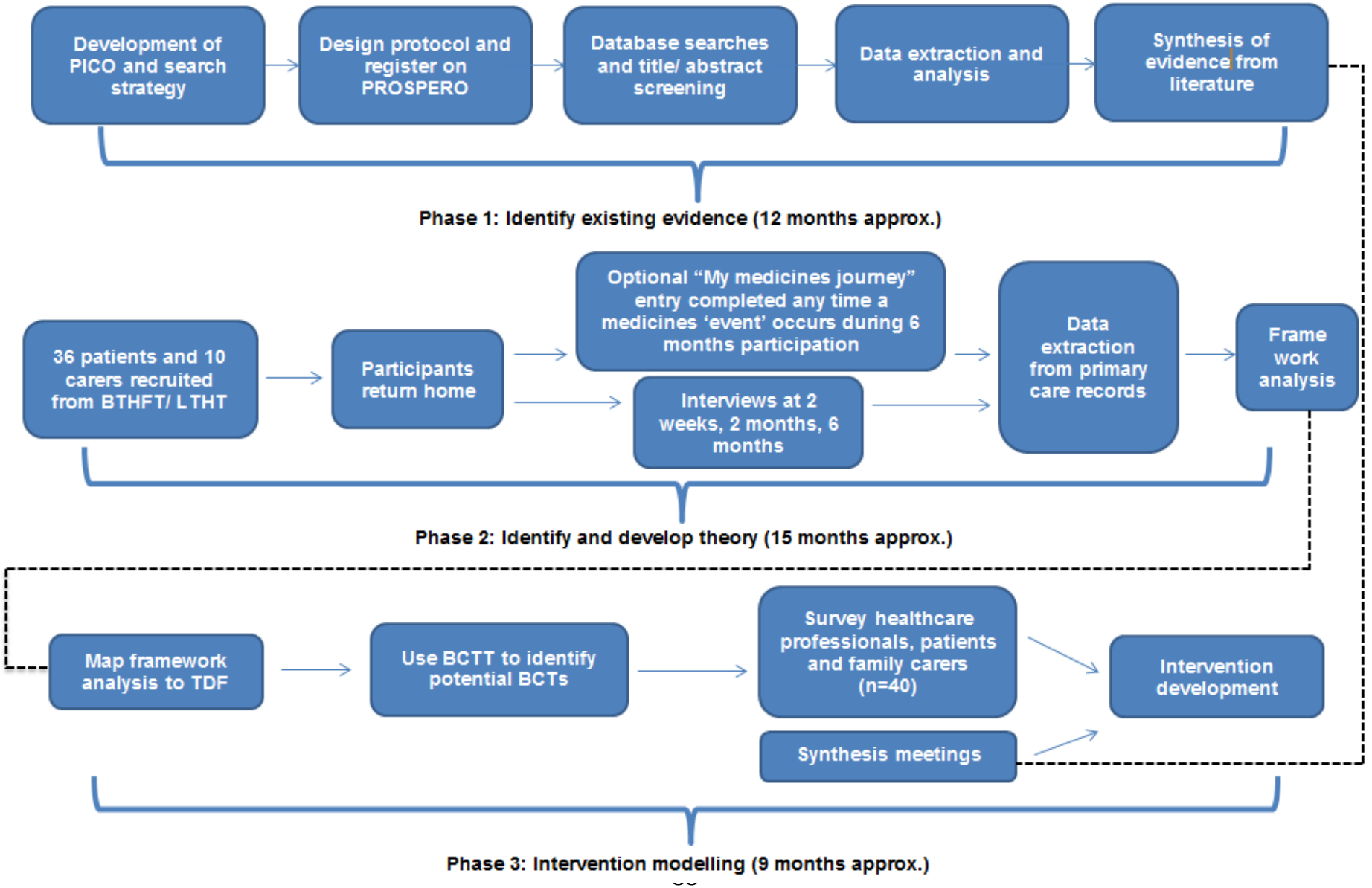


Figure 9: Phases of the research study

3.4 Methods

The methods for each phase will now be presented (**Figure 9**), along with an overview of the study setting.

3.4.1 Study setting

This study involved Leeds and Bradford Hospital Trusts. Leeds was a chosen site from the study outset as the proposal (see **Section 1.1** and **Appendix 1**) was set out by the Trust to meet their perceived needs. Bradford was later chosen as it would offer a comparison in terms of its demography, post-discharge service provision and current practice. A comparison was beneficial to explore whether patient experience is due to the Trust and/ or local service provision and whether the findings would be likely to resonate in other settings i.e. transferability of findings.

Two recruitment sites, from 13 available across both Trusts, were chosen based on the type of care provided, the number of care for the elderly wards and the level of willingness to participate. This study involved St James's University Hospital (SJUH) in Leeds Teaching Hospitals NHS Trust and Bradford Royal Infirmary (BRI) in Bradford Teaching Hospitals NHS Foundation Trust. BRI hosts four elderly wards (two acute assessment wards and two for older patients requiring longer stays). SJUH provides two acute assessment wards, four older adult inpatient wards and four medically fit for discharge wards. A pragmatic approach was taken to begin recruitment in as many of these wards as possible, with regular review of progress to target sample size (**Section 3.6.4**).

3.4.2 Demography of Leeds and Bradford

The health of people in Leeds and Bradford is generally worse than the England average, life expectancy for both men and women is lower (Public Health England 2018). The demographics of the two local areas differ in certain aspects, such as deprivation and diversity, so widening the potential sampling frame for this study.

Bradford is one of the 20% most deprived districts in England and life expectancy for both men and women is lower than the England average (Public Health England, 2018). Bradford is the fifth largest local authority within England, with its total population increasing year on year (City of Bradford Metropolitan District Council, 2020). Whilst Bradford's population is, on the whole, younger than England's average, estimates predict that the number of older people over the age of 65 will increase by 40,000 over the next 25 years (+45% increase) (City of Bradford Metropolitan District Council, 2020). Leeds' population also continues to grow, particularly in the most deprived communities (Leeds Observatory, 2018), and life expectancy for both men and women is lower than the England average (Public Health England, 2018). The population is becoming more diverse in terms of age, countries of origin and ethnicity (Leeds Observatory, 2018). Again, whilst Leeds is a 'young city', the population is still ageing, with a projected growth in the over 65s by over 15,000 people (+13% increase) (Leeds Observatory, 2018).

Population ageing has implications for healthcare organisations as these older individuals are frequent users of healthcare services, due to their multimorbidity (City of Bradford Metropolitan District Council, 2016). Bradford, for example, has the highest prevalence of diabetes within England. Since 2008, the prevalence of and number of patients diagnosed with T2DM has risen year on year, with a current estimate of 8% of the Bradford population diagnosed (England average 6.4%) (City of Bradford Metropolitan District Council, 2016). Hence, steps need to be put in place now to ensure the healthcare system will be able to function effectively and efficiently in the future.

The populations of both Bradford and Leeds are classed as ethnically diverse. Bradford has the largest proportion of people of Pakistani ethnic origin (20.3%) in England (City of Bradford Metropolitan District Council, 2020. Leeds' census identifies more than 140 ethnic groups, with 18.9% of the population reporting a minority ethnic background (Leeds Observatory, 2018).

3.4.3 Justification for the focus on older patients

The population aged 60 and over is predicted to double between the years 2000 to 2050 (World Health Organization 2015). Current data from England's Office for National Statistics illustrates that generally, females aged 65 in 2015 had a life expectancy of 21.1 years and men of 18.7 years. This is a 9% and 12.8% rise respectively since 2001 (Office for National Statistics 2015). This population ageing also increases the prevalence of frailty (Clegg et al. 2013). Frailty has been defined as the *"age related decline in many physiological systems"* that reduces a person's resilience (Clegg et al. 2013). Living with frailty furthers deterioration in quality of life, worsens health outcomes and is associated with increased healthcare utilisation (Ament et al. 2014; Andreasen et al. 2015). Current estimates indicate that a third of all older patients will experience frailty (Clegg et al. 2013). National efforts are, therefore, focused on supporting these individuals (Department of Health 2001; Oliver et al. 2014).

3.4.4 Patient and public involvement and engagement (PPIE)

Whilst patients should be engaged as partners in their own medicines management, there is also an international drive to involve patients and members of the public in service redesign and quality improvement (INVOLVE 2012; Healthcare Quality Improvement Partnership 2017). It is a "c*ore democratic principle that people who are affected by research have a right to have a say in what and how publicly funded research is undertaken*" (INVOLVE 2012). Furthermore, their involvement has been shown to noticeably improve research quality (Domecq et al. 2014; Batalden et al. 2016) by offering unique insights as 'experts by experience' (Healthcare Quality Improvement Partnership 2017). Making the patient voice a central focus in medication safety research is key to ensuring relevance and developing studies that are more aligned to patient need (Healthcare Quality Improvement Partnership 2017). PPIE has been embedded throughout this study (**Section 3.9**) and has helped the researcher to champion and celebrate the significance of the patient perspective and experience.

3.5 Phase 1: Identify the existing evidence

As outlined in the MRC guidance (Craig et al. 2019), the first stage of intervention design is to identify the existing evidence base. The most effective way to do this was to search the literature comprehensively and systematically for examples of trialled interventions.

3.5.1 Rationale for type of literature review

As outlined in **Section 2.2**, there are different types of literature reviews that can be used to produce a synthesis of best evidence (Grant and Booth 2009). As part of the evidence synthesis, interventions need to be described fully (details of components, who delivered it, for how long, in what context) so that any recommended elements could be reproduced (Craig et al. 2019). A quality assessment of each study is also required, so that clear recommendations can be identified and appropriate weight of argument given to the findings. Therefore, the chosen literature review method needed to involve rigorous data extraction and in-depth synthesis.

Realist reviews of interventions are growing in popularity as they aim to offer some explanation of why interventions work, how they cause change, and in which contexts, rather than just whether they work or not (Rycroft-Malone et al. 2012). Whilst this type of review fits well with the nature and philosophical lens of this study, interventions are usually tested by traditional experimental methods (e.g. randomised controlled trials) and their descriptions are limited. Due to inadequate published detail about the intervention content and lack of process evaluation data, a realist review was unable to be performed, and a more conventional method, from the positivist paradigm, had to be used.

To this end, a systematic literature review with meta-analysis was pragmatically chosen because it includes: exhaustive, comprehensive searching; clear guidelines for the conduct of the review; quality appraisal; detailed synthesis; and appropriate analysis techniques (Grant and Booth 2009). After conducting the traditional systematic review, a theory-based analysis was carried out to ascertain an understanding of the causal

mechanisms that influenced how the interventions might have worked, so thereby moving towards a more realist approach.

3.5.2 Guiding questions, aims and objectives

This review aimed to describe and evaluate the effectiveness of trialled interventions designed to support post-discharge medicines management.

The key questions guiding this systematic review were:

- What are the key components, modes of delivery and intensity of trialled interventions?

- What effect does the period of intervention, the number or types of professionals involved, and the relative point of engagement have?

- Are interventions underpinned by any specific theory at all?

- What discrete behaviour change techniques are involved in each intervention and which theoretical domains are targeted?

3.5.3 Method

Systematic reviews have very clear conventions for their conduct (Shamseer et al. 2015) to ensure rigour and quality, stemming from the traditional positivist paradigm. The Cochrane Collaboration, producers of internationally recognised high standard systematic reviews, have outlined strict procedures which have been incorporated within the methods presented here (The Cochrane Collaboration 2015).

Type of evidence

Historically, evidence from studies is ranked in terms of its strength (Aveyard 2007). The Cochrane Collaboration (2015) emphasises the need to include the strongest evidence to answer research questions relating to the effects of interventions. Sackett et al. (1996) demonstrated that the most reliable evidence for determining effectiveness comes from randomised controlled

trials (RCT). Next consideration should be given to cohort studies, followed by surveys and case reports, qualitative studies, and, finally expert opinion (Burns et al. 2011). In this review, RCTs of interventions to support post-discharge medicines management were the focus, based on this hierarchy of evidence.

Study eligibility

The first step was to identify the literature to include in the search (Aveyard 2007). Studies had to comply with the criteria in **Table 8**, outlined in the structured 'PICOS' format: participant, intervention, comparison, outcome of interest and study type (The Cochrane Collaboration 2015). These criteria were developed from the research questions, aims and objectives.

Information sources

A comprehensive search for published studies from 1st January 2003 to 1st September 2019 was carried out in a variety of appropriate electronic databases (MEDLINE, EMBASE, CINAHL, PsycINFO and the Cochrane Database of Systematic Reviews). The start date of 2003 was chosen to coincide with predicted uptake of MRC guidance by researchers, as demonstrated by Datta and Petticrew (2013), and its subsequent implementation within trials.

Table 8: Inclusion and exclusion criteria based on the PICO underpinning the systematic review

Category	Criteria
Participants	*Inclusion criteria:* Studies involving human adults where the mean age of participants is over 65 years, who have been admitted to, and are being prepared for discharge from a hospital. Studies involving both children and adults of all ages will be included if the data pertaining to the adults aged 65 years and over is reported separately.
Intervention	*Inclusion criteria:* Interventions must include some focus on medicines i.e. must include one or more activities that support post-discharge medicines management. Interventions can involve healthcare professionals, patients or their family carers. *Exclusion criteria:* Interventions focused on medication but with no support for post-discharge medicines management and without specific measure to evaluate outcomes of interest.
Comparator	Usual care, which is defined as care that did not include any additional activities to support post-discharge medicines management other than normal provision.
Outcomes of interest	Outcomes of specific interest are primarily a reduction in hospital readmission rates. Secondary outcomes relating to the safe use of medication (e.g. medication-related problems, discrepancies) and quality of life were also included as these factors contribute to successful transitions and can be mediated through medicine management. There will be no restriction imposed on length of time of follow-up of outcomes.
Study type	*Inclusion criteria:* Randomised controlled trials (RCT) or cluster RCT. English language. Published in the timeframe 1st January 2003 to 1st September 2019. *Exclusion criteria:* Any other study design with no control group.

Search strategy

The search strategy was prepared in consultation with an experienced Subject Librarian for Pharmacy. Medical Subject Headings (MeSH) and keywords were refined and combined using Boolean operators. Key search terms included those related to continuity of care (e.g. transitional care, patient hand-off and patient discharge), combined with those related to medicines management (e.g. pharmacy services, medication systems and medication safety). The search was limited to English language only. Additional papers were identified by manually searching the reference lists of resultant publications and through forward citation search. The search strategy for MEDLINE is shown in **Appendix 3**. Once finalised, this was adapted according to the requirements of each specific database.

Data management

Following the database search, results were uploaded to the EndNote X7 software facilitating data management during the filtering and selection processes. The collated library was shared between two reviewers (JT and a peer PhD researcher).

Selection process

Titles and abstracts from the resultant search were screened against the inclusion and exclusion criteria. Duplicates were removed. Rejected titles were reviewed by the peer researcher and any disagreements were discussed between the reviewers' opinions. By this process, the exclusion of potentially relevant publications and subsequent mistakes was minimised (Shamseer et al. 2015).

All abstracts identified as being decidedly relevant were included at this stage. Final inclusion was decided on after the full text had been more fully scrutinised. The selection process was fully documented and reported in a PRISMA flowchart (**Section 4.2**) (Stovold et al. 2014).

Data collection process

Once agreement on the list of eligible studies had been reached, data extraction took place. Patient characteristics (average age, gender, sample size), type of setting (country, hospital and ward type), specific intervention details (what, which healthcare professionals were involved, the period of engagement, the activity components, what the points of engagement had been, control measures), underpinning theory, duration of follow-up, outcome measures and findings were extracted. The second reviewer checked all information for its accuracy and completeness. Variances were resolved by in-depth deliberations between the two reviewers, consulting with a third reviewer (research supervisor) if necessary.

Protocols and further detail from the study authors was sought where possible to supplement the information in the publication. This action has been shown to improve the completeness of descriptions by at least 27% (Glasziou et al. 2008). Over a period of four weeks, two attempts to contact the primary authors were made.

Quality assessment

This systematic review adopts a traditional positivist stance, and as such the standards by which quality is assessed stem from this paradigm. Conventional quality assessment is performed by rating each study's risk of bias and helps evaluate the weight findings can be given and how far they can be generalised into routine practice (Hartling et al. 2009). The Cochrane Collaboration have developed a Risk of Bias tool, which helps reviewers decide if a study has attained the clearly prescribed minimum quality criteria (The Cochrane Collaboration 2015). This assessment requires the extraction of information pertaining to the randomisation process, any deviations from protocol, missing outcome data, measurement of the outcome and the selection of reported result (National Collaborating Centre for Methods and Tools 2017). Performance bias was not assessed because blinding of participants and intervention personnel would be impossible. The Risk of Bias assessment was conducted independently by the two reviewers, with consensus reached where there were any discrepancies in thinking between them.

3.5.4 Analytical plan

The extracted intervention components were, firstly, coded independently by the two reviewers, guided by an adapted version of Leppin et al.'s taxonomy (2014), which the reviewers modified for activities to support post-discharge medicines management (**Table 9**). Any differences were resolved through discussion, seeking a third reviewer (research supervisor) when necessary. This coding allowed for comparisons of the selected interventions to be made.

Clinical heterogeneity between all study populations, interventions and outcomes was present. Therefore, a meta-analysis stratified by intervention component, could only be performed for some of the included studies that reported hospital readmission data (where the risk ratio (RR) and 95% confidence intervals (CIs) could be calculated) using the longest reported follow-up period. Due to the high level of heterogeneity between studies, the outcome effects were pooled using a Mantel-Haenszel random effects model (The Cochrane Collaboration 2015) using the Cochrane Review Manager (RevMan) V5.3 software. The I^2 statistic was calculated and a funnel plot constructed to assess publication bias (Quintana 2015). A narrative synthesis was prepared to supplement this meta-analysis, in order to report the common components of interventions, how and when they were delivered and by whom.

For the theory-based analysis, intervention components were first coded to the BCTT and then mapped to the TDF so that behaviour constructs that the intervention targeted could be identified (Cane et al. 2012). This method has previously been used in other systematic reviews (Little et al. 2015; Morrissey et al. 2016) to help identify possible mechanisms of action. The original 12 domain version of the TDF (V1) was chosen for this work as this has the most extensive mapping to the BCTT (Michie et al. 2008) and the empirical BCTT work was performed using this version (Michie et al. 2005). Since no BCTs have been linked to the TDF domain 'nature of behaviour' in the literature, this domain was excluded in the analysis (Dyson et al. 2013; Patton et al. 2018).

Table 9: Taxonomy of activities adapted by the reviewers for post-discharge medicines management, adapted with permission (Leppin et al. 2014)

Medication-related activity component	**Description**
Follow-up:	
Telephone	Use of a telephone or videophone for provider-initiated communication after discharge that does not occur in the control arm
Home visit	Physical visit by intervention provider to patient's place of residence when this does not happen in the control arm
Patient education	Patient-directed education related to medication but not focused on encouraging self-management and not occurring in the control arm
Self-management (education or coaching)	Patient-directed education or coaching directly focused on improving the patient's ability to self-manage their medication needs that does not happen in the control arm
Medication intervention: reconciliation	Creating the most accurate list possible of all medications a patient is taking and comparing it to the current order, with the goal of providing correct medications at all transition points when this does not happen or is performed by usual care staff in the control arm
Medication intervention: review	Critical examination of a patient's medication with the objective of reaching an agreement with the patient about treatment optimisation when this does not happen in the control arm
Patient-centred discharge document	Some difference in the format or usability of discharge materials to make them more relevant or accessible when compared to the control arm
Collaboration within care team	Healthcare professionals co-operatively working together, sharing responsibility for problem-solving and making decisions to carry out medication-related plans for patient care
Timely cross sector communication	Engagement with other sector provider in communication about patient medication status when this does not occur or occurs at a later date in the control arm
Patient hotline	Presence of an open line for patient-initiated communication when this either does not exist in the control arm

Initially, three reviewers (JT plus a health psychologist and a health services researcher) mapped every intervention component to the BCTT independently (Michie et al. 2013). A meeting was held to discuss individual mapping and to identify discrepancies. Subsequently, two reviewers (JT and the health services researcher) met, on multiple occasions, to reach consensus on all the BCTs where there had been disagreements in coding. A concluding meeting with all members of the team was held to agree final consensus.

Mapping of the BCTs to the TDF was an iterative process that used published expert consensus on any BCTs likely to influence each TDF domain (Michie et al. 2008). For those BCTs that were not listed, or had not been linked to the TDF, a more recently published consensus exercise involving some domains of the TDF (V2) was considered (Cane et al. 2015). Finally, for any remaining identified BCTs which had not been or could not be classified, the reviewers met to confer and arrive at a consensus, drawing on their clinical knowledge and professional expertise of healthcare practice in the NHS (e.g. medicines reconciliation, when it is performed and how it is routinely conducted). The final mapping was agreed by all reviewers.

3.5.5 Quality criteria

Systematic reviews require methodological rigour in order to minimise error and bias (The Cochrane Collaboration 2015). Following this good practice guidance ensured that methods were robust and PRISMA guidance (Shamseer et al. 2015) was adhered to during the reporting of key findings.

In 2007, a validated tool called AMSTAR (assessment of multiple systematic reviews) was developed by nominal group technique to assess the quality of systematic reviews (Shea et al. 2007). AMSTAR recommends that quality can be assured by: ‘a priori’ study design, comprehensive literature search, auditable and transparent presentation of findings and bias assessment. **Table 10** illustrates how Phase 1 work upheld the quality principles outlined by AMSTAR.

Table 10: Quality criteria within Phase 1

AMSTAR quality criteria	How this was assured during Phase 1
Was an "a priori" design provided?	Research question and PICOS developed in advance
Was there duplicate study selection and data extraction?	Two independent researchers conducted study selection and data extraction
Was a comprehensive literature search performed?	Four electronic databases covering relevant international publications were searched. The clinical trials database, PROSPERO and DARE were also accessed
Was the status of publication (i.e. grey literature) used as an inclusion criterion?	Clear inclusion criteria were available and followed
Was a list of studies (included and excluded) provided?	Fully auditable records available
Were the characteristics of the included studies provided?	Aggregated data was extracted and presented in a table
Was the scientific quality of the included studies assessed and documented?	Risk of bias was assessed following The Cochrane Collaboration guidance (2015)
Was the scientific quality of the included studies used appropriately in formulating conclusions?	The results of rigour and quality were synthesised and considered during analysis
Were the methods used to combine the findings of studies appropriate?	Homogeneity tests were performed and a random effects model employed to pool results in a meta-analysis
Was the likelihood of publication bias assessed?	A funnel plot was produced and reviewed for publication bias
Was the conflict of interest stated?	N/A

3.5.6 Phase 1 output

Overall, Phase 1 work highlighted those types of intervention component that have been associated with post-discharge medicines management and have significantly reduced hospital readmission rates. The analysis also revealed a

list of the common BCTs used within the trialled interventions and their TDF construct targets. These findings were used alongside the primary research output (Phase 2) to help underpin intervention modelling (Phase 3), ensuring that the resultant recommendations were evidence based.

3.6 Phase 2: Identify and develop theory

The second phase of work involved collecting longitudinal qualitative data to help map and explore the patient experience of post-discharge medicines management. This is an important step in intervention design as it allows a thorough assessment of appropriate behavioural target(s) (Michie et al. 2014; Craig et al. 2019) in preparation for intervention modelling (Phase 3).

The rationale for using longitudinal data originated from the PCLSG. From early conversations, patients' medicines management needs and abilities changing over time were identified, and these often did not manifest themselves until after discharge. Together the PCLSG mapped the post-discharge time frame and illustrated that key problem points may include medicines supply in the community and primary care follow-up. These events may not be experienced within the first few weeks after hospital discharge, so it was recommended that the follow-up timeframe for each participant was to be six months.

3.6.1 Aims and objectives

Aim

To explore medicines management from the perspective of older people after discharge from secondary care.

Objectives

To explore the perceptions and reveal the experiences of post-discharge medicines management for older people living with frailty and long-term conditions.

To examine the behaviours and support mechanisms which allow these patients and/or their family carers to manage their medicines safely post-discharge.

3.6.2 Theoretical perspective

Whilst the meta-analysis within Phase 1 was positioned within a traditional positivist paradigm, this study adopts a critical realist approach (**Section 3.2**). It relies on an inductive and interpretive analysis that is firmly rooted in the participants' perceptions of their experiences. It is accepted that knowledge is co-constructed between the researcher and the participant (Bunniss and Kelly 2010). Inductive reasoning underpinned this phase of work so that no important factors were missed, as McGowan et al. (2020) have shown that the use of deductive analysis can limit findings.

Drawing on both objectivist and subjectivist philosophy; critical realism acknowledges that not only is there a real social world that researchers can attempt to understand, but that some knowledge is closer to reality than others (Fletcher 2017). Through the critical realist lens, this work aimed to explain social events (i.e. post-discharge medicines management) through reference to causal mechanisms and their effects.

The quality criteria by which this study should be judged, therefore, stem from the appropriate paradigm and include concepts related to credibility, dependability, transferability, and confirmability (Lincoln and Guba 1985). These will be further explored in **Section 3.6.9**.

3.6.3 Study population

Due to the small number of studies exploring patients' and family carers' experiences of post-discharge medicines management highlighted in **Chapter 2**, this study proposed to explore their perspectives. Previous reviews of discharge interventions have given rise to the need to target interventions towards high-risk populations (Laugaland et al. 2012; Spinewine et al. 2013; Kansagara et al. 2015) as they have the greatest capacity to benefit. As detailed in the literature overview (**Chapter 2**) older patients, living with multiple chronic conditions (including frailty (Stevenson et al. 2019)) and

polypharmacy, are at the highest risk of experiencing MRH (Coleman et al. 2005; Ahmad et al. 2014; Parekh et al. 2018a). Therefore, this population became the focus of this qualitative study.

It is known that older people are a heterogenous population and cannot be treated the same (Age UK 2012). Assumptions made regarding the younger old can therefore be inappropriate for the older old (Age UK 2012), hence careful consideration of the target age group for this research was necessary. The severity and incidence of frailty increases with age (Clegg et al. 2013), as well as the prevalence of limiting longstanding illnesses (Age UK 2017) and the use of five or more medicines (Gao et al. 2018). Whilst Phase one's systematic review explored interventions for those older people aged 65 and over, Phase two's work focused on the population aged 75 and over.

This target age was decided upon as a consequence of:

- Predicted doubling of the over 75 population within the next 30 years (Age UK 2017)
- An increased risk of hospital admission in over 75s (58% vs 51% in 60-74 year olds) (Age UK 2017)
- A higher level of polypharmacy (58% in over 75s vs 43% in under 75s) (Gao et al. 2018)
- Greater levels of frailty (9% in those aged 75-79 years vs 4% in those aged 65-69 years) (Clegg et al. 2013)
- The greater proportion of over 75s living alone (49%) (Age UK 2017).

Physiological changes associated with ageing and increased risks from polypharmacy also reinforce the need for individualised post-discharge treatment plans, optimisation and patient-centred care (Spinewine et al. 2007; Kalyani et al. 2017; Wastesson et al. 2018). These factors are especially relevant to patients living with long-term conditions where individuals should have a personal care plan that considers the individual's holistic needs (Jairam et al. 2015). To help provide a focus on high-risk populations and to guide relevant sampling, T2DM was chosen as an exemplar long-term condition for this study.

There are 4.5 million people in the United Kingdom living with diabetes, 90% of whom have T2DM (Diabetes UK 2016). Approximately 37% of people in England and Wales with diabetes are aged 70 and over (Diabetes UK 2016). Hospital stays involving these patients are likely to result in multiple medication changes (Mixon et al. 2015), which need to be promptly reconciled following transition to home. Furthermore, patients who take hypoglycaemic medicines are more likely to experience MRH (Avery et al. 2002; Parekh et al. 2020). MRPs and sub-optimal medicines use result in patients not fully benefiting from their treatment (National Institute for Health and Care Excellence 2015a). Successful care transitions, supported by medicines management, are, therefore, imperative for high-risk patients.

Most older people (58%) return to their own home after a hospital stay (NHS Benchmarking Network 2017), often with varying health or social POCs, as evidenced during observations of practice (**Section 2.8.3**). Phase 2 consequently targeted patients aged 75 years and over, living with T2DM and frailty (as important exemplars of long-term conditions, where medication safety across transitions is vital) who are returning home following hospital discharge.

3.6.4 Sampling strategy

Quantitative researchers often make use of power calculations to determine an appropriate sample size. This allows them to use statistical inference to estimate, within precise margins of error, the distribution of a phenomenon of interest in the population from which the sample has been drawn, when that population is too large to study in its entirety (Murphy et al. 1998). Qualitative researchers use probability sampling far less, and instead rely on non-random, purposive techniques, such as opportunistic and theoretical sampling methods (Murphy et al. 1998; Gray 2004). Within this study, where the aim is to obtain an insight into experiences, the sample was required to be information rich. Thus the sample needed to be purposefully selected to allow the topic to be viewed from all relevant perspectives (Murphy et al. 1998; Gray 2004).

Pen characters, depicting the types of patient perspective that needed to be included in this study, were adapted from the literature (Ipsos Mori for Age UK

2014). These five characters (Derek, isolated older person; Sally, minimal level of support; Bob, greater level of support; Fred and Margaret, helping each other; and Miriam, active older person) helped guide the sampling, aiming for a maximum diversity of medicines management support needs (**Table 11**).

Table 11: Pen portraits, adapted from 'Living with Frailty' Ipsos Mori for Age UK (2014)

Isolated older person – no support Derek lives in a rural area and does not have any formal or informal support – either because he has been assessed as having low needs or has never had an assessment. He gets by but finds it difficult to cook and clean for himself, as opening packaged food and lifting heavy items like the vacuum cleaner have become difficult. His local community pharmacy helps him with his medicines by ordering and delivering them each month, so he doesn't have to travel into town. He has never been married, or his wife passed away some time ago. He doesn't have any children. Although he has been living in the same locality for most of his life, he has no remaining family, and his friends have either moved to a different area or passed away.
Local authority - minimal level of support Sally lives alone in an inner-city area and receives domiciliary care, which is funded by the local authority. Sally moved into her current home around five to ten years ago and has lived in this area for all her life. Sally is frail and finds it very hard to get around without the aid of others. As a result, Sally tends only to leave the house when her daughter takes her shopping once a week. Her daughter makes sure she orders Sally's tablets when necessary via the GP surgery and always pops them into a weekly compliance aid for her. Sally has occasional informal support from other family members.
Local authority - greater level of support Bob has lived in a high rise flat just outside the city centre, on his own or with his late wife, for the past 20 years. Due to his complex long-term conditions and deteriorating health, he has become housebound and requires a lot of support around the house from domiciliary care, funded by the local authority. He has a son who lives a distance away, who comes to visit every now and again, but does not offer any help around the flat. Bob is dependent on the delivery service from his local community pharmacy, who blister packs all his oral medication. Due to his diabetes, Bob also requires daily insulin injections. The district nurses visit him regularly to administer these as Bob is unable to do it himself.

Helping each other

Fred and Margaret have been married for over fifty years. Fred enjoyed a reasonably successful career and as a result the couple can enjoy an affluent retirement. They see their children rarely and therefore rely on one another for support. They both have a long-term condition. Fred uses a stick, so they must take things slowly, but they are still able to get out and about. Although they don't visit any formal support services, they do manage to go to their local supermarket once a week, as Margaret can drive, and they can park in the disabled bays close to the entrance. Fred can walk slowly around the supermarket when he holds on to the trolley and enjoys helping Margaret with the shopping in this way. They call into their community pharmacy to collect their monthly prescriptions and enjoy chatting to the staff members, who know them well. They don't have any formal support from carers but live in a caring community with neighbours they can call upon if need be.

Active older person

Miriam lives in extra-care or sheltered housing in a private or local-authority-run scheme and doesn't get many visits from family members. Since her husband died ten years ago, Miriam has been living for the days when she visits support services, namely, a twice-a-week lunch club and a once-a-month visit to a tea party organised by a charitable organisation. She enjoys meeting friends new and old at these events and taking part in the activities such as knitting. Miriam is well-up on her different medicines and knows them all by name. Whilst she likes to order her medicines herself from her GP practice, she prefers to let the pharmacy deliver them to her.

Sample size

A study's sample size is informed by its objectives, research questions and its design (Onwuegbuzie and Leech 2007). Qualitative work seeking to generate an in-depth understanding of how and why outcomes are as they are, often requires less participants than quantitative work that aims to generalise across all contexts (Baker et al. 2012).

In this study, a recruitment target of 36 participants was set (target 24 patients recruited from SJUH and 12 from BRI, based on hospital size and number of wards available for recruitment). Assuming an estimated retention rate of 50% (Bower and Smith 2016; Fylan et al. 2018), a final sample size of 18 fully completed cases (defined as a participant completing all three interviews) was anticipated. Family carers who supported these patients with their medicines were also invited to participate.

This sample size was informed by:

- Experience from the University of Bradford's NIHR funded ISCOMAT Programme. Colleagues performed longitudinal interviews with heart failure patients who had been discharged from hospital. In their project, 20 patients were recruited with the outcome of 16 completed cases (age range of participants 40-89 years) (Fylan et al. 2019a).

- Literature. Published studies that reported using similar methods and/or interviewed patients and carers at care transitions used similar sample sizes (Ellins et al. 2012; Knight et al. 2013; Waring et al. 2014; Andreasen et al. 2015).

- A data saturation experiment (Guest et al. 2006). Based on a content analysis of data gathered from 60 interviews, Guest et al. (2006) identified that the full range of thematic discovery occurred almost entirely within the first 12 interviews.

- The concept of information power as a pragmatic model for qualitative sample size assessment (Malterud et al. 2016). Information power indicates

that the more information the sample holds, relevant to the actual study, the lower number of participants is needed. Malterud et al. (2016) suggest that this depends on: the aim of the study, sample specificity, the use of established theory, as well as both the quality of dialogue and the analysis strategy.

Whilst an initial target sample size of 36 participants was set (as required for ethics applications), qualitative research aims to sample until no new information arises from the participants (Bowling 1997). The most common method of determining the final sample size is by saturation (Baker et al. 2012), i.e. to sample as many as it takes until no new insights emerge. This suggests that sufficient data has been gathered to answer the research questions and that no new information will arise from any further data collection (Thorne 2020). Recently, the concept of saturation has come under debate, with some researchers (Braun and Clarke 2019; Thorne 2020) believing it has little place in qualitative work, that it is poorly operationalised and is highly dependent on an interpretive judgement related to the aim of the data analysis (Braun and Clarke 2019; Thorne 2020). Braun and Clarke (2019) however, propose that data saturation is compatible with a realist ontology because *"there is an imagined basis for determining 'nothing new' to be found"*. In this study, data analysis occurred concurrently with data collection and continued until saturation, meaning no new information emerged from the analysis, was reached.

Inclusion and exclusion criteria

Section 3.6.3 outlined the rationale for focusing participant recruitment towards patients at high-risk of MRPs. Therefore, this study includes those patients who are: older, living with long-term conditions (with a focus on T2DM and frailty as exemplars) and using multiple medicines. Patients, supported by their carers if appropriate, were invited to participate if they were:

- Aged 75 and over
- Identified as living with frailty and T2DM
- Using five or more medicines with at least one change or recommendation at discharge

- Returning to a domiciliary setting after discharge
- Competent to consent at the point of discharge.

Resources for translation were available so non-English speaking participants could be recruited. Due to the longitudinal, qualitative nature of this study, patients unable to communicate due to aphasia or those lacking capacity were excluded. Further exclusion criteria included patients on the end of life pathway.

Recruitment

Patients admitted to the chosen wards were screened for eligibility by the researcher, ward pharmacist, research nurse or ward staff. Patients who were eligible to take part in the study were approached during their hospital stay by the researcher. In this initial conversation, the study outline was presented using a pictogram of the 'research journey', co-created by the PCLSG (**Figure 10**). The PCLSG also helped develop key points for this early conversation that were used by the researcher when approaching patients, including an outline of the benefits of taking part, the importance of the research and the level of commitment required. Participants were offered an information sheet (co-designed with the PCLSG) and a privacy notice (**Appendix 4**).

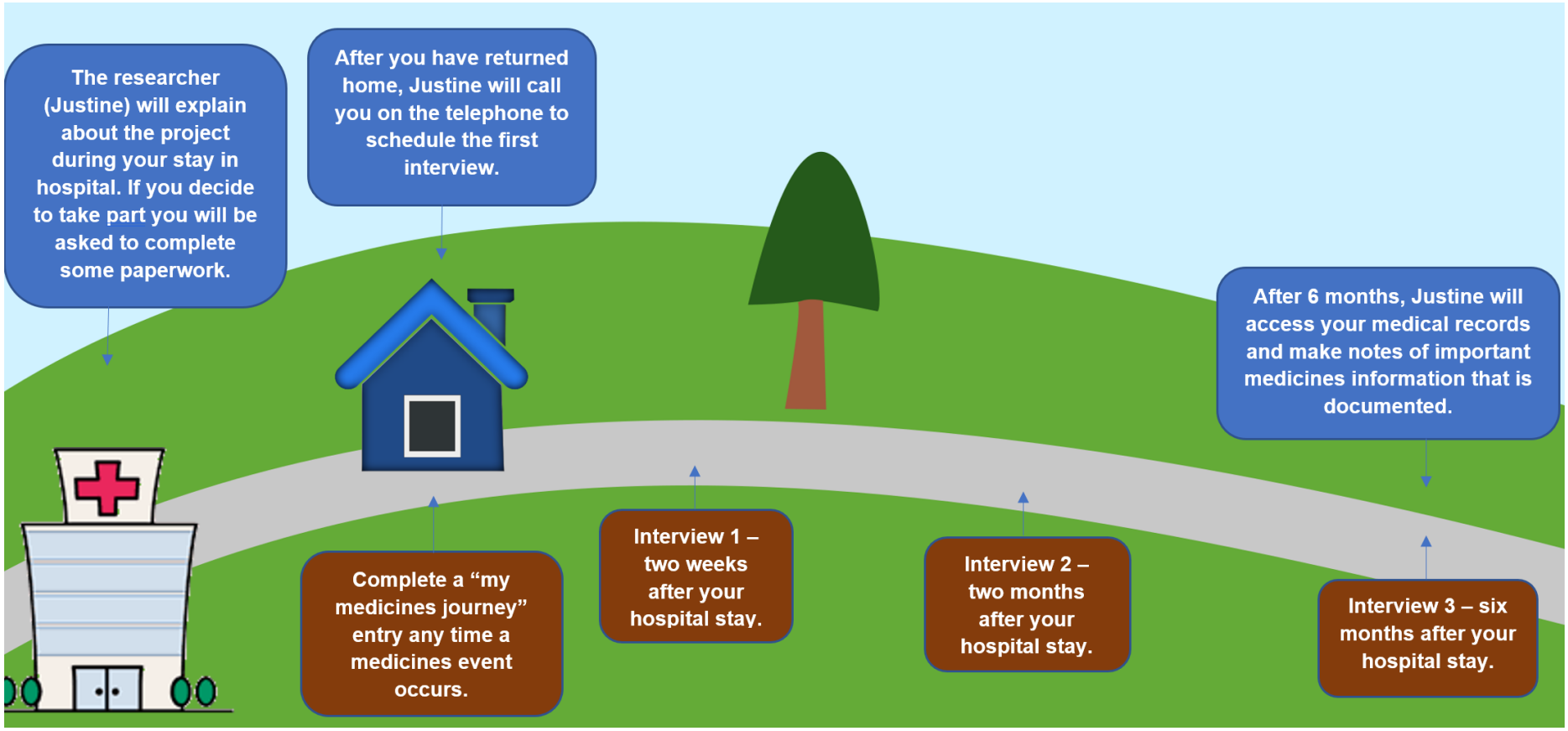


Figure 10: The research journey from the patient information sheet (**Appendix 4**)

3.6.5 Methods

Conducting interviews is a useful method when less is known about the topic, and in particular when exploring multiple inter-dependent complex behaviours, such as medicines management (Atkins et al. 2017). Detailed interviews, exploring the experiences and perceptions of the participants were therefore used, which allowed wider scale data collection (Murphy et al. 1998). Becker and Geer (1957) stated that interviews have their limitations, an example of which is the participants' ability to recall events accurately. Another criticism is that interviews offer idealised accounts of behaviour, rather than an observation of the actual event (Murphy et al. 1998). To overcome this, interviews occurred three times over six months, and participants were asked to complete a diary about any important medication-related events, concerns or opinions (Zimmerman and Wieder 1977). Interviews were also triangulated with actual dates and fact-based details from the participants' primary care medical records, which aimed to confirm interview data (Mays and Pope 2000) and provide a more comprehensive picture of the patient experience (McEvoy and Richards 2006).

Becker and Geer (1957) argue that the most comprehensive method of qualitative research is participant observation. Using this method alongside the interviews would have allowed rich information to be gathered about the experiences which preceded and followed an event, including explanations of its meaning by participants, before, during, and after its occurrence (Murphy et al. 1998). Due to the logistical challenge of observing a participant's unscheduled, unpredictable and ad-hoc medicines management processes in the days and weeks following hospital discharge however, observation methods were considered exceptionally challenging and, ultimately, not feasible.

Interviews

Interviews are widely used in research relating to attitudes and behaviour (Murphy et al. 1998). They can take place on a one-to-one basis or in a group. Focus groups are useful to trigger a greater number of insights for discussion than those realised through one-to-one dialogue or self-reflection (Austin and

Sutton 2019). They rely on participants coming together in one location at a specified time, which could restrict the participation of those severely frail or housebound patients. Therefore, one-to-one interviews in the patient's home were judged to better suit this study.

Types of interview

Interviews can be fully structured or unstructured. Structured interviews have arisen from the positivist paradigm and often use standardised questions where the wording is the same for each participant (Bowling 1997; Austin and Sutton 2019). Arguably, this design removes context and prevents range and depth (Gray 2004). Conversely, the unstructured interview has no specific set questions and relies on the spontaneous interaction between the researcher and participant to drive and negotiate their way through the conversation (Austin and Sutton 2019). This style can be of value when it is desirable for participants to illustrate their own understanding of the world (Murphy et al. 1998). However, it can be challenging for a novice researcher. Furthermore, there were a pre-determined set area of topics that needed to be covered in order to answer the research questions. An unstructured interview format could have distracted the research away from this. Semi-structured interviews make use of a topic guide that describes the key information required, but the specific structure and wording is more open (Gray 2004). Semi-structured interviews allow for prompts and additional probing where deemed appropriate to do so, allowing the researcher to explore wider concepts. In addition to this, the fluid nature of this type of interview allows the conversation to divert into new zones of relevance that might not have been obvious to the researcher at the outset (Gray 2004). A semi-structured interview design was, therefore, chosen for this study.

Serial interviews are helpful in longitudinal qualitative research when exploring evolving and complex processes (Murray et al. 2009). They have also been used to identify changes in needs over time. Additional benefits include improved rapport, thereby allowing richer data collection (Murray et al. 2009). Multiple interviews were thought to be necessary in order to investigate the changing medicines-related priorities that patients may experience or

behaviours displayed, for up to six months after hospital discharge (Aminzadeh and Dalziel 2002; Knight et al. 2013; Krumholz 2013). As highlighted in **Section 3.6**, the PCLSG also advocated serial interviews based on their experiences of post-discharge medicines management. There is no guidance on how long a longitudinal study should last, although a minimum of two times points is stipulated to elicit details on change over time (Calman et al. 2013). Semi-structured interviews were therefore conducted at three time-points reflecting key moments in the patient pathway. It was recognised that some participants would be readmitted to hospital during their follow-up period, and so with their consent they continued to be tracked. The study resumed after subsequent discharge only if capacity was maintained.

Topic guide development

Central to the semi-structured interview is the topic guide or interview schedule. This list of key topics aids the flow of an interview and ensures important areas for discussion are not forgotten (Gray 2004). Topic guides (**Appendix 4**) were developed, underpinned by the TDF to ensure all behaviour constructs were explored (Michie et al. 2014; McGowan et al. 2020). Other topics for discussion were generated through work with the PCLSG, research objectives, personal experience of pharmacy practice and the scoping work. Examples include medication-related interactions with healthcare professionals or other organisations, self-care strategies and instances of MRPs were highlighted on the topic guide. Also included was any patient reference to those enhanced experiences of medicines management.

To be effective, topic guides need to be free of jargon, unambiguous and must not lead the participant (Gray 2004). To produce a suitable topic guide for this study, prospective questions were collated, grouped and arranged (Austin and Sutton 2019). The PCLSG found this version far too lengthy and assisted to split the questions appropriately over the three interviews and in a rational order. They also offered invaluable feedback on the language used.

Further considerations for interviews

The location of the interview is important, not simply from a comfort or convenience perspective (Herzog 2005; Sivell et al. 2019). The concepts of space and place can help researchers engage with reflexivity, promote more holistic discussions, and balance the power dynamic between the interviewer and interviewee (Gagnon et al. 2014; Sivell et al. 2019). Interviews purposefully conducted in the patients' homes, with their consent, helped with a visualisation of medicines management within the context of their lives, whilst also building rapport and acknowledging them more as an ordinary individual, rather than as a 'patient' (Herzog 2005; Sivell et al. 2019). Additionally, conducting the research in the home setting increased insight with regard to the population and the research topic (Herzog 2005; Gagnon et al. 2014). This aspect caused me to challenge my own assumptions of what medicines management is, or more significantly, should be. Importantly, being in their home has been shown to minimise power imbalances between participants and researchers (Sivell et al. 2019). Having a clinical background, I felt this was vital for the interview because I did not want to be thought of as a 'medicines expert' since I would be present in my role as a researcher.

During the early stages of study design, the PCLSG highlighted that family carers who help the participant with their medicines may prefer to be or be interested in taking part during the interview. Gray (2004) argues that joint interviews are useful to fill gaps in experiences, to collect differing opinions and to corroborate perspectives. More comprehensive data can be collected, and a seldom heard point of view can be given voice (Arksey 1996). For this study, it was also an opportunity to explore how patients and carers worked together in medicines management. Whilst it was decidedly beneficial to interview patient-carer dyads where appropriate, careful handling of these interviews was needed. The literature highlighted the importance of giving equal voice to both individuals (Zarhin 2018), of carefully avoiding passivity of the patient participant and of managing any diversions in attention (Gray 2004).

Diaries

Recall may affect the credibility of interview data, as there are concerns that participants may forget key details or incidents in the time between interviews. Critical realists allow for the possibility that participant accounts may be partial too (McEvoy and Richards 2006). Hence, a diary tool was created to: supplement the interviews and act as a memory aid, to stimulate interview discussion, and to provide additional evidence. Participants and their family carers were asked to complete semi-structured event-based entries (Alaszewski 2006) between the first and last interview. To encourage use of this data collection tool, it was entirely co-designed by the PCLSG (**Appendix 5** describes in-depth details about the design process). The diary encouraged the periodic documentation of any contact with healthcare professionals and any MRPs together with details of the resolution. Participants were also encouraged to note any medicines-related processes that were helpful, e.g. using their own reminder system (**Appendix 4**). Every effort was made to include all participants in this activity. However, if it proved to be too challenging for participants to complete, it was removed.

Primary care data extraction

Serial qualitative interviews and diary entries were triangulated with data from healthcare providers' records, wherever possible. This triangulation was important in confirming the participant's account and for completeness (McEvoy and Richards 2006).

The participants' primary care practices were contacted, and a copy of the completed consent form was sent via secure NHS mail. Access to primary and secondary care records were then sought for those participants taking part in all three interviews. Key dates, types of contact with the healthcare system and qualitative details relating to post-discharge medicines management were extracted by the researcher.

3.6.6 Data collection

Interviews were digitally recorded and transcribed verbatim. Any paper diary entries were collected from the participants after their final six-month interview.

During interviews, participants illustrated their experiences with artefacts, such as homemade checklists. To capture these important aspects, participants were asked for their verbal consent for a photograph to be taken. Any identifying information was then edited out of the photograph.

After six months, the researcher compiled anonymised information relating to the transfer of medication-related information, key dates, qualitative comments and prescribing data from the primary care record. This involved collecting a de-identified printed complete participant record from the practice. These records were reviewed, and relevant information extracted into a document depicting the timeline of events.

All data were anonymised at the point of collection and stored securely in line with the Data Protection Act 2018 and General Data Protection Regulation 2019 (Legislation.gov.uk 2020).

3.6.7 Research governance

Because this study involved older patients living with frailty, it was a priority that participation did not cause extra burden or harm for them. The study was non-intrusive, and the methods were designed flexibly to meet the needs of participants e.g. the diary could be removed if the participant found it too challenging. All methods, data collection tools and participant documentation were co-created with the PCLSG to as to ensure they were both appropriate and manageable.

Written informed consent (**Appendix 4**) was obtained prior to the participant undergoing any of the study activities. The process by which this consent was gained included:

- A discussion between researcher and the participant (with their representative if appropriate), about the nature and objectives of the study and possible risks associated with their participation

- Written information presented in a format that suited the individual e.g. large font participant information sheet (**Appendix 4**)

- The opportunity to ask questions and talk with others about participation

- An assessment of capacity using a protocol (**Appendix 4**) based on the Mental Capacity Act 2005 (Legislation.gov.uk 2020). For consent to be ethical and valid, participants had to be capable of giving consent for themselves (Department of Health 2005)

- An appropriate amount of time (24 hours) to make a decision whether to participate or not.

Due to my professional and ethical obligations, if any safeguarding concerns arose e.g. witnessing of inappropriate care processes or potential for harm from medication error, I had a duty of care to intervene. Actions to take, should any MRPs be discovered, were discussed with supervisors to ensure uncompromised participant safety. These professional responsibilities needed to be carefully balanced alongside the academic researcher role. It was not the intention, firstly, to perform a clinical review of the patients' medicines, nor to make any clinical judgements regarding their treatment. The lived experience of the participant was paramount, and therefore a minimal effect from reporting such safeguarding concerns to the research integrity would be evident. Any incidents were fully documented, given due attention during data analysis and reported on in the write up so the nature, scale and potential impact of them remained clear. Finding safety issues may also shed light on the quality of care in patient experience (Urban 2014).

Ethical approval

This study involved patients in England and approval from the Health Research Authority including full NHS Research Ethics Committee review was sought. After the ethics application received a successful outcome on the 9th July 2018 (**Appendix 6**), site submissions were made to the Research and Innovation departments at LTHT and Bradford Teaching Hospitals NHS Foundation Trust, which were subsequently approved.

Researcher well-being

McHenry (2015) documented the emotional burden that can be placed upon interview participants. They may experience discomfort and fatigue, or the interviews themselves may be very long. Alongside this, immense effort on the

part of the researcher is required to build and sustain relationships with participants. Without doubt there is the emotional cost of leaving the participants once that relationship has come to its end, or more sadly, if participants die. This was something that needed careful management and I had access to appropriate advice and counselling as necessary. Any such instances were discussed during supervision meetings.

3.6.8 Analytical plan

Qualitative data analysis is concerned with exploring and understanding experiences and phenomena (Blaikie 2010). Methods of analysis identify important categories, patterns and relationships within the data often without predefined measurements or hypotheses (Flick 2013). This process is known as induction. Qualitative analysis often involves coding, conceptualisation and categorisation of data and various analytic methods can be employed to support the researcher (Gray 2004). There is no outright dominant method or rules for qualitative analysis. However, Gray (2004) argues that coding is central. Coding allows researchers to break down data (from interview transcripts for example) into categories and subcategories. Classification then occurs with connections between categories being drawn. Types of analysis include discourse (analysis based on language), ethnographic (interpretive and descriptive analysis) and grounded theory (analysis to build theory) (Murphy et al. 1998).

Within this study, it was important to explore the data both cross-sectionally (synchronically) and longitudinally (diachronically) (Thomson and Holland 2003). The cross-sectional analysis captures a particular moment in time, enabling comparisons across the sample. Longitudinal analysis captures each participant's narrative over time (Thomson and Holland 2003; Calman et al. 2013).

Inductive analysis

Thematic analysis is a method that is widely used during descriptive analyses to identify, interpret and report themes within the data (Austin and Sutton 2019). Braun and Clark (2006) described thematic analysis as six iterative

phases: familiarising yourself with the data, generating initial codes, searching for themes, reviewing themes, defining and naming themes, and producing the report. Braun and Clarke (2006) describe a theme as capturing *"something important about the data in relation to the research question and [representing] a patterned response within the data set"*. There are many advantages to this type of analysis; it is a relatively quick and easy method to learn and undertake, it can generate unanticipated insights and it is particularly appropriate for dealing with large amounts of data (Braun and Clarke 2006). It has, however, come under scrutiny as being less robust, systematic and transparent.

To overcome these criticisms, the 'framework' approach to data management and interpretation was developed in the 1980s (Gale et al. 2013). Framework analysis is a type of thematic analysis that *"identifies commonalities and differences in qualitative data, before focusing on relationships between different parts of the data, thereby seeking to draw descriptive and/or explanatory conclusions"* (Gale et al. 2013). Such a method of analysis aligns well then with the critical realist paradigm. The 'Framework' differs to traditional thematic analysis methods described above by the creation of an analytical framework that is applied to the data set and afterwards used to chart data into a matrix. In this way data can be compared across and within individual cases. The analytical process is guaranteed to be much more systematic, auditable and comprehensive, as all participant cases are considered, not just dominant ones.

Framework analysis

Interviews were coded and managed in groups of up to eight to make concurrent data collection and analysis manageable. Such action allowed for careful consideration of data saturation.

Framework analysis (Ritchie et al. 2014) assisted in the management of interview and diary data in the following steps:

1. First, a sub-set of seven interviews (two weeks post-discharge) were coded within the NVivo 11 software. Codes were collated and aggregated into an analytic framework to guide the creation of the framework matrices.
2. The analytic plan was reviewed and adapted to ensure that all codes could be positioned under one of the headings (**Figure 11**).
3. Six matrices were created within the NVivo 11 software. Interview transcripts for each participant were re-read and key pertinent issues summarised within each box. This summary was linked to supporting participant quotations through the software.
4. Any ideas or experiences within the transcripts that would not fit within the matrix were discussed with a supervisor, and further changes made to the analytical plan as appropriate.
5. This process continued until data saturation occurred, with no new ideas or themes emerging.
6. The matrices were then individually interrogated to define the key elements within each summary. Two rounds of refinement occurred.
7. The detected elements were then iteratively sorted into categories. Higher level categories became themes and lower level categories became sub-themes. The emerging thematic analysis was refined through discussion with the supervisory team (**Figure 12**).

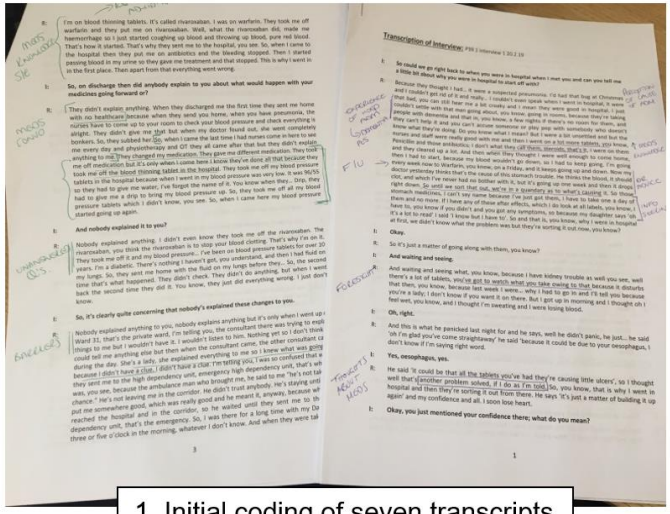
Once the analysis was complete for all interviews occurring two weeks post-discharge, coding began on those interviews completed at two and six months after discharge. A new analytical framework was not created because subsequent codes could all fit within the established matrices.

Primary care data extraction

Data from the primary and secondary care record were synthesised into a map for each participant. These maps provided a visual representation of the six-month post-discharge pathway, from the system perspective, and highlighted contact with healthcare providers. They were used alongside the participants' interview transcripts in the inductive analysis.

Synthesis of diary data

Diary entries were collected from those who engaged with the tool and were reviewed to triangulate interview and primary care data. Any new insights were mapped onto the relevant framework matrix and included in the analysis.



1. Initial coding of seven transcripts

	A
1	Ability to recall ceased medicines and associated side effects
2	Acknowledgement of own limitations and complete reliance on husband
3	Acknowledgement that would have liked some information about medicines; what taking and why
4	Anger at lack of communication about medicines processes whilst in hospital - wanted to manage own meds
5	Assuming that poor CP GP communication is to blame for dosette box packing
6	Attempting to use discharge paperwork but don't understand it
7	Aware that can make a mistake when filling own dosette box, uses written list as a defence
8	Awareness of change in meds due to number of tablets being given
9	Awareness of change of medication timing
10	Awareness of difficulties; change of routine post discharge
11	Awareness of increase in quantity of tablets
12	Barriers to asking questions whilst inpatient
13	Burden of post discharge support, feels obliged to support family member
14	Burden of taking action to ensure onward supplies falls on carer
15	Carer able to perform own checks but aware that others without support might not
16	Carer anticipates delay in supply, trying to prevent problems due to 7 day supply and day of the week when starting pack
17	Carer draws on prior experiences of managing medicines for family members
18	Carer has organised workload and developed routine around supporting medicines, routine around work and meals, burden
19	Carer has pro active plan to ensure follow up monitoring occurs
20	Carer has synchronised appointments and nurse visits
21	Carer is main source of information and support to patient
22	Carer is proactive in maintaining supply of meds
23	Carer leaves meds in eye line so no mishaps or issues with nurses not finding it
24	Carer left wondering why information has not been transferred between settings
25	Carer needing to follow up community pharmacy for supply
26	Carer perceives that she wasn't kept fully informed

2. Codes collated and summarised into analytical framework of six categories

Analytic framework for matrix v1 – arising from 7 interviews 14.12.18

1. Pre-discharge preparedness
   - 1.1 Quality of conversations
   - 1.2 Types of information
   - ~~1.3 Types of staff~~
   - ~~1.4~~1.3 Supply at discharge
   - ~~1.5~~1.4 Disempowerment
   - ~~1.6~~1.5 Emotions
   - 1.6 Foresight & forward planning
   - 1.7 1.7 Barriers
2. Levels of engagement
   - ~~2.1 Pro-active activities~~
   - ~~2.2 Information seeking~~
   - ~~2.3~~2.1 Carer activation
   - ~~2.4~~2.2 Patient activation
   - ~~2.5~~2.3 Passivity & acceptance
   - ~~2.6~~2.4 Capability
3. Pro-active error avoidance (Scaffolding other systems)
   - ~~3.1 Strategies~~
   - ~~3.2~~3.1 Strategies - GP system
   - ~~3.3~~3.2 Strategies - Community pharmacy system
   - ~~3.4~~3.3 Ensuring onward supplies
   - 3.4 Ensuring follow up
   - 3.5 Consequences

jgreenw7 Removed as no comments focus on types of staff specifically

jgreenw7 Added new group as some participants discussed barriers to conversations and asking questions

jgreenw7 This fits better under 3 and 4 (also is not distinct enough on its own)

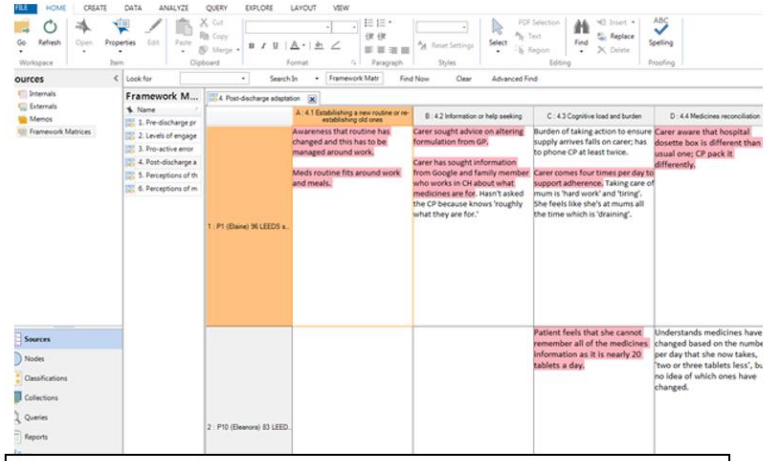
jgreenw7 Combined with help seeking below as not distinct enough

jgreenw7 Removed because strategies will fall under each of the below

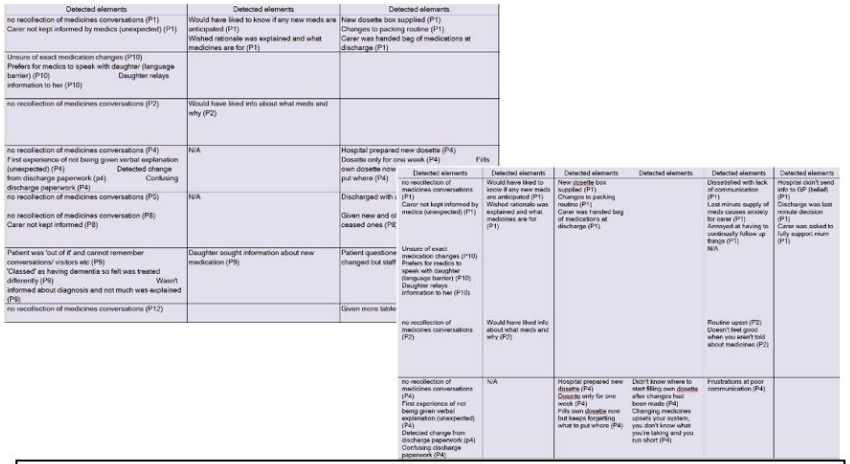
jgreenw7 Added as participants discussed consequences of error or perceived consequences

3. Iterative revision of analytical framework

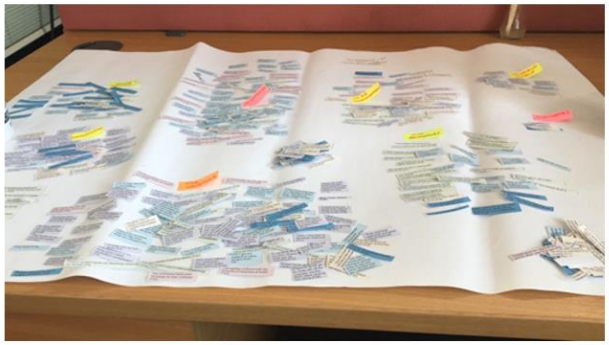
Figure 11: Generating the analytical framework

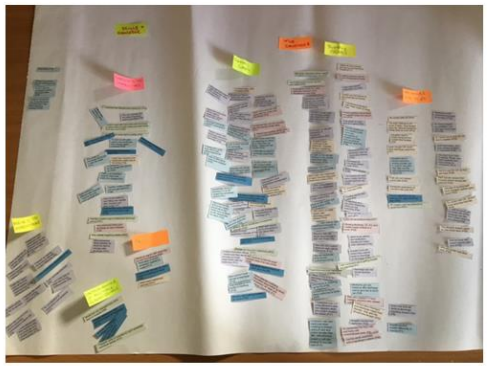


4. Summarising each participant's thoughts within the six matrices using Nvivo



5. Interrogating each matrix to identify the key elements of each summary





6. Iterative sorting and categorising of key elements into themes and sub-themes

Figure 12: Data management and analysis

Analysis of Patient Safety Incidents

Throughout the interviews, participants described a number of potential safety incidents (PSIs). The National Patient Safety Agency, now part of NHS Improvement, defines PSIs as, “unintended or unexpected incidents that could lead to harm” (NHS England 2020). Severity scores have been developed to assess the clinical harm from PSIs. However, they often rely on knowing the patient outcomes. Only one valid, reliable, and practical method is available to researchers for the rating of potential patient outcomes, where at least four adjudicators are asked to determine each PSI’s clinical significance using a visual analogue scale (Dean and Barber 1999).

To explore the severity of these potential medicines-related PSIs, brief descriptions and supporting verbatim participant quotes were presented independently to four HCPs (hospital pharmacist, primary care pharmacist, geriatrician and GP with specialist interest in elderly care), who were asked to decide firstly if a PSI had occurred, and secondly, to rate the severity using a validated zero to 10 scale (0=no risk of harm; 10=death) (Dean and Barber 1999; Avery et al. 2013). Next, a mean score was calculated across all raters, and interpreted as: <3 minor, 3-7 moderate, and >7 severe. Where half of them (n=2) believed that the event was not a PSI, adjudication was sought from the Medicines Safety Officer at LTHT. If the adjudicator agreed that it was a PSI, they provided a rating of severity which was used in the calculation of the mean score (means were, therefore, based on three judges’ ratings in this instance).

As well as physical harm, the level of psychological harm or distress has similar importance. The same PSIs were presented to the PCLSG for estimation of the level of distress the event may have caused the participant; using the same scale of zero to 10 (0=no distress; 10=severe emotional distress). Mean scores were calculated and interpreted as previously described.

Inter-rater agreement between the four adjudicators was calculated using the percentage agreement of interpreted level of harm. Other measures of agreement are available (such as Cohen’s kappa or Fleiss K). However these

could not be used due to the number of raters who were unique and because targets were not randomly selected (Hallgren 2012).

To help with analysis, PSIs were categorised using Nicosia et al.'s taxonomy of MRPs (2020): problems with obtaining medicines, taking medicines, medicines effects, or co-ordination and information.

3.6.9 Quality criteria

Throughout this study, various strategies were applied to uphold its quality, specifically so that reviewers of this work can have confidence in the findings. **Table 12** lists these strategies and how they link to Lincoln and Guba's trustworthiness criteria (1985).

3.6.10 Phase 2 output

This phase of work explored the lived experience of post-discharge medicines management. Inductive analysis was used to model the intervention (Phase 3), ensuring that its development was underpinned by patient experience and to aid the identification of the influential barriers and enablers of medicines management.

Table 12: The quality criteria as applied to this phase of the study

Trustworthiness criteria (Lincoln and Guba 1985)	**Strategies** **(Mays and Pope 2000; Anney 2014)** ([1]Discussed in previous rows)	**Detail**
Credibility – the confidence that can be placed in the truth of the research findings	Prolonged engagement in the field Peer debriefing Triangulation Member checking	Researcher spends six months with each participant, building trust and rapport; providing a greater understanding Support sought from research group colleagues and supervisors to test analyses and provide feedback Multiple sources of information gathered to corroborate findings; three interviews, diary entries, health records Analyses will be presented to PCLSG for validation
Dependability – the stability of findings over time	Stepwise replication Audit trail Peer debriefing[1] Triangulation[1]	Interview transcripts (25%) will be independently analysed by a different researcher and results compared A full report of all research decisions, how data were collected, recorded and analysed will be available
Transferability – the degree to which the results can be transferred to other contexts	Purposive sampling Thick descriptions	Selection of key informants, based on maximum variation, guided by pen characters Comprehensive (or thick) descriptions of individual participants, research setting, and methods will be available to help other researchers replicate the study
Confirmability – the extent to which the findings are clearly derived from the data	Reflexivity Audit trail[1] Triangulation[1]	A reflexive document will be kept, including all events that happened in the field and personal reflections

3.7 Phase 3: Intervention modelling

This final phase of work draws on the findings of the previous phases to detect the BCTs that could be combined within a complex intervention for older people, to better support the post-discharge medicines management. Intervention modelling refers to the clarification of precisely what to target through the identification of behavioural determinants and how to target it using BCTs (Michie et al. 2008).

During this phase, an in-depth understanding of the behaviours that could be targeted by the intervention, including the occasions when and the context of where they are performed, alongside their potential barriers and facilitators were elicited. This work continued to be underpinned by the TDF and closely follows methods outlined by Michie et al. (2014).

3.7.1 Objective

To use a best-evidence synthesis, combined with patient experience to design an intervention that will support post-discharge medicines management.

3.7.2 Theoretical perspective

Critical realists use the process of retroduction to help identify underlying structures and mechanisms that account for why events happen the way they do (McEvoy and Richards 2006). Phase 3 work adopted this critical realist approach, underpinned by the TDF and BCTT, to move from the level of observation and lived experience described in Phase 2, towards the development of a complex intervention targeting the underlying behavioural mechanisms.

3.7.3 Methods

The MRC guidance highlights that it is important to fully identify the evidence base and underpinning theory for successful intervention development (Craig et al. 2019). Therefore, this intervention modelling phase of work utilises the evidence base from the systematic review (Phase 1), supplemented by the interviews with older people and their carers (Phase 2), and makes reference to the relevant theory (TDF and BCTT) to identify potential behavioural

techniques or components. Whilst this process generated an evidence-based list of potential components, further stakeholder engagement was required to shape the characteristics of the intervention, identify any weaknesses and provide further refinements (Craig et al. 2019). This stakeholder engagement also allowed for consultation of the validity of the selected components (**Section 3.7.4**) i.e. the relevancy of the components and their reliability to deliver improved outcomes once in place (Boateng et al. 2018).

In Phase 2, an inductive analysis of interviews was performed as a rigorous method of identifying all important medicines management factors (McGowan et al. 2020). As a result, the data-driven generation of three themes surrounding post-discharge medicines management emerged. The initial step to model the intervention based on these empirical findings, was to consider the barriers and facilitators to patients' medicines management behaviours within the context of the chosen theory (TDF) (**Section 3.3.1**). This categorisation then allowed for the generation of a list of potential BCTs, through mapping of the TDF domains to the BCTT. Finally, expert opinion was sought for further refinement of the list and ultimately to provide valuable insight into the feasibility of implementation. Each step of the process (**Figure 13**) will now be discussed in further detail below.

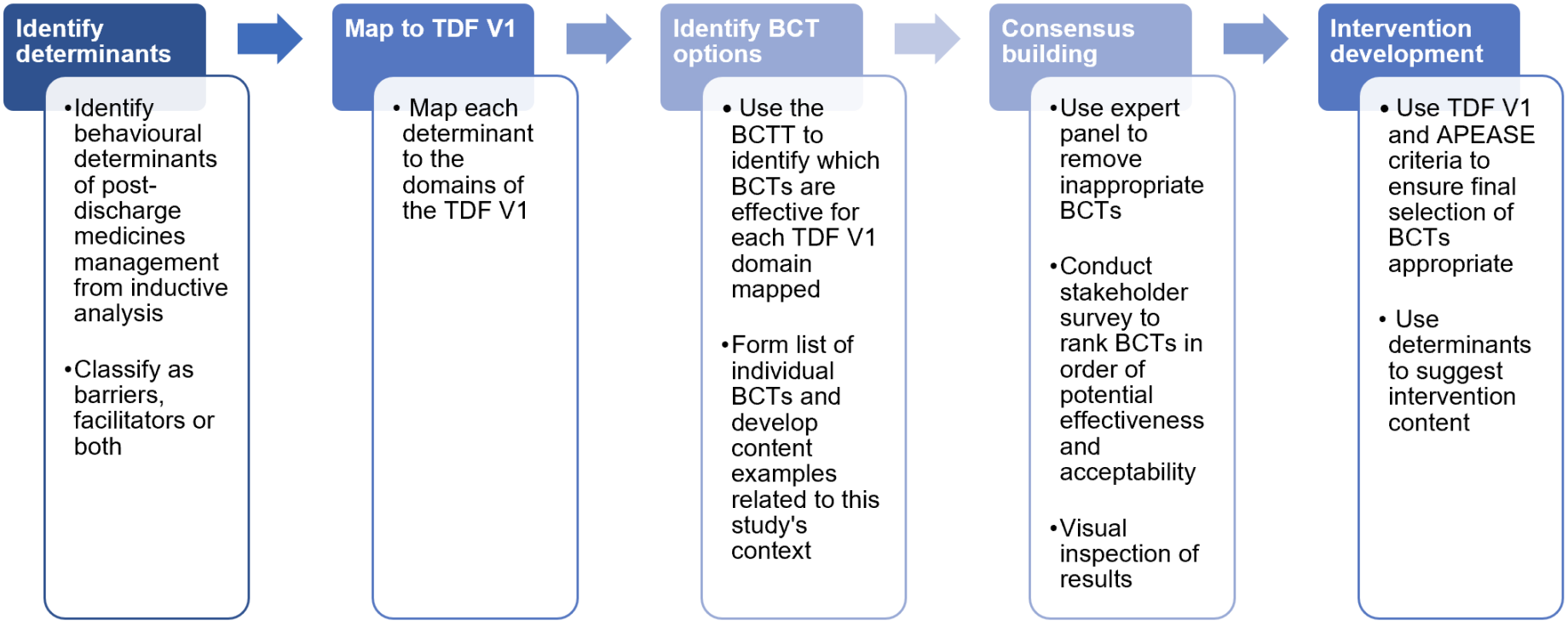


Figure 13: Phase 3 methods

Step 1: Identification of barriers and facilitators

Whilst the identification of barriers and facilitators can be carried out deductively by using the TDF domains as codes during analysis (Sinnott et al. 2015; Atkins et al. 2017; Patton et al. 2018), others have performed this in a more inductive manner (Burgess et al. 2015; Martis et al. 2018). There is a benefit to initially performing an inductive analysis, followed by consideration of how the arising themes are appropriately suited to the TDF (McGowan et al. 2020). This method facilitates more synergistic findings and makes certain that no detail is overlooked, especially for those factors that may not fit within the TDF. Therefore, to identify the barriers and facilitators, the Framework matrices from Phase 2 were scrutinised and the influencing determinants of post-discharge medicines management behaviours were identified. Each individual determinant was then reviewed in the context of the participants' experiences and categorised as either a barrier to or a facilitator of behaviour. If the determinant facilitated post-discharge medicines management for one participant, but acted as barrier for another, it was categorised as both. The domains of the TDF were reviewed in turn and each determinant mapped to the most fitting domain. Verbatim quotes were used to support this process to ensure determinants were not misrepresented. The final mapping was overseen and checked by a health psychologist with expertise in applying the TDF.

Step 2: Drafting the initial pool of BCTs

When using this method of intervention development, researchers next need to determine which are the most valuable TDF domains to target i.e. which domains will most likely bring about the necessary behaviour change (French et al. 2012; Cadogan et al. 2015). Previous studies have made these decisions through the use of frequency counts within interview transcripts (how many times each domain was coded) or which domains participants spoke about most strongly during the qualitative interviews (Cadogan et al. 2015; Patton et al. 2018). In others, the research team have decided the most prominent, or core, determinants (Glidewell et al. 2018) or likely mechanisms of action (Steinmo et al. 2016) for their intervention's focus. Since this study was not

designed to produce frequency counts and because strength of opinion is not easily interpreted from the interviews, this study, thus, followed a pragmatic approach to determine which domains, and therefore which BCTs to target within this intervention.

This meant that once all of the barriers and facilitators were established, the BCTT and its associated validated mapping exercises were used to identify the techniques which could be effective when combined within an intervention. Validated mapping of the BCTT and BCTs to the TDF exists within the literature and was relied upon for systematic and auditable selection of all possible BCTs. Michie et al.'s mapping exercise (2008) provided the primary source of information as this has the most complete mapping, followed by Cane et al.'s (2015) for additional support where there were gaps.

Each domain of the TDF that had been mapped to behavioural determinants in step 1 was taken in turn. The primary and secondary mapping exercise sources were consulted and all BCTs linked to this domain were listed. This was repeated until all BCTs had been listed for every TDF domain.

Step 3: Refining the BCT pool using consensus

Following the formation of the initial pool of BCTs, expert opinion was sought to guide the selection of the final intervention components. Boateng et al. (2018) suggest that initial pools should be at minimum two to five times as long as the desired final number of options, to make sure that the requisite margin for selection of optimum combinations of items is provided. Therefore, careful methods needed to be employed that would reliably remove less effective or non-acceptable BCTs, and prioritise those that had the potential to be beneficial in real-life practice. For successful consensus, it was decided that various sources of expertise were required (van der Weijden et al. 2019). Four stakeholder groups were considered relevant in this step: patients and family carers, HCPs, local service commissioners, and researchers working in the same field. This range of individuals was considered representative of the people who would implement and use the intervention (also known as target population judges) and those experts who could provide important insight into the final prioritisation of components (Elwyn et al. 2006; Boateng et al. 2018).

The first step of the stakeholder engagement was to build consensus around the removal of BCTs that were considered unethical, did not uphold NHS principles or values (Department of Health and Social Care 2015), or were thought to be highly unacceptable for older patients. Since the BCTs mainly originate from the field of health promotion (Michie et al. 2008) some within the initial pool were clearly not fit for purpose in this context. Due to the large number of BCTs requiring review in the initial pool, a pragmatic decision was made to form a 'power panel' of six experts (Glidewell et al. 2018) who discussed all of the BCTs and identified those to remove. The experts included: a hospital and primary care Consultant Pharmacist for Older People, a community pharmacist, a social work academic, an older patient, and two health services researchers with experience in this topic. Each expert was asked to individually review the BCTs and consider them in light of the research context and findings from Phase 1. A group meeting was then held where panel members were asked to express their views about the suitability of each BCT for continued inclusion. Where views differed, the panel reached a consensus through discussion.

After the removal of these inappropriate BCTs, a partially refined list was explored in more detail. Here, wider consensus was sought from the full range of stakeholders, to rank and prioritise the remaining BCTs in terms of their acceptability and effectiveness. There are many ways to gather stakeholder consensus, for example through online Delphi processes where options are ranked in iterative rounds (Elwyn et al. 2006; Steinmo et al. 2016), face to face meetings where ideas are presented for critical assessment (van der Weijden et al. 2019) or survey (Boateng et al. 2018). Given time and resources constraints, this step of intervention modelling needed to affirm content validity of the BCTs quickly and robustly. Hence, a survey design was chosen.

To achieve authentic content validity, the BCTs, which were generically presented and rather abstract, needed to be unambiguously described with appropriate definitions (Guion 1977). Therefore, each BCT was allocated a relevant example, with regard for this study's context, developed by the panel.

Two examples were:

BCT 1: Information regarding behaviour, outcome

Example: Provide the patient with written or verbal information e.g. provide information about their medicines management responsibilities after hospital discharge, or when/ how to get help if a problem is identified.

BCT 19: Homework

Example: Set homework tasks e.g. via buddy or peer support who could check with the patient to see how they have got on with medicines management tasks.

To prioritise the BCTs, certain factors needed to be evaluated. As a way to consider all relevant criteria, Michie et al. (2014) advise the use of the APEASE criteria when developing interventions. These are: acceptability to key stakeholders, practicability in implementation, effectiveness, affordability, how far it leads to unintended adverse outcomes, and equity (Michie et al. 2014). As a first step towards consensus of the final components, the decision was made to ask the stakeholders to consider only potential effectiveness, acceptability and whether any unintended adverse outcomes could result. This was a pragmatic choice to ensure that stakeholder respondents remained engaged throughout the process and did not fatigue when completing the consensus exercise.

To this end an online survey was created using Google Forms, which asked respondents to determine if each BCT:

1. Could be effective in promoting medicines management in older people?

2. Would be an acceptable method to older patients?

3. Could lead to any unintended adverse effects for patients (such as unintentional non-adherence, confusion, poor quality of life)?

This survey (**Appendix 7**) was piloted with five colleagues (two pharmacists, one administrator and two health services researchers) who had not been involved in the study design. Their feedback (**Table 13**) highlighted concerns and areas for improvement. Once reworked, the survey link was emailed to a convenience sample of 40 stakeholders. Respondents were also asked to forward the survey link to any colleagues whom they felt were in a position to answer the survey.

Since this step of consensus aimed to further remove any remaining ineffective or unacceptable BCTs and was focused on content validity, no sample size calculations were performed, as statistical reliability was not deemed important. A pragmatic target response rate of 25 completed surveys was considered appropriate for this aim. A reminder was sent after two weeks. No demographic details were collected from participants.

Once the survey had closed, responses were collated into a spreadsheet and analysed using Microsoft Excel. Total scores were calculated: each BCT received a point for each respondent rating it as i) effective, ii) acceptable, and iii) avoiding unwanted effects. Each BCT could score a maximum of three points per respondent. Total scores were tabulated across all BCTs and they were ranked in order.

Table 13: Feedback from survey pilot

Feedback from colleagues	Survey changes
Introduction is very long and small font size	Separated some content into a personalised email, reducing the amount of text on the first page. Font size could not be changed due to website restrictions
I wanted to write some reasoning for my answer	Optional response box added for each BCT in case participant wants to offer further comments
Could you add an 'unknown' option alongside yes/ no	This would not be helpful in this exercise. Qualitative box would allow further explanation if needed
I am interested in the BCTT, could you provide me with a reference	Link to BCT work at University College London by Michie et al. added to end of survey
There are too many BCTs to rate; time to complete 16 min – 60 min. This may affect response rate.	Formed panel to remove any BCTs that were not relevant. This reduced number of BCTs to 35
Could you include a couple of practice questions	The survey is already lengthy, need to be cautious about adding in further questions
I did not really know what unintended adverse effects were, could you give examples?	Examples offered in introduction (such as unintentional non-adherence, confusion, poor quality of life)
Some BCTs are difficult to understand (3, 4, 15, 16, 38 and 41). BCT 46 and 47 look the same.	BCT 4, 16 and 41 removed by panel. BCTs 3, 15, 38, 46 and 47 modified
Some BCTs are very similar and are presented in categories of similar BCTs – this negatively affected my concentration and engagement	BCTs were shuffled

Step 4: Final analysis and refinement

To select and model the final set of components, a last stage of analysis was completed. Starting with the BCTs that scored the most points from the stakeholder consensus survey, reverse mapping of the BCTs to the TDF domains was conducted, once again using the primary and secondary mapping sources. Each BCT was taken in turn and the TDF domains that it targets were listed, making sure to capture all domains as the BCTs often span multiple. For example, the BCT 'rehearsal' maps not only to the TDF domain skills, but also to that of beliefs about capabilities. In this way, the number of BCTs required to target all of the TDF domains mapped in step 1 could be ascertained. This backwards mapping, along with visual inspection of the tabulated scores from step 3, were used by the expert panel to determine the final selection of BCTs.

To ensure further validity and refinement of this final component selection, the highest scoring BCTs were judged against each of the APEASE criteria. These criteria prompted the consideration of important implementation factors, including: acceptability to the target audience, practicalities of delivery, likely effectiveness, affordability when scaled up, potential side effects or unintended consequences, and equity (Michie et al. 2014). The expert panel members were asked to give their opinions about the APEASE criteria for each of the highest scoring BCTs during a group discussion. The panel were asked to reflect on the criteria in light of: their knowledge and experience of healthcare practice, the results from Phase 1 which identified the common effective components within trialled interventions as well as how they had been operationalised, and other published literature focusing on the application of each BCT within healthcare interventions. All points of view were considered valid, documented, and each criteria was rated collectively by the panel as 'yes' or 'no', or 'yes and no' where it depended on the final content of the BCT or the context of the setting.

Finally, content examples were generated for each BCT that would target the original behavioural determinants identified within step 1. Initial examples were generated by the researcher, then reviewed jointly by the expert panel and

adapted through discussion. This resulted in a table illustrating the determinants of post-discharge medicines management behaviour, mapped to the relevant TDF domains and BCTs, as well as examples of how that BCT could be operationalised within a complex intervention for older people and their carers.

3.7.4 Research governance

The work performed in this phase was deemed to be consultation by the Sponsor and not primary research, consequently no ethical approval was required.

3.7.5 Quality criteria

This phase of the study answers questions of whether the components of the intervention are theoretically valid and whether they are relevant in the real world. Therefore, the concepts of content and face validity were valuable here and helped to ascertain whether the study was conducted reliably.

Previous studies have determined which TDF domains to focus their intervention design towards, based on author decision (Glidewell et al. 2018) or interview content (Cadogan et al. 2015). This may have led to a prioritisation of incorrect domains. This was not a limitation in this current study, however, because all TDF domains were considered as a target for the intervention from the outset. Whilst the identified BCTs were considered theoretically sound on the basis that they stemmed from validated sources, and the work was performed in conjunction with a health psychologist, face validity further tested whether the individual components were applicable and realistic within the real world. In order to do this reliably, stakeholders who would use and deliver the BCTs in practice were sought and invited to rank them. These individuals were experts by experience and were well placed to make trustworthy judgements about whether the content was acceptable and valid in the context of current healthcare. The ‘power panel’ was also employed to make collaborative judgements about the face validity of the final selection of the BCTs using the APEASE criteria.

In order to avoid any bias within the stakeholder survey, work was completed to standardise the BCTs, guaranteeing that they were presented and assessed in a similar way. Care was also taken to ensure that all descriptions were of equal value.

3.8 Overall study output

The final output of this study will be recommendations for an acceptable multi-component intervention which will help older patients better manage their medicines at home after discharge. These recommendations will be underpinned by best evidence derived from patient experience, current published knowledge, and theory. Whilst this process did not allow for a full definition of the intervention to be developed, it did reveal potentially effective and acceptable delivery mechanisms (Steinmo et al. 2016).

3.9 Patient and public involvement

As described in **Section 3.4.4**, this study has been extensively informed through consultation and collaborative work with older patients and their family carers. Due to the immense value of working with the PCLSG, specific changes to the research design resulting from direct discussions with users and carers have been earnestly highlighted throughout this thesis.

Following on from the initial two workshops (**Section 2.8.2**), the PCLSG have continued their contribution throughout this study and have become widely involved. All members have attended quarterly workshops which have positively assisted project development and management. **Table 14** lists the activities that the PCLSG have been involved in and how their input has assisted the researcher.

Table 14: PCLSG involvement and engagement

Co-design Activities	Involvement Activities
Developing documents: Participant information sheet Consent form Diary tool Reminders (for interviews and diary entries)	• Consideration of how to present information and what to include • Ensuring documents are understandable, easy to read and complete • Review and feedback on versions • Piloting of diary for usability
Discussions: Ethical considerations Recruitment challenges	• Highlighting considerations that may have been overlooked otherwise e.g. burden of completing interviews • Helping to understand why challenges are present and to identify possible solutions
Defining terminology: Interview topic guide development	• Ensuring that interview questions are fit for purpose, unambiguous and free of jargon
Role play: Recruitment scenarios Interviews	• Building researcher confidence • Consideration of what to say and how to say it
Data collection: Patient safety incident rating Intervention modelling	• Working as part of an expert panel
Data analysis: Reflections and interpretations of four interviews	• Voicing interpretations from their own lived experiences • Identifying new ideas for further exploration
Dissemination activity: Newsletter Winter 2018 design Newsletter Summer 2019 design Preparing results flyer for dissemination to participants	• Developing content • Ensuring design and format is appropriate for the target audience • Writing about their experiences

3.10 Chapter summary

This chapter has described the three phases of work that have been conducted in order to meet the study's aims. The philosophical stance and theoretical assumptions underpinning each phase have been presented and made clear, along with the quality criteria by which this study should be judged. This study has employed a number of data collection and analysis methods, including systematic review and meta-analysis, semi-structured interviews, primary care data extraction, rating of PSIs, and theory-driven intervention development with stakeholders. The synthesis of the literature identified within Phase 1 and patient participant experience gathered through interview as well as primary care data extraction from Phase 2, helped inform and underpin the intervention modelling that took place in Phase 3. These sequential, mixed methods ensured that the selection of the intervention components was grounded in the lived experience and underpinned by best evidence, which is of value in effective complex intervention design. In the following chapters, **4** describes the work conducted during the critical literature review, including the meta-analysis and theory-based analysis (Phase 1), **Chapter 5** presents the findings of the qualitative interviews (Phase 2), and finally **Chapter 6** describes Phase 3 intervention design work, including consensus building.

Chapter 4: Identifying the existing evidence; a systematic review and theory-based analysis of the effects of interventions that support care transitions through enhanced post-discharge medicines management

This chapter presents the findings from work in Phase 1 as described in **Section 3.5**. The results of the systematic review and the meta-analysis of interventions to support post-discharge medicines management for older people are presented. The findings have been published in the peer-reviewed journal Age and Ageing (Tomlinson et al. 2020a), featured in an editorial (Cardwell 2020) and reviewed in an evidence-based medicine verdict of the British Medical Journal (Collins 2020). A further theory-based analysis was also performed, involving the mapping of intervention components to the Behaviour Change Technique Taxonomy (BCTT) (Michie et al. 2013) and the Theoretical Domains Framework (TDF V1) (Michie et al. 2005). The theory-based analysis has been drafted into a manuscript and is currently undergoing peer-review by BMC Health Services Research.

4.1 Introduction

As outlined in **Chapter 2**, medicines management processes and behaviours support safe and effective medicines use. Medication-related problems and interruptions to, or discontinuity of, medicines management occur frequently when older patients are discharged from hospital (Coleman 2003; Arora et al. 2010; Garcia-Caballos et al. 2010; Knight et al. 2013). This can lead to hospital readmission and poorer quality of life (Ahmad et al. 2014; Parekh et al. 2018a). Enhancing medication safety, is, thus a crucial element for successful healthcare transitions (Burke et al. 2013).

A previous systematic review of interventions that support medication continuity (Spinewine et al. 2013) indicated that patient education at discharge reduced the risk of adverse medication-related events, although the authors concluded that the evidence remained limited. A more recent American meta-

analysis further highlighted the value of pharmacy-supported interventions, particularly those involving patient-centred follow-up, in reducing hospital readmissions (Rodrigues et al. 2017). However, neither of these studies evaluated the effectiveness of those interventions delivered specifically to older populations, whose medicines experiences are different to the general public, due to multi-morbidity, polypharmacy, and access to services. These reviews also failed to explore the mechanisms of action within interventions, namely how and why they work and in which context.

Other systematic reviews have identified discharge interventions that reduce negative patient outcomes. However, their focus was broader than medicines (Hansen et al. 2011; Leppin et al. 2014). This current review builds on previous knowledge through the evaluation of interventions aimed at supporting successful transitions of care for older patients by enhancing post-discharge medicines management. To further explore the interventions' mechanisms of action, a secondary theory-based analysis of the included trials was completed using the TDF V1. This action increases current understanding of how and why interventions exert their effects on medicines management behaviours.

The methods for this review are fully reported in **Section 3.5.3**.

4.2 Study selection

The search identified 2394 unique citations. A total of 2278 were excluded following title and abstract review. Full-text publications were assessed for 116 studies, resulting in 24 meeting the selection criteria. Reasons for exclusion are presented in **Figure 14**. Full-text manuscripts were not available for two studies, despite contacting the respective authors. Consensus between reviewers was 94% with no studies excluded after discussion.

4.3 Study characteristics

The studies selected for review were conducted in 12 countries covering a range of public and privately-funded healthcare systems (**Appendix 8** details the full study characteristics): Australia (Basger et al. 2015; Tong et al. 2017), Northern Ireland (Bolas et al. 2004; Scullin et al. 2007), Canada (Lalonde et al. 2008; Tamblyn et al. 2019), France (Legrain et al. 2011), the Netherlands

(Ahmad et al. 2012; Buurman et al. 2016), Denmark (Ravn-Nielsen et al. 2018; Graabæk et al. 2019), Spain (Casas et al. 2006), USA (Coleman et al. 2006; Koehler et al. 2009; Gurwitz et al. 2014; Chan et al. 2015; Haag et al. 2016; Tuttle et al. 2018), Sweden (Gillespie et al. 2009), Taiwan (Huang and Liang 2005), Singapore (Lee et al. 2015; Char et al. 2017), and England (Holland et al. 2005; Hockly et al. 2018). Randomisation was by individual (n=21), or by cluster of hospital ward or community pharmacy (n=3) (Ahmad et al. 2012; Tong et al. 2017; Tamblyn et al. 2019). A total of 17,664 participants were enrolled (range from 25 participants (Haag et al. 2016) to 4656 participants (Tamblyn et al. 2019)) and the samples' mean ages ranged from 66 years old (Chan et al. 2015; Hockly et al. 2018) to 86 years old (Gillespie et al. 2009).

Nine studies described interventions provided during hospital admission (Bolas et al. 2004; Scullin et al. 2007; Lalonde et al. 2008; Legrain et al. 2011; Basger et al. 2015; Tong et al. 2017; Hockly et al. 2018; Graabæk et al. 2019; Tamblyn et al. 2019), seven of which were delivered by the inpatient pharmacy team and one by geriatricians (Legrain et al. 2011). One involved an electronic intervention (Tamblyn et al. 2019). Intervention components were most often delivered once during the inpatient stay.

A further nine interventions were commenced during admission and continued post-discharge, bridging the hospital to home transition (Huang and Liang 2005; Casas et al. 2006; Coleman et al. 2006; Gillespie et al. 2009; Koehler et al. 2009; Chan et al. 2015; Lee et al. 2015; Buurman et al. 2016; Ravn-Nielsen et al. 2018). Five of these involved nurse-delivered interventions, who were sometimes acting as 'transition coaches' to facilitate the patient's role in self-care. Three were pharmacist-led (Gillespie et al. 2009; Koehler et al. 2009; Ravn-Nielsen et al. 2018) and one was multi-disciplinary (Lee et al. 2015).

A further six studies evaluated interventions that commenced post-discharge (Holland et al. 2005; Ahmad et al. 2012; Gurwitz et al. 2014; Haag et al. 2016; Char et al. 2017; Tuttle et al. 2018), of which five were delivered by pharmacists. One study (Gurwitz et al. 2014) involved automatic electronic transfer of patient information to the primary care provider. Overall, intervention delivery ranged from a single time point to 12 months post-

discharge. The most intensive activity period was between discharge and three months post-discharge.

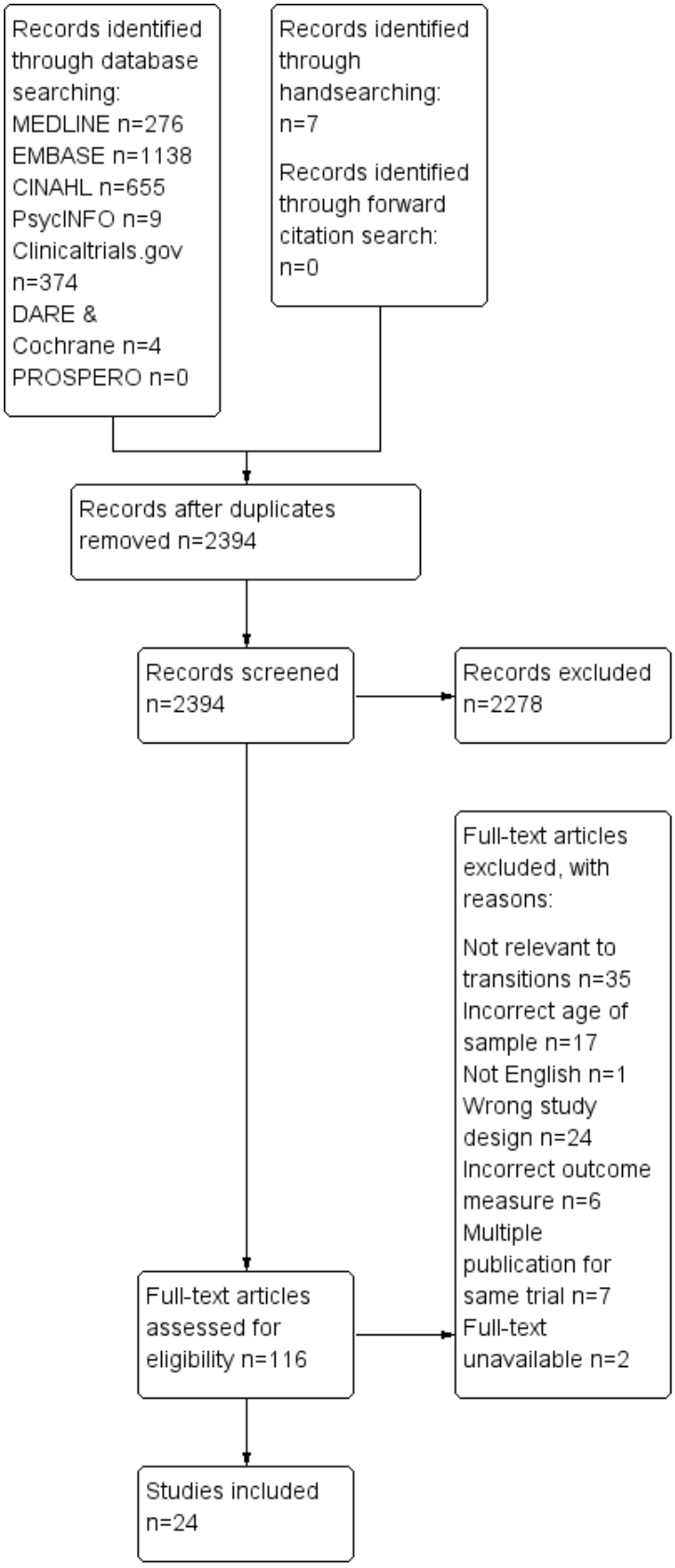


Figure 14: PRISMA flowchart illustrating study selection, inclusion and exclusion, reproduced from Tomlinson et al. (2020a) under the Creative Commons CC BY NC licence ©Oxford University Press

4.4 Risk of bias assessment

In accordance with Cochrane guidance (The Cochrane Collaboration 2015), all studies were assessed for high or low risk of bias within each of five domains (performance bias was not assessed as it was considered impractical to blind participants and delivery staff in interventions of this type). Whilst previous reviews have reported some domains as 'unclear risk', this was avoided within this study since an 'unclear' risk is not of value when assimilating results. If studies did not report on a particular domain, then it was assumed (conservatively) that a high risk of bias was present. Twelve studies scored low in all five risk of bias domains (Holland et al. 2005; Gillespie et al. 2009; Koehler et al. 2009; Legrain et al. 2011; Gurwitz et al. 2014; Lee et al. 2015; Haag et al. 2016; Char et al. 2017; Ravn-Nielsen et al. 2018; Tuttle et al. 2018; Graabæk et al. 2019; Tamblyn et al. 2019) (**Figure 15**). Nine studies were rated as having the highest risk of bias based on their randomisation and allocation concealment methods (Bolas et al. 2004; Huang and Liang 2005; Casas et al. 2006; Coleman et al. 2006; Scullin et al. 2007; Ahmad et al. 2012; Basger et al. 2015; Chan et al. 2015; Hockly et al. 2018).

4.4.1 Random sequence generation

Twenty-one studies reported using an appropriate method for generating a random sequence. Using specialist computer programmes and websites to produce the sequence in blocks of varying lengths (Bolas et al. 2004; Holland et al. 2005; Koehler et al. 2009; Buurman et al. 2016; Tuttle et al. 2018) or engaging a clinical trials unit (Gillespie et al. 2009) were both popular methods. Three studies did not describe how their sequence was generated and thus scored a high risk of bias for this domain (Ahmad et al. 2012; Basger et al. 2015; Chan et al. 2015).

4.4.2 Allocation concealment

Many studies used a closed, opaque envelope technique to ensure that group allocation was concealed until the point of randomisation (Koehler et al. 2009; Basger et al. 2015; Haag et al. 2016; Char et al. 2017). One study used a third-

party telephone service to ensure that bias was not present (Holland et al. 2005). Studies that scored a high risk of bias did not describe the methods for concealing their randomisation sequence.

4.4.3 Blinding of outcome assessment

High risk of bias was found mainly in the blinding of the outcome assessment domain (n=7 studies). This occurred mostly because researchers were aware of which group the participants were allocated to when collecting the outcome measures (Bolas et al. 2004; Huang and Liang 2005; Scullin et al. 2007; Tong et al. 2017). Some outcome measures were, however, collected via electronic reporting systems to reduce detection bias (Holland et al. 2005; Coleman et al. 2006; Gillespie et al. 2009; Koehler et al. 2009).

4.4.4 Incomplete outcome data

One study reported missing medication discrepancy data for 18 participants (21.7%) (Lalonde et al. 2008). They were also unable to follow-up six patients for self-reported measures and did not report which arm they were randomised to. This may have introduced attrition bias. All other studies accounted for their participants and all had less than 10% difference in attrition between arms.

4.4.5 Selective reporting

Two studies reported a range of outcome measures within their protocols (Ahmad et al. 2010; Buurman et al. 2010) but did not report full findings in their manuscripts. This is considered a reporting bias.

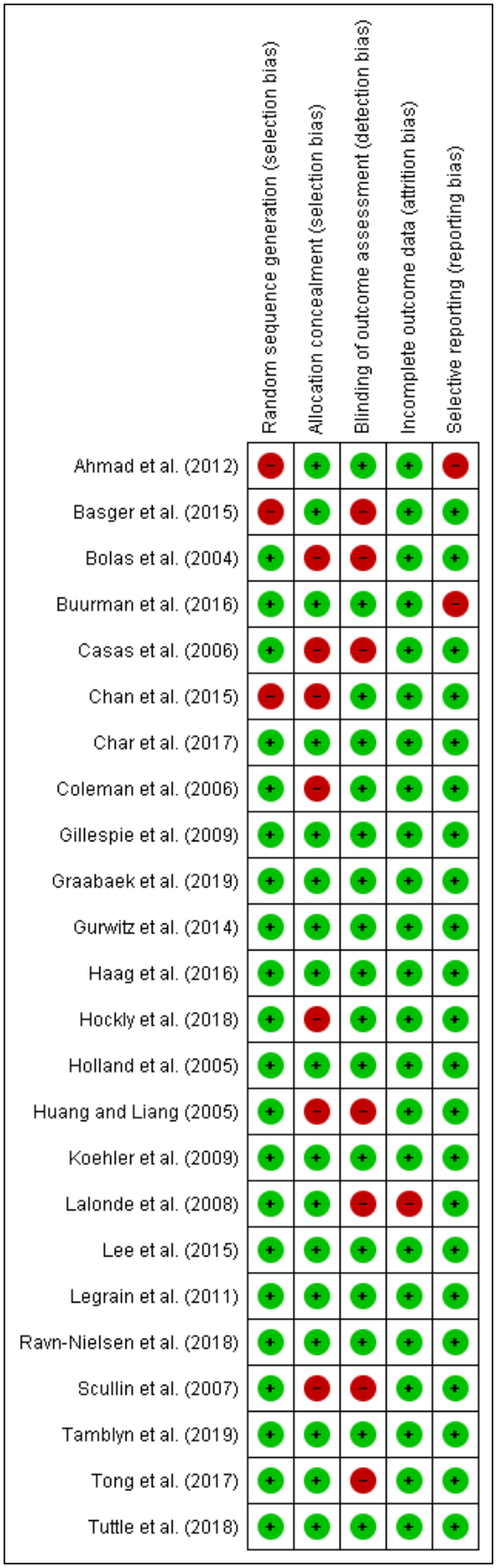


Figure 15: Risk of Bias assessment summary, reproduced from Tomlinson et al. (2020a) under the Creative Commons CC BY NC licence ©Oxford University Press

4.5 Narrative findings

Appendix 8 summarises the medication-related activity components coded within each study using the adapted taxonomy (see **Section 3.5.4**). Inter-rater agreement was high (77%). Where there was disagreement, the reviewers discussed the study with reference to verbatim quotes and protocols until consensus was agreed.

Studies used varying numbers and combinations of activities within intervention bundles. Most studies utilised three or more activities (mean = 4.6; range 1 to 8). Three studies involved single-component interventions (Gurwitz et al. 2014; Tong et al. 2017; Hockly et al. 2018). The range in times from discharge to first post-discharge activity was two days to two months.

4.5.1 Interventions offered during hospital admission

Appendix 8 shows that the most commonly reported activities were patient education (n=5; 56%), MR (n=6; 67%), provision of patient-centred documentation (n=4; 66%) and timely cross-sector communication (n=7; 78%). Two studies showed a reduction in hospital readmissions (Scullin et al. 2007; Legrain et al. 2011) whilst Basger et al. (2015) demonstrated a statistically significant difference within the vitality domain of the SF-36 (health-related quality of life). All three of these interventions included medication review and reconciliation, patient education and transfer of information. However, only Legrain et al.'s study (2011) was considered to have a low risk of bias. Discrepancies in medicines were reduced by Hockly et al.'s intervention (2018) requiring transfer of discharge information ($p<0.01$), Tamblyn et al.'s (2019) MR intervention (OR 0.24; CI 0.12-0.57) and Bolas et al.'s (2004) intervention ($p<0.005$) involving patient education and a personalised medication sheet. Only Tamblyn et al.'s study (2019) was considered to be high quality, with the other studies having selection or detection biases.

4.5.2 Interventions commenced during hospital admission and including continuing support post-discharge

The most widely used activity was patient education (n=9; 100%) (**Appendix 8**). Three studies provided education once: Casas et al. (2006) provided a two-hour educational programme at discharge; Huang et al. (2005) a medication safety information brochure; and Ravn-Nielsen et al. (2018) used a 30-minute motivational interview. Two studies utilised 'transition coaches' to deliver education throughout the period of follow-up (Coleman et al. 2006; Buurman et al. 2016). Three studies provided education at admission and discharge using pharmacists (advising on medication changes) or nurses (to advise on treatment of chronic conditions) (Gillespie et al. 2009; Koehler et al. 2009; Lee et al. 2015). One study (Chan et al. 2015) provided disease-specific education in the participants' native language. Medicines reconciliation (n=7; 78%) and patient-centred discharge documentation (n=5; 63%) (such as a 'personal health record' containing medicines information (Coleman et al. 2006)) were also used. Post-discharge telephone calls (n=5) were conducted more frequently than home visits (n=1) to provide reinforcement of self-management (Casas et al. 2006; Coleman et al. 2006), further education (Huang and Liang 2005; Koehler et al. 2009; Chan et al. 2015; Ravn-Nielsen et al. 2018) and assessment of the level of adherence (Gillespie et al. 2009; Lee et al. 2015). Three studies (Huang and Liang 2005; Coleman et al. 2006; Lee et al. 2015) used both methods, conducting a home visit within the first week post-discharge and subsequent weekly telephone calls.

Five of these studies demonstrated a statistically significant reduction in all-cause hospital readmissions (Huang and Liang 2005; Casas et al. 2006; Coleman et al. 2006; Koehler et al. 2009; Ravn-Nielsen et al. 2018). All included follow-up (telephone, home visit or both) and education, which continued for between seven (Koehler et al. 2009) and 180 days post-discharge (Ravn-Nielsen et al. 2018). Four of these studies (Huang and Liang 2005; Casas et al. 2006; Coleman et al. 2006; Chan et al. 2015) were considered to be at the highest risk of bias because allocation was not concealed, or outcome assessors were not blinded. Chan et al. (2015) did not

find any difference between arms using the Care Transitions Measure (CTM-3), which assesses the quality of the transitional care experience (p=0.18). However, Huang et al. (2005) found a greater improvement in the SF-36 measure within their intervention arm (I:+18.6 vs C:+15.3; p<0.001).

4.5.3 Interventions commenced post-discharge

Most post-discharge interventions were provided by pharmacy staff (n=5): community pharmacists (Ahmad et al. 2012); outpatient polyclinic pharmacists (Char et al. 2017); and trained intervention pharmacists (Holland et al. 2005; Haag et al. 2016; Tuttle et al. 2018). **Appendix 8** shows that reconciliation and review were provided in most of the intervention bundles (n=4; 66%). Home visits (n=4) were conducted more frequently than telephone calls (n=1).

Of the six interventions, none showed a statistically significant reduction in hospital readmission and all were considered to be high quality. Holland et al. (2005) demonstrated a 30% increase in readmission rates (p=0.009) in their intervention arm, involving review and education, and a decrease in EQ-5D scores (I: -7.36 vs C: -3.24; p=0.042). Other studies reported a reduction in medication-related problems (Ahmad et al. 2012), though not statistically significant, and improvement in medication discrepancies by using pharmacists for post-discharge review or reconciliation (p<0.001) (Char et al. 2017).

4.6 Meta-analysis

As described in **Section 3.5.4**, nineteen studies reported hospital readmission data and were, therefore, combined using meta-analysis. One could not be included (Bolas et al. 2004) as the results were reported in a way that did not allow calculation of RR. Significant variability across studies was observed (I^2 = 70%). The meta-analysis, stratified by component, showed a modest overall effect size (RR 0.91 [0.87, 0.95]) and demonstrated that the activities associated with reduced hospital readmissions were self-management education or coaching (RR 0.81 [0.74, 0.89]), telephone follow-up (RR 0.84 [0.73, 0.97]) and MR (RR 0.88 [0.81, 0.96]), as shown by the Forest plot (**Figure 16**). Other components that were close to statistical significance were

patient-centred discharge documents (RR 0.85 [0.70, 1.02]), timely cross sector communication (RR 0.90 [0.79, 1.02]), and education (RR 0.91 [0.80, 1.03]. There was no evidence of publication bias (**Figure 17**).

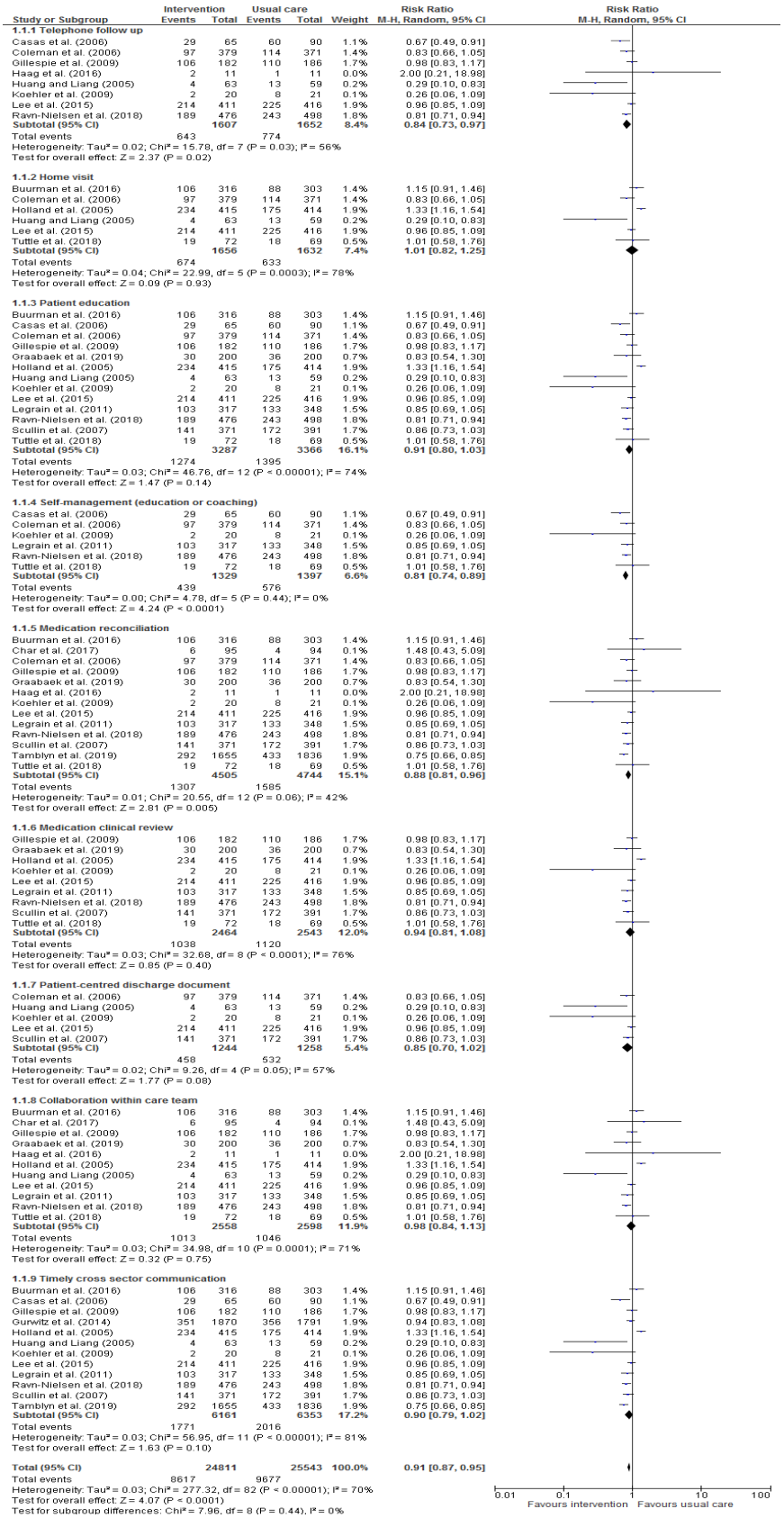


Figure 16: Forest plot illustrating meta-analysis stratified by intervention component, reproduced from Tomlinson et al. (2020a) under the Creative Commons CC BY NC licence ©Oxford University Press

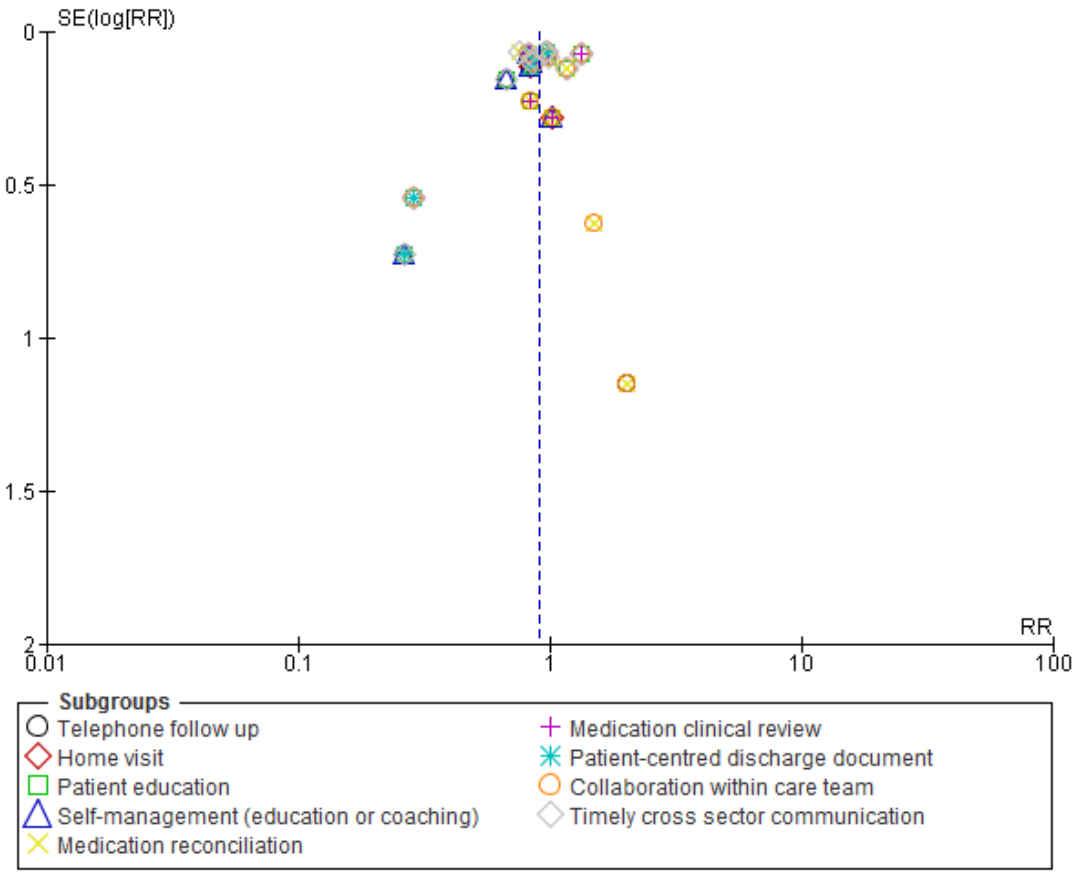


Figure 17: Funnel Plot for the detection of publication bias, reproduced from Tomlinson et al. (2020a) under the Creative Commons CC BY NC licence ©Oxford University Press

4.7 Theory-based analysis

To complement the evaluation of effect size, further theory-based analysis was completed to gain an understanding of how these interventions might work. The results are presented here.

Most interventions focused on behaviour change from the patient and HCP perspectives. Three studies (Gurwitz et al. 2014; Hockly et al. 2018; Tamblyn et al. 2019) focused only on HCP behaviours and used the fewest BCTs (three per intervention). Coleman et al. (2006) was the only study that focused solely on patient behaviours (21 BCTs within intervention).

Due to the heterogeneity of the studies, direct comparison of outcome measures was not possible. This made it particularly challenging to ascertain effectiveness linked to particular BCTs, individual TDF domains and medicines

management. It was, however, still possible to identify commonalities between interventions in terms of components.

4.7.1 Mapping of interventions to the BCTT

Figure 18 presents all studies' individual interventional components mapped to the BCTT. A total of 49 individual BCTs (53%; n=49/93) from across 14 of the 16 BCTT groupings were identified within the 24 studies. The majority of BCTs were aimed at changing either patient behaviours (n=49) or both patient and HCP behaviours simultaneously (n=40). The studies that utilised the most distinct BCTs were Ravn-Nielsen et al. (2018) (n=45), Ahmad et al. (2012) (n=44) and Chan et al. (2015) (n=39) the majority of which targeted patient behaviours. All three of these studies made use of motivational interviewing, a multifaceted behaviour change technique, which accounts for the large number of BCTs. In contrast, the interventions that used the least number of techniques were Hockly et al. (2018) (n=3), Tamblyn et al. (2019) (n=3), Gurwitz et al. (2014) (n=3), Tong et al. (2017) (n=7), and Char et al. (2017) (n=9). These tended to be less complex interventions, focusing solely on information transfer between care providers (Gurwitz et al. 2014; Tong et al. 2017; Hockly et al. 2018) or MR (Char et al. 2017; Tamblyn et al. 2019).

The most popular techniques amongst all interventions were those grouped within the 'goals and planning' section of the BCTT (**Figure 19**). This group generally describes techniques focused on setting, reviewing and solving the issues around goals.

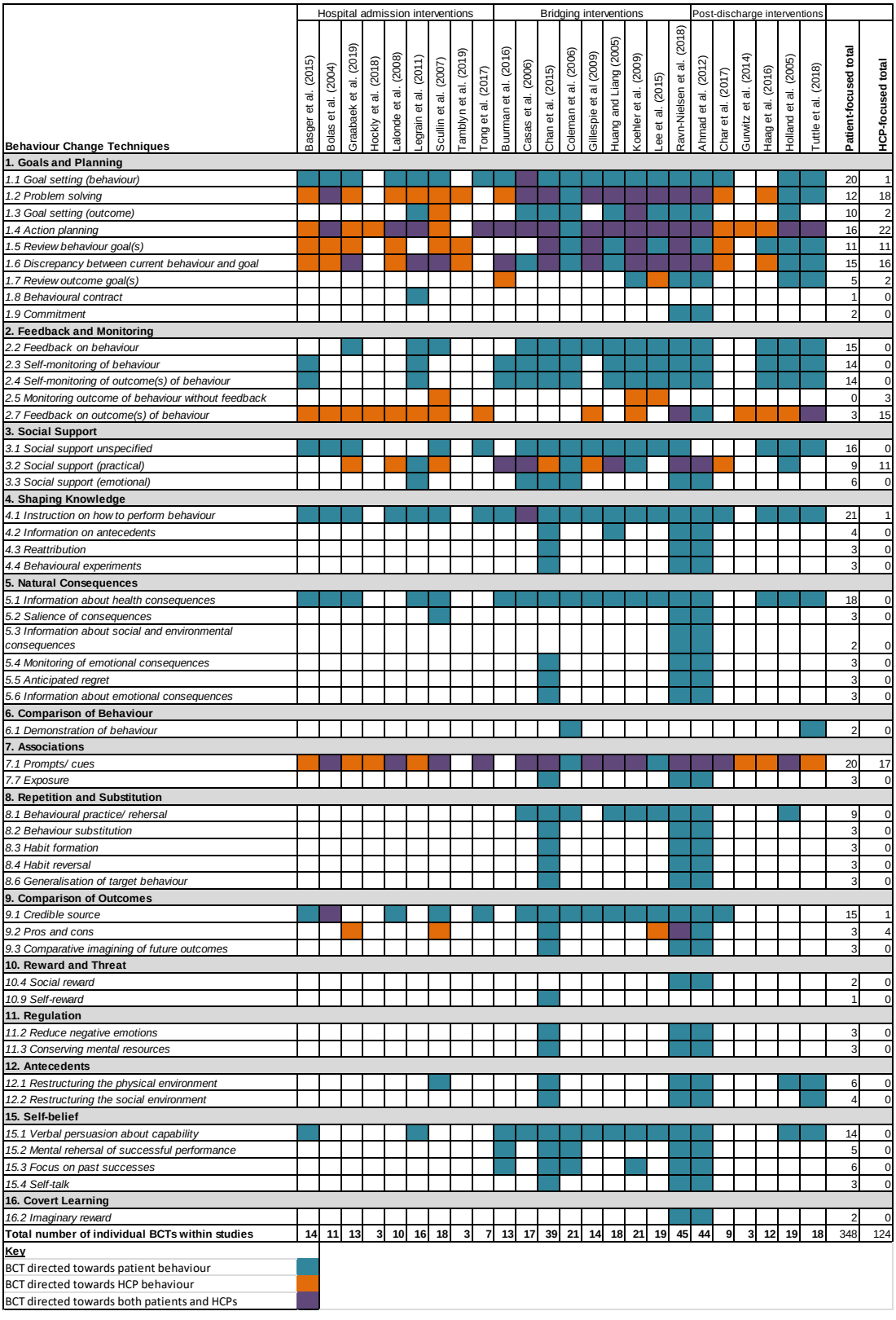


Figure 18: Study interventional components mapped to the BCTT

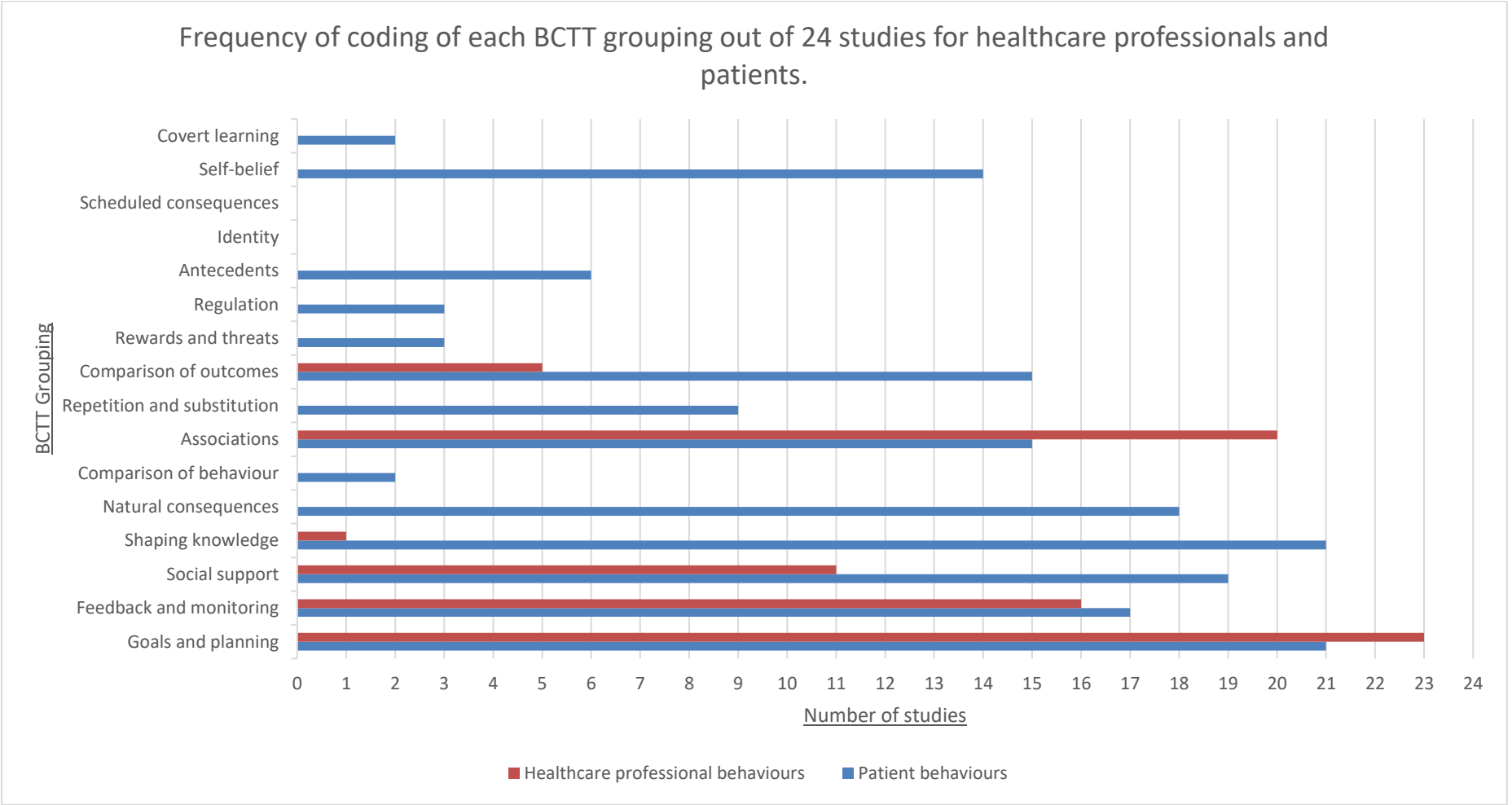


Figure 19: Frequency of BCT coding

Feedback and monitoring techniques and social support techniques were also well represented within the interventions. These techniques focused on the ongoing monitoring and review of behaviours and outcomes, with or without the patient. Those interventions that focused on feedback and monitoring primarily targeted patient behaviours, with only two studies focusing on both patient and HCP behaviours (Ravn-Nielsen et al. 2018; Tuttle et al. 2018). Ravn-Nielsen et al.'s intervention (2018) offered the patient feedback on outcomes of behaviour during a 30-minute motivational interview at discharge, which included education and self-management coaching. They also communicated outcomes verbally to the physician when problems were identified and transferred information to the primary care provider. Tuttle et al. (2018) similarly provided feedback on these outcomes to the medication prescriber and offered support to patients by reviewing their self-management strategies.

Those interventions focusing on HCP behaviours predominantly used feedback on outcomes of behaviour. Interventions facilitated this activity mainly through the transfer of discharge information between care providers to alert them to medication changes, which then prompted action (Bolas et al. 2004; Gillespie et al. 2009; Basger et al. 2015; Chan et al. 2015). Three interventions monitored outcomes without offering feedback to the patient (Scullin et al. 2007; Koehler et al. 2009; Lee et al. 2015). This was most often via medication review where monitoring of therapeutic goals was conducted without patient involvement. For those studies focusing on patient behaviours, the majority used feedback on the behaviour (n=15), self-monitoring of the behaviour (n=14) and self-monitoring of outcome (n=14).

Social support can be coded as practical, emotional or unspecified within the BCTT. Although most interventions mentioned techniques linked to social support, many (n=16) did not specify which type of support was provided, although all of them targeted patient behaviours. Most specified support (n=9) was practical; six BCTs targeted HCP behaviours, four targeted patient behaviours, and five targeted both. Examples of practical support for HCPs included collaboration between hospital physicians and GPs (Huang and Liang 2005), and hospital pharmacies communicating with community

pharmacies to resolve prescription issues (Chan et al. 2015). Practical support for patients, for example, involved self-management educational programmes with assessment of medication administration technique (Casas et al. 2006), adherence support (Ahmad et al. 2012) and home visits that promoted self-management (Coleman et al. 2006). Only six interventions targeted emotional support for the patient (Casas et al. 2006; Coleman et al. 2006; Legrain et al. 2011; Ahmad et al. 2012; Chan et al. 2015; Ravn-Nielsen et al. 2018).

Another four well utilised techniques were: instruction on how to perform the behaviour (shaping knowledge); information about health consequences (natural consequences); prompts and cues (associations); and presenting verbal or visual communication from a credible source in favour of or against the behaviour (comparison of outcomes). The remainder of the techniques were used sparingly (**Figure 18**) and two of the BCT groupings (scheduled consequences and identity) were not identified within the interventions reviewed (**Figure 19**).

4.7.2 Mapping of the BCTT to the TDF

Five interventions included components that encompassed all domains of the TDF (Holland et al. 2005; Ahmad et al. 2012; Chan et al. 2015; Ravn-Nielsen et al. 2018; Tuttle et al. 2018). Most of the others utilised between 7 and 10 of the domains (**Figure 20**). The three simplest interventions that focused only on HCP behaviours (Gurwitz et al. 2014; Hockly et al. 2018; Tamblyn et al. 2019) targeted the least domains (three to four domains). All three of these interventions were electronic-based and served to transfer information (Gurwitz et al. 2014; Hockly et al. 2018) or highlight MR issues (Tamblyn et al. 2019). Hockly et al. (2018) and Gurwitz et al. (2014) shared the same domains (n=4): social and professional role; knowledge; motivation and goals; and memory, attention and decision process. Tamblyn et al. (2019) focused on the same domains excepting memory, attention and decision processes.

Motivation and goals and knowledge were the only domains that were evident within all studies. The domain social and professional role and that of memory, attention and decision were cited in 23 studies. The least utilised domain was environmental context and resources, with only six interventions incorporating

this (Holland et al. 2005; Scullin et al. 2007; Ahmad et al. 2012; Chan et al. 2015; Ravn-Nielsen et al. 2018; Tuttle et al. 2018). The domain of emotion was present within 15 studies and is unfortunately the second least represented.

	Hospital admission interventions									Bridging interventions									Post-discharge interventions						
TDF Domain	Basger et al. (2015)	Bolas et al. (2004)	Graabaek et al. (2019)	Hockly et al. (2018)	Lalonde et al. (2008)	Legrain et al. (2011)	Scullin et al. (2007)	Tamblyn et al. (2019)	Tong et al. (2017)	Buurman et al. (2016)	Casas et al. (2006)	Chan et al. (2015)	Coleman et al. (2006)	Gillespie et al. (2009)	Huang and Liang (2005)	Koehler et al. (2009)	Lee et al. (2015)	Ravn-Nielsen et al. (2018)	Ahmad et al. (2012)	Char et al. (2017)	Gurwitz et al. (2014)	Haag et al. (2016)	Holland et al. (2005)	Tuttle et al. (2018)	**Total studies**
1. Social/ professional role																									**23**
2. Knowledge																									**24**
3. Skills																									**22**
4. Belief about capabilities																									**17**
5. Beliefs about consequences																									**21**
6. Motivation and goals																									**24**
7. Memory, attention and decision processes																									**23**
8. Environmental context and resources																									**6**
9. Social influences																									**21**
10. Emotion																									**15**
11. Behavioural regulation																									**14**
Total domains targetted	**10**	**7**	**8**	**4**	**7**	**10**	**10**	**3**	**7**	**10**	**10**	**11**	**10**	**9**	**10**	**10**	**10**	**11**	**11**	**7**	**4**	**9**	**11**	**11**	

Key
Patient behaviour
HCP behaviour
Both patient and HCP behaviour

Figure 20: Study interventional BCTs mapped to the TDF

4.8 Discussion

This systematic review aimed to evaluate the evidence for interventions that support successful transitions of care for older people through enhanced medicines management. Interventions that bridged the transition for up to 90 days were found to be more likely to support successful transitions and reduce adverse outcomes. These interventions used on average more components than those focusing solely on hospital admission or post-discharge time periods (6.2 v 3.6 v 3.8 respectively), reflecting their greater intensity and longitudinal nature.

In this review, patient education, MR and timely cross sector communication were the most widely used activities. Interventions were delivered by a range of HCPs, with no professional appearing to influence any one intervention's effectiveness more than the other. Ten studies also involved family carers (Holland et al. 2005; Huang and Liang 2005; Casas et al. 2006; Scullin et al. 2007; Legrain et al. 2011; Ahmad et al. 2012; Lee et al. 2015; Char et al. 2017; Ravn-Nielsen et al. 2018; Tuttle et al. 2018); mostly as an information source during reconciliation activities. Family carers often support older patients during their day-to-day health management and can effectively promote self-management (Wong-Cornall et al. 2017). They could, therefore, be engaged in wider activities amongst these interventions and further work should identify opportunities for carer involvement within medication continuity.

In addition, evidence indicates the importance of involving patients and other key stakeholders in the co-design of interventions (Boyd et al. 2012). Of the interventions identified, only three (Scullin et al. 2007; Koehler et al. 2009; Legrain et al. 2011) alluded to co-designed elements of their components. They reported involving stakeholders such as healthcare professionals and managerial staff, with none mentioning patient and carer involvement. In the UK there is a drive to involve patients at every stage of healthcare, including design and development of interventions (INVOLVE 2012; Craig et al. 2019). Patients are generally willing to and want to be involved in decisions that affect their care. Having the opportunity to participate in co-design can reveal

important patient behaviours, goals, priorities and concerns that would otherwise remain undetected.

From the findings of this study, key professional behaviours that could enhance post-discharge medicines management for their patients have emerged which may be targeted by future interventions. HCPs (both secondary care and those operating within post-discharge services, such as the NHS Discharge Medication Service or PCN Pharmacist delivered SMR) ought also to consider the results in the context of their own professional practice. Self-management is an effective component and future interventions should, therefore, incorporate self-management coaching and/or education within HCP's routine practice. Indeed, NICE suggests that all patients have a self-management plan as part of medicines optimisation for chronic condition management (National Institute for Health and Care Excellence 2015a). Furthermore, when performing medicines reconciliation and review, HCPs should adapt their behaviours to ensure that the patient and/or their carer is involved every time, as standard. Encouraging patients to take an active role in their care is crucial and future interventions must ensure that HCPs communicate in an appropriate way with their patients for this to be achieved. For example, HCPs must include advising patients on which medicines have been changed and helping them to plan their new medicines routines as a component of delivering educational messages. The provision of patient-centred documentation was common within interventions and therefore interventions should encourage HCPs to reduce the amount of jargon within discharge paperwork and ensure they are written with the patient in mind (rather than with the next HCP in mind).

4.8.1 Meta-analysis

The most effective component within these interventions was self-management coaching or education. Self-management, the actions taken by patients to recognise, treat and manage their own health, is a term associated with multiple definitions and interpretations. Whilst eight studies characterised their interventions as containing self-management elements, definition and detail was lacking to allow an understanding of what these components

entailed. These activities appeared to vary widely between studies and it was often challenging to deduce whether they related to self-management of prescribed medicines or the underlying disease. Basger et al. (2015), for example, stated that “opportunities for self-management were discussed with the patient” within their enhanced pharmacy discharge service; whilst Coleman et al. (2006) described medicines self-management as ensuring the patient is knowledgeable about their medications and that they can effectively navigate the medicines management system. This definition from Coleman et al. (2006) seems to encompass the important aspects of self-management of medicines, such as: seeking support from HCPs, managing supplies and a good understanding of medicines to support management. However, some factors that may be missing include adherence support, checking medicines for errors or monitoring for effects and side effects. Without detailed descriptions from the original authors, it is difficult to ascertain how far the interventions went in supporting self-management.

Promoting self-management in older patients has received global attention as it is thought to improve a patient’s ability to manage their long-term conditions (Pollack et al. 2016). Despite this, self-management activities were used in less than half of included studies (n=8). It is known that older people with low levels of social, cognitive, and physical functioning are generally less able self-managers (Cramm et al. 2013). Therefore, how such individuals are supported in self-managing their medicines through interventions such as these requires further attention. In a review of interventions to support self-management of older patients, Pollack et al. (2016) identified that success was reliant on patient knowledge, access to resources to manage health and self-efficacy (confidence in one’s own ability to problem solve, make decisions and take action). How well the interventions in this review attempted to address these factors is unclear.

Telephone follow-up (RR 0.84 [0.73, 0.97]) also reached statistical significance within the meta-analysis. Other reviews of telephone follow-up interventions have been unable to demonstrate a reduction in readmission rates (Mistiaen and Poot 2006; Crocker et al. 2012; Jayakody et al. 2016). Crocker et al. (2012) on the other hand highlighted that patient engagement

with post-discharge clinical contact was improved. This contact may, therefore, provide opportunities for reinforcement of educational messages as well as detection or resolution of MRPs. Barriers to implementation (e.g. time, cost and staff availability) may limit its use. Another study showed that telephone follow-up is a frequent component of interventions (Hansen et al. 2011). This study found that most follow-up conversations used specific scripts to inquire about symptoms after discharge, plans for follow-up and medicines use.

In a study identifying the role of the community pharmacist within transitions of care, many interventions (75%) involved home visits rather than telephone follow-up (Nazar et al. 2015). These face to face visits were described as an opportunity to provide education and counselling, check medication adherence, remove excess and/or out of date medicines, and provide test results. Kansagara et al. (2015) were unclear as to whether a home visit was a necessary component, especially as this activity can be very resource intensive. Within the older patient population, many individuals tend to be housebound and, consequently, unable to visit primary care providers. If no home visit option exists, such patients will not be able to take part in these types of interventions. Whilst telephone follow-up was found to be more effective than home visit within this review, there is a value to seeing the patient in their home context as this helps to create a picture of how they manage their medicines, demonstrated by Nazar et al. (2015).

Follow-up occurred from within two days (Coleman et al. 2006; Buurman et al. 2016) up to two months (Gillespie et al. 2009) in the studies reviewed. In a study of discharge interventions, Hansen et al. (2011) described timely follow-up as occurring between one- and four-weeks post-discharge. In addition, Laugaland et al. (2012) found that successful follow-up occurs within two-weeks. Therefore, the optimal time for follow-up is unclear.

Medicines reconciliation, performed manually or via electronic intervention, was shown to significantly reduce hospital readmission (RR 0.88 [0.81, 0.96]) and was linked to fewer medication errors (Bolas et al. 2004; Ahmad et al. 2012; Basger et al. 2015; Tamblyn et al. 2019). The benefits of reconciliation

appear disputed in the literature. When provided after hospital discharge, reconciliation has not been shown to effectively reduce post-discharge harm, nor improve health outcomes (McNab et al. 2018). In contrast, reconciliation provided during admission has demonstrated a reduction in healthcare utilisation and improved patient safety (Kwan et al. 2013; Mekonnen et al. 2016).

Ensing et al. (2015) conducted a review of the optimal role for pharmacists within transitions of care. Their study found strong evidence that medication review was a successful component; however, their patient population was broader than older people. They characterised the medication reviews as level one (prescription review), level two (adherence support review) or level three (clinical review). Only the level two review explicitly involved the patient, with level three being conducted in close collaboration with physicians. Of their fifteen studied interventions, six were coded as conducting medication review; five were level three and only one was level two (Ensing et al. 2015). Within the present review, medication review was not considered to be statistically significant, although assessment of the review level was not performed.

Patient-centred health documentation has practical and psychological benefits for patients, such as bolstering memory, as a tool for sharing information or boosting empowerment to ask health-related questions (Sartain et al. 2015). Within this review, it is unclear how patients made use of their personalised documentation. All examples though did include an up to date list of their medicines presented in an acceptable format.

There is a consensus that timely cross-sector communication does support COMM at transitions (Avery et al. 2012a; Kripalani et al. 2014). Whilst much emphasis has been given to improving communication at transitions (Kripalani et al. 2007b), this meta-analysis did not find a significant effect on readmission rate (RR 0.90 [0.79, 1.02]). There have been technological advances to support timely communication and many of the included studies transferred information to the primary care provider, community pharmacy or outpatient services at discharge. Specific methods included: fax (Bolas et al. 2004; Scullin et al. 2007; Lalonde et al. 2008; Koehler et al. 2009; Hockly et al. 2018;

Tamblyn et al. 2019), telephone (Legrain et al. 2011; Ravn-Nielsen et al. 2018), email (Chan et al. 2015), and secure electronic platform (Casas et al. 2006; Gurwitz et al. 2014; Haag et al. 2016). We found no interventions that described a method allowing primary care providers to readily communicate back to hospital providers. Whilst it is known that this is improving with the use of novel electronic information transfer tools (Refer to Pharmacy (Gray 2015), PharmOutcomes (Nazar et al. 2016)), these systems are used more for data collection in terms of how many follow-ups were conducted by community pharmacy. They do not allow the ready communication backwards, from primary to secondary care and this is a barrier to medication continuity within the UK primary care sector when clarification or further information is required after discharge (Avery et al. 2012a).

Finally, it is encouraging to note that the components seemingly more effective are those that encourage doing "something with the patient", rather than "to them" (Hansen et al. 2011), demonstrating the potential of prioritising patient communication and engagement within an intervention.

4.8.2 BCTT and TDF mapping

In this theory-based analysis, interventions were mapped to behaviour change theory in order to understand through which mechanisms they may have worked. The majority of interventions were delivered by HCPs, aiming to change patient behaviour. Some of the interventions directly influenced the patients to change their medicines management behaviours (e.g. a home visit to remove old medicines changed patient behaviour about taking old medicines), others were delivered by HCPs who encouraged the patient to change their behaviour (e.g. educating patients about their changed medicines in order to promote behaviour change), and finally, some influenced the HCPs to change professional behaviours (e.g. asking them to undertake a comprehensive medicines review where this was not done in usual care). In this final case, it was hypothesised that even though the intervention targeted HCP behaviour (e.g. promoting medicines reconciliation), there may still have been a resultant effect on the patient (e.g. following medicines reconciliation the HCP may be more likely to talk to the patient about their medicines,

encouraging important patient behaviour change). Therefore, it was very challenging to separate out these intertwined behaviours and develop a clear understanding of who is affected by the intervention and in what way. Despite this challenge, the reviewers used their clinical and professional knowledge to anticipate whose behaviour would be targeted by the intervention, via which BCTs and TDF determinants, to develop an idea of the 'dose' that the participants received (defined as the amount of intervention offered by the provider and received by recipient (Rowbotham et al. 2019)).

Analysis of study findings showed that the most prevalent BCTT groupings are: goals and planning; feedback and monitoring; social support; and shaping knowledge. These are all important aspects of medicines management, for example: defined plans for adherence; monitoring and follow-up (Cross et al. 2020); who should be involved when, how and why; and what support the patient may need (Nieuwlaat et al. 2014). It is most reassuring then that these BCTs were identified within the studied interventions, emphasising their prospective contribution for any future intervention.

Two BCTT groupings were not coded within any interventions (scheduled consequences and identity). The BCTT is derived mainly from BCTs used within the field of health promotion (Michie et al. 2013). Therefore, some will not be relevant in the context of medicines management. Scheduled consequences, for example, contains BCTs such as punishment and remove reward frequency, which are not necessarily ethical or in keeping with NHS standards in this context. Those BCTs in the identity group (such as valued self-identity or identification of self as a role model) may be appropriate in the context of medicines management. For example, in patient-carer dyads, one of the individuals may be the 'manager' of medicines. This concept is quite difficult to operationalise within the context of the BCT and it is unsurprising that these groupings were not used within interventions.

Priority appeared to have been given to patient behaviours within these interventions. This assumes that the patient has an active role in their care and is important within medicines optimisation since putting the patient at the centre of their care is likely to result in better outcomes. What remains unclear,

is how these BCTs were implemented and whether behaviours were adopted effectively, because component descriptions within the studies were lacking sufficient specific detail. Nevertheless, this analysis demonstrates that any future intervention should focus on harnessing individual patient strategies and formalising them to ensure effective management even when the patients have returned home.

A small number of interventions focused solely on tasks aimed at HCPs, suggesting lack of patient involvement and perhaps no exploration of patients' individual needs. Considering that the patient often leaves hospital with multiple changes to an already complex drug regimen, this could be a missed opportunity to involve them in discussion and decisions about their medicines.

Although the majority of interventions offered components targeted towards patient behaviours, the nature of these tasks was predominantly prescriptive i.e. focused on giving information and instructions to patients (provision of written documents, verbal instruction) rather that working with them in partnership. Only a very small number of interventions involved the patient constructively, e.g. through role play (Coleman et al. 2006), counselling, motivational interviewing (Ahmad et al. 2012; Chan et al. 2015; Ravn-Nielsen et al. 2018) or developed strategies that could highlight potential issues before they happened and addressed any concerns that patients may have had. Those interventions that focus on these aspects, often failed to operationalise them and for this reason it remains unclear precisely what, for example, 'counselling' entailed. In a review of 29 studies describing medication counselling in older people, 15 different components were identified (Capiau et al. 2020). Without detailed description of the exact intervention provided, it is not only difficult to replicate these components, but the extent to which these interventions helped the patient cannot be ascertained. In a pharmacy context 'counselling' is usually a relatively short verbal intervention or consultation and not an extended conversation or discussion.

Constrained by the lack of detail about these components and what they entailed, it was also not clear whether HCPs were provided with appropriate training to deliver these components. Traditionally, motivational interviewing

and (extended) counselling tasks, for example, are not commonly delivered by pharmacists and fall outside the scope of their everyday practice. Whilst many studies mentioned training of healthcare professionals, they failed to describe the content and depth of this training (Gillespie et al. 2009; Koehler et al. 2009; Legrain et al. 2011; Basger et al. 2015; Buurman et al. 2016; Haag et al. 2016; Tuttle et al. 2018). Ravn-Nielsen et al. (2018) and Ahmad et al. (2012) provided a medication review workshop and motivational interviewing course for their study pharmacists. These courses were delivered over two or three days and it is unknown whether this is a suitable course length for becoming proficient in motivational interviewing. Holland et al. (2005) offered a two-day lecture course involving identifying adverse drug reactions, prescribing, improving concordance and communication skills. Scullin et al. (2007) was the only study to specifically detail the content of their accelerated training programme and describe the topics covered within each session.

Evidence exists showing the importance of personalising information and tailoring it to individual patients' needs. Whilst there is evidence that some of these interventions attempted to tailor interventions to patients, detail about the level of personalisation was lacking. For example, it is largely unclear whether 'personalisation' involved simply adding a patient's name to a document or a complete restructure of the intervention itself.

One of the striking findings from this review was that the outcomes investigated were rarely behaviour focused. Rather, most of the interventions focused on outcomes related to error, harm and health in general. Whilst these outcomes are important, recording changes in behaviour following implementation of new interventions would allow for the investigation into whether the intervention was effective in helping patients cope with their medicines management across the pathway, particularly at the point of transitions. Similarly, very few interventions (n=4; Ahmad et al. (2012) (theory of planned behaviour (Ajzen 1991)); Tuttle et al. (2018) (5As model of behaviour change (Glasgow et al. 2006)); Lee et al. (2015) (conceptual framework of integrated practice units (Porter and Teisberg 2006)); Huang and Liang (2005) (McKeeham and Coulton's discharge plan model (1985))) were explicitly underpinned by theory. As a consequence, most of these

interventions were task rather than behaviour driven. Although most interventions did not explicitly aim to change behaviour, it is quite likely that they may facilitate change due to the nature of some components, such as motivational interviewing and counselling. Future interventions should also focus on the measurement of efficiency and efficacy linked to behaviour change.

For the purposes of this analysis, every intervention was broken into its individual components. It is important to acknowledge that although every component was analysed individually, their effects cannot be taken in isolation. When considered in isolation, the component might be weak, but in the context of the full intervention and in interaction with the other components, clinical effectiveness could be greater. In other words, the effectiveness of the intervention may be greater than the sum of the effectiveness of each individual component.

4.8.3 Comparisons to other literature

This is the first systematic review and meta-analysis of its kind to evaluate interventions for older people that support successful transitions through medicines management. Other reviews have compared interventions that aim to: reduce 30-day readmission rate (Hansen et al. 2011; Leppin et al. 2014; Rodrigues et al. 2017); improve transitions of care generally (Kansagara et al. 2015; Rochester-Eyeguokan et al. 2016); improve patient safety (Laugaland et al. 2012); reduce medicines-related problems at transitions (Garcia-Caballos et al. 2010; Spinewine et al. 2013); bridge the transition through medication-related activities (Daliri et al. 2019); and identify the optimal role of pharmacists during transitions of care (Ensing et al. 2015; Nazar et al. 2015; Nicholls et al. 2017; Lussier et al. 2020).

Previous reviews of discharge interventions have shown that complex interventions are significantly more effective than those that utilise a single activity (Hansen et al. 2011; Laugaland et al. 2012; Kripalani et al. 2014; Kansagara et al. 2015) and that their effects are sustained (Kansagara et al. 2015). These discharge interventions did not have a medicines focus however. In Hansen et al.'s (2011) study, they found that 55.8% of their interventions

tested a single component. This contrasts greatly with the present review where none of the RCTs tested a single component study and 63% (n=15/24) tested 5 or more components. This may demonstrate the growing use of complex interventions. Similar to the present review, Hansen et al. (2011) found that those interventions which bridge the transition were more effective, especially where longitudinal relationships were created. Patient-centred discharge information and telephone follow-up were included in all effective interventions. The authors concluded that these activities were thought to encourage patients to self-manage in the period between discharge and formal primary care follow-up. In a later systematic review, Daliri et al. (2019) also found that bridging interventions reduced hospital readmission (RR 0.79 (CI 0.65 – 0.96) and that readmission rates were further reduced by 17% per additional intervention component.

In a review of interventions aimed to increase patient safety, Laugaland et al. (2012) found certain features promoted success. These included: bridging support; involving a key liaison person; empowerment and educational activities for carers and patients; a multi-disciplinary approach; and a standardised discharge letter. Laugaland et al. (2012) illustrated that medication safety was an important component. However, all their focus was on MR and no other medicines-related activity was discussed. Furthermore, whilst this list is quite prescriptive, they draw attention to the fact that a 'one-size fits all' approach is not appropriate. Most importantly they identified that the family can be the first line of defence against potential risks, yet little work has been done on building partnerships with families. This is echoed in this present review.

Leppin et al. (2014) identified discharge interventions that used between one and seven discrete activities. Their most commonly reported activities were case management (defined as supported care co-ordination), patient education, home visit and self-management. Their meta-analysis showed that interventions which augmented self-management were 20% more likely to reduce the rate of readmission (RR 0.68 vs RR 0.88) than interventions that did not support self-care. They also discovered that interventions containing

more than five components were statistically associated with fewer hospital readmissions (RR 0.63 vs RR 0.91).

Later, Kansagara et al. (2015) and Rochester et al. (2016) also pointed out that more attention was given to interventions that are multi-component and multi-modal. Whilst these interventions were more effective, they found it challenging to pinpoint the 'active ingredient' of the complex interventions due to poor protocol descriptions. Kansagara et al. (2015) also emphasised that the importance of bridging support and the introduction of flexibility within intervention design were necessary to be able to respond appropriately to individual patient need. Rochester et al. (2016) made a strong case for improved communication methods and stressed that interventions needed to target multiple time points across the transition.

Within the literature that focuses predominantly on medication safety at transitions, interventions combining in-hospital planning activities (such as education and counselling) with post-discharge follow-up activities were the most successful (Garcia-Caballos et al. 2010; Spinewine et al. 2013; Daliri et al. 2019). Rodrigues et al. (2017) found that the involvement of a pharmacy team within interventions reduced the rate of 30-day readmission by 32% (OR 0.68; CI 0.61-0.75). Similarly, Lussier et al. (2020) were able to demonstrate a clinically significant reduction of 28% in 30-day hospital readmission when community pharmacists were involved in transitions of care.

Communication features predominantly in these interventions, although, the content of these conversation-based activities is not thoroughly described and often alludes to a transfer of information, rather than a meaningful dialogue. For example, Rodrigues et al. (2017) describe 'counselling' as 'the patient is the recipient of information (or giver)' or Daliri et al. (2019) describe 'education' as 'written information or oral consultation'. This does not appear to be a patient-centred discussion and more detail is needed to draw conclusions about the level of support given in these types of interventions. Nicholls et al. (2017) made links between patient educational interventions and increased knowledge, resulting in better adherence to medication. They demonstrated that this is only effective when health literacy is considered, and that the

information is tailored to the patient need. This level of detail was not available within this systematic review, although one study did offer information to the patient in their own language (Chan et al. 2015). Due to the lack of detail, it is unclear to what level documents were personalised to the patient need. For example, Lalonde et al. (2008) described creating a Medication Discharge Plan for each patient. Unfortunately it is simply described as a standardised list of patient and pharmacotherapy information. This document is also sent to the patient's physician and community pharmacy. It is unclear whether any terminology was modified between documents. Coleman et al. (2006) described a patient-centred handheld record within their RCT. Whilst this document is specifically for the patient to use, they again describe a standardised document with specific information. Likewise, any tailoring to patient need is noticeably lacking.

Systematic reviews identifying the role of pharmacists within transitions of care appear to focus mostly on the identification and rectification of errors (Nazar et al. 2015) by activities such as MR (Nicholls et al. 2017) and medicines review (Ensing et al. 2015). Ensing et al. (2015) found that the most frequently reported component of their interventions was a patient-centred follow-up. It is unclear, though, how this was different from a 'healthcare professional' centred follow-up. In the current review, no attempt was made to identify the focus of the follow-up as this level of detail could not be extracted. There is no uniform description of medication review across the studies within this systematic review. Some studies explicitly described the process (for example, Graabæk et al. (2019) detailed the creation of a medication history, a patient interview to assess adherence and identification of MRPs and development of recommendations), whilst others, such as Scullin et al. (2007) stated 'drug treatment was reviewed daily'. In some cases, medication review was used as an all-encompassing term for MR, patient education and the identification of problems (Basger et al. 2015). Interestingly, some studies (Ahmad et al. 2012; Buurman et al. 2016; Ravn-Nielsen et al. 2018; Graabæk et al. 2019) described working with the patients as partners during medication review, which appears different to those examples provided by Ensing et al. (2015).

4.8.4 Quality of the review

Describing complex interventions

Defining and describing components within complex interventions can be a highly subjective process and it can, therefore, prove challenging to compare them (Laugaland et al. 2012). Best judgement was used during this process, especially when intervention descriptions were lacking detail and clarity. Additional documentation such as study protocols were sought where needed and outside expertise in primary and secondary care pharmacy practice and health psychology was drawn upon to help classify the components.

As described in **Section 4.8.2**, assumptions needed to be made regarding whose behaviour (patient, HCP or both) was targeted by the intervention. Components aimed to change professional behaviour may still have downstream influence on the patient and therefore it was often challenging to map the patient behaviour from these studies that described interventions provided by HCPs. Despite these challenges, it was appropriate to conduct this process to understand the approximate 'dose' of each intervention and possible mechanisms of action in order to inform decisions around intervention design (e.g. whose behaviour to target and how) (see **Chapter 6**).

Heterogeneity considerations

Shepperd et al. (2009) recommend the use of a typology or taxonomy, as was successfully used within this review, to help standardise components across studies, allowing for more meaningful comparisons. Whilst this helps create relatively homogenous groups for investigation, there is a risk of misclassification. To further reduce any associated bias, two researchers independently coded the components within the bundles and compared results. Any disagreements were resolved through discussion or involved a third party where necessary. Intervention components were only coded to the taxonomy where it explicitly stated it was delivered i.e. self-management support had to be reported as well as patient education in order for both activities to be coded.

Elucidating likely mechanisms of action

Another strength of this review was that it attempted to identify not only if the interventions worked, but also why and how. When interventions are complex and multifactorial, it can be difficult to ascertain which factors explain efficacy (Morrissey et al. 2016). Theory based analysis can, therefore, help researchers to understand the reported effects. Since underpinning theoretical assumptions were not reported in most studies, this review retrospectively mapped the interventions to the BCTT and the TDF to clarify which behaviour change processes are potentially responsible for the effects (Little et al. 2015; Morrissey et al. 2016). To do this effectively, a broad framework was chosen (TDF) to ensure the full range of possible factors were found.

Review process

This review followed Cochrane best practice procedure (The Cochrane Collaboration 2015) and, in this way minimal bias was present in the methods. A thorough search was carried out in appropriate databases. Study selection, data extraction, quality assessment and coding were assessed by two reviewers to limit any bias.

4.8.5 Limitations

The included studies were highly heterogeneous, drawn from varying populations (with different levels of health literacy and socio-economic status) and care settings. They included different combinations of components and delivery time points. It is, hence, difficult to attribute success to individual components within bundles and the meta-analysis illustrates a modest overall effect size. Therefore, these results cannot demonstrate causality and cannot be used to draw firm conclusions. There is also currently no validated medication continuity-related measure, which would have allowed more thorough analysis. The systematic review included studies implemented within a range of international healthcare systems and care settings, which limits their representativeness somewhat to the UK context.

English language restrictions and unavailability of full-texts may have introduced bias, due to resource implications which could not be avoided.

Most of the included studies contained methodological flaws that affected the risk of bias assessment. It was unclear whether appropriate methods were in fact utilised and not reported, or simply not performed at all. To improve future trials, studies must ensure absolute blinding of outcome assessors and that allocation concealment and randomisation are appropriately performed and documented.

Challenges of describing and designing complex interventions

The level of detail about each intervention, its components and delivery varied. This limits the usefulness of this systematic review, as recommendations about who would benefit, when and set within which contexts are not able to be confidently drawn. As described in **Section 3.5.1**, a realist review that includes evidence wider than RCTs would be more beneficial. The low level of detail within each study, however, meant that a realist review could not be performed. Significantly more detail about the intervention and its implementation was seen in the newer studies, such as Ravn-Nielsen et al. (2018) and Graabæk et al. (2019), which could be due to advances in realist thinking surrounding pragmatic trials and implementation science.

None of the included studies described their interventions as ‘complex’ and were perhaps not designed with the MRC guidance (2019) in mind. Indeed, none detailed this guidance within their manuscripts. This may help explain why only four of the studies referred to an underpinning theoretical framework on which their intervention was based. This also meant that the majority of the BCTT and TDF coding relied on inferences from the available text and was, therefore, highly subjective.

Whilst use of theory has been made a priority within the MRC guidance (2019), this may still not be enough to predict which elements of the intervention would be desirable for patients or staff (Datta and Petticrew 2013). For example, the theory may recommend a type of intervention, which in practice is challenging and costly to deliver, reducing its utilisation in practice. This illustrates the importance of co-design of any intervention with those who will use it (e.g. patients) and those who will commission and deliver it (e.g. healthcare professionals). Only three of the studies (Scullin et al. 2007; Koehler et al.

2009; Legrain et al. 2011) documented having designed the studies with key stakeholders (e.g. healthcare professionals). Remarkably, none explicitly mentioned patient or public involvement.

Contextual factors

Knowing the contextual factors (e.g. organisational, professional and political issues) that may have influenced the success or failure of an intervention is important (Datta and Petticrew 2013). This helps other researchers identify the context of when, and in what circumstances the intervention may be successful and gives support for wider implementation. In a cRCT of breastfeeding support group interventions, Hoddinott et al. (2010) found negative outcomes in three of seven sites. They utilised a combination of quantitative and qualitative methods to help them understand why and to build an explanatory model. In these three sites where rates of breastfeeding were reduced, they found factors of deprivation, organisational change and personnel had a profound impact (Hoddinott et al. 2010). Unfortunately, many of the study reports included in this review simply did not contain this level of detail about the physical and social settings, so this level of analysis could not be performed.

Outcome measures

The MRC guidance (2019) also reinforces that outcome measures must be appropriate and carefully designed to ensure effective evaluation of complex interventions. Often the choice of outcome measure is driven by the funder (organisational targets or political pressures) and is a distal measure (e.g. 30-day readmission rate, mortality). Measures rarely reflect the more proximal behaviour change that the intervention is designed for. This disparity has the potential to affect the overall study outcome and reduce clinical and statistical significance. Kansagara et al. (2015) challenges the reliability of readmission as a metric and suggests more useful alternatives such as emergency department attendance, patient satisfaction and other outcomes linked to patient safety. This is further highlighted within Holland et al.'s intervention (2005) within this review. This RCT found an increased rate of readmission within the intervention arm, resulting in a negative effect for the intervention.

Here, using readmission rate as the primary outcome has not been useful as it does not demonstrate any relationship to the quality of care received by the patient, and it is unclear whether these readmissions were appropriate and unavoidable. A more reliable and useful measure would have been the rate of preventable readmissions. However, this is more difficult to measure (and is somewhat subjective). Datta and Petticrew (2013) argue that outcomes of complex interventions are likely to be plural and multi-dimensional, including short, medium and long-term. They recognise the importance of bio-psycho-social outcomes (e.g. patient experience) as well as clinical. In our studies, distal measures were far more frequently measured than patient behaviour measures (e.g. medication adherence, ability to self-manage).

Fidelity

RCTs are heralded as the gold standard in the hierarchy of evidence because their components are standardised across settings and high fidelity can be achieved (Hawe et al. 2004). Datta and Petticrew (2013) argue that whilst this is useful for clinical trials of investigational medicinal products, complex health interventions should be flexible by nature towards patient need and the local circumstances. Tailoring the intervention to the local context may also reduce the incidence of weak or non-significant findings (Hawe et al. 2004). Therefore, there is a drive to standardise the function or the aim of the intervention, but not necessarily the form. They argue that clear documentation of these variances is required in order to compare interventions. Only one of our studies documented differences in intervention delivery across sites (Casas et al. 2006), however, it is likely that other tailoring occurred due to the nature of these interventions.

Supplementary evidence

The use of policy documents and qualitative data (e.g. from process evaluations) can help produce thick descriptions of the interventions and may elicit further contextual factors for consideration (Shepperd et al. 2009). Supplementing traditional RCT data with qualitative interviews, for example, can further the understanding of why, how and to what extent participants benefitted from an intervention (Drescher et al. 2004). In this review, study

authors were contacted where possible and asked to supply any additional information and complete protocols. There was a poor response to this request and, therefore, it was impossible to obtain enough information across the studies for supplementary evidence to be useful. Wide scale searches for additional documentation were not conducted due to limited resources.

Sustainability and scaling up

The actual time taken and the resources used to deliver the intervention components were rarely reported but are crucially important to consider in the context of busy healthcare settings. Process evaluation is recommended to be recorded alongside intervention outcomes (Craig et al. 2019). For example, Graabæk et al. (2019) studied patient flow through their study, along with the acceptance rate of recommendations and the amount of time taken to deliver each component. This information is helpful to ascertain whether the intervention could successfully be implemented in other settings. Graabæk et al. (2019) utilised on average, 86 minutes per patient, whilst Ravn-Nielsen et al. (2018) reported an average of 114 minutes spent per patient. Knowing the approximate time to deliver interventions will allow for careful planning prior to further implementation. These were the only two studies to include this level of detail. Without information about the other studies, comparisons cannot be drawn and the longer-term sustainability of resource intensive interventions such as these and how they can be integrated into ‘usual care’ cannot be considered.

BCTT and TDF mapping

Since several interventions lacked in-depth detail about crucial components and how they were delivered, assumptions had to be made based on professional and research experience on the subject of medicines management in the UK. For example, where interventions described MR, assumptions were made based on the steps to be expected from policy guidelines, observations in practice and clinical practice. Furthermore, three studies reported using motivational interviewing, without detailed descriptions of the content of the interaction. However, experience and expertise in the field of health psychology was sought, allowing extrapolation when coding the

components to the BCTT. For this reason, it is possible that for some interventions, the number of BCTTs involved was over-estimated. This was offset by holding several meetings in an iterative process to reach a consensus.

Simultaneously, the reviewers established rules linked to components based on clinical knowledge and expertise. For example, in all interventions that mentioned MR, the authors standardised the BCTs assigned and assumed the component was the same in every instance, unless an alternative description was documented explicitly in the study.

Challenges of assigning BCTs and onward mapping to the TDF using the available taxonomy from Michie et al. (2013) also arose, as some components were not a perfect fit. In such instances, the authors first utilised the existing literature (Michie et al. 2005; Michie et al. 2008; Cane et al. 2015) and in cases where available evidence did not apply, consensus was reached based on experience and knowledge in psychology and healthcare in the UK.

4.8.6 Implications for future intervention development

Findings from Phase 1 suggest that intervention modelling should:

1. Include elements of self-management, telephone follow-up and MR
2. Begin during admission and continue into the post-discharge phase for at least 90 days
3. Draw from valuable BCTT groupings, such as goals and planning, feedback and monitoring, social support and shaping knowledge.

4.9 Chapter summary

This chapter has systematically reviewed trialled interventions for older people in order to investigate their effectiveness at supporting care transitions. Overall, Phase 1 suggests that interventions which bridge the care transition most effectively support older patients' medication continuity, whilst also having the greatest impact on reducing hospital readmission. Interventions which included self-management, telephone follow-up and MR activities were most likely to be constructive. The theory-based analysis has identified certain

BCT groupings and discrete BCTs that are common amongst studies aiming to support successful care transitions through medicines management. Elements that could be valuable when combined within a complex intervention are: goals and planning; feedback and monitoring; social support; instruction about how to perform the behaviour; and prompts/ cues. Whilst many interventions mapped to seven or more determinants of behaviour change, as identified within the TDF, careful assessment of the barriers to behaviour change should be conducted in the first instance to ensure all appropriate domains are targeted. Environmental context and resources was an under-represented domain and should be considered within future interventions. Further work needs to identify how best to engage with patients and their carers to better support post-discharge medication continuity. The following **Chapter 5** explores the patient experience of post-discharge medicines management, which will be synthesised with the findings from this chapter during intervention modelling.

Chapter 5: Identify and develop theory; mapping the patient experience

5.1 Introduction

This chapter presents the research undertaken during Phase 2 to explore older patients' experiences of post-discharge medicines management. The methods are reported fully in **Section 3.6**. This work is presented in two parts: an analysis of qualitative semi-structured interviews, supported by data retrieved from the participants' primary care records and their diaries; followed by an examination of potential patient safety incidents described by the participants. The chapter concludes with a discussion of the key issues arising from the findings. The framework analysis has been published in the peer-reviewed journal Health Expectations (Tomlinson et al. 2020b).

5.2 Recruitment response

Following the screening of 3304 inpatients at two acute hospital trusts, 104 were approached during their hospital stay between August 2018 and August 2019. After subsequent discussion with the researcher or research nurse, and after reading the participant information booklet, 42 patients consented to take part in the study. Unfortunately, before the first interview, a number of these patients were either readmitted to hospital (n=2), became too ill (n=4), lost interest (n=6) or died (n=3) (**Table 15**).

A total of 27 interviews were conducted with participants approximately two weeks after their hospital discharge (mean age 84.4 years; average length of index admission 11 days; mean number of medicines changes/ recommendations per participant 4.6). Eight participants asked a relative (or relatives) to join in because they helped to look after their medicines. From the sample, fifteen participants were interviewed at around two months after their index admission. Twelve participants were lost to follow-up due to: failed contact (n=4), death (n=2), worsening of illness (n=5) or moving into a care home permanently (n=1). A further two participants were withdrawn between the second and third interview because of worsening of illness (n=1) and

moving into a care home (n=1). Therefore, thirteen participants completed all three interviews.

Table 15: Response to recruitment across both sites

Activity	Leeds	Bradford	Total
Number of patients screened	2519	785	3304
Number of patients eligible to participate	70	65	135
Patients deemed inappropriate to approach by ward staff, due to severity of illness, cognitive impairment etc.	11	20	31
Patients approached by research team	59	45	104
Participants recruited during hospital stay	23 (plus 7 family carers)	19 (plus 2 family carer)	42 (plus 9 family carers)
Participants lost to follow-up after discharge, withdrawn or excluded before first interview	7	8	15
Step one interviews (2 weeks post-discharge) completed	16	11	27
Step two interviews (2 months post-discharge) completed	10	5	15
Step three interviews (6 months post-discharge) completed	10	3	13

5.3 Participant characteristics

Participants' names were changed to protect identity and were given pseudonyms. Participant characteristics varied in terms of age, their living circumstances, the level of support they had for their medicines and number of medication changes during admission (**Table 16**). Participants' ethnicity was White British, except Winifred (78) who was from a Black Caribbean background. All used English as their primary language, with the exception of Eleanora (83) who spoke Italian. She moved to the UK 54 years ago.

Table 16: Participant characteristics

PSEUDONYM	AGE	PEN CHARACTER CATEGORY (AT POINT OF DISCHARGE)	LIVES WITH?	WHO HELPS?	LENGTH OF INDEX ADMISSION	NUMBER OF MEDICINES CHANGES/ RECOMMENDATIONS
Elaine	96	Local authority - minimal	Alone (house)	Daughter	12 days	8
Margaret	82	Local authority - greater	Alone (house)	Rehab team	16 days	6
Betty	85	Local authority - minimal	Husband (sheltered accommodation)	Husband and daughter	3 days	3
Mary	81	Helping each other	Husband (house)	Husband	9 days	2
Patricia	85	Local authority - minimal	Alone (house)	Daughter	21 days	10
Hazel	91	Local authority - minimal	Alone (house)	Daughter and grandson	10 days	4
Eleanora	83	Local authority - greater	Husband (house)	Daughter	19 days	4

Robert	80	Active older person	Wife (house)	Wife	5 days	4
Dorothy	82	Local authority - minimal	Grandson (house)	Son and grandson	11 days	2
Joan	78	Local authority - greater	Alone (flat)	-	36 days	12
Harry	90	Local authority - greater	Alone (house)	Daughter and rehab team	2 days	2
Elizabeth	87	Local authority - minimal	Alone (house)	Daughter	10 days	7
Ruth	90	Active older person	Alone (sheltered accommodation)	Son	5 days	4
Marilyn	86	Local authority - greater	Husband (house)	Rehab team	13 days	2
Alice	92	Isolated older person	Alone (house)	-	2 days	2
Marie	81	Active older person	Alone (flat)	Daughter	9 days	6
James	79	Local authority - greater	Alone (flat)	Daughter	9 days	4

Barbara	91	Local authority – minimal	Alone (flat)	-	3 days	3
Doris	88	Isolated older person	Alone (sheltered accommodation)	-	6 days	1
Nancy	82	Local authority - minimal	Husband (house)	Husband	Unknown	3
Shirley	81	Isolated older person	Alone (sheltered accommodation)	-	7 days	1
Elsie	84	Local authority - minimal	Alone (house)	Rehab team	6 days	2
Winifred	78	Active older person	Alone (house)	Her sons and daughters	6 days	7
Enid	81	Active older person	Alone (sheltered accommodation)	-	5 days	3
John	84	Local authority - minimal	Wife (house)	Wife	29 days	2
William	79	Local authority - minimal	Alone (house)	Daughter	16 days	10
Charles	82	Active older person	Alone (house)	Daughter	22 days	9

All participants had at least one medication change or recommendation made about their medicines on their discharge documentation. Some returned home with temporary support from the rehabilitation team (Margaret (82), Harry (90), Elsie (84), and Marilyn (86)), whilst others relied on packages of care from community teams (e.g. community matron visits) or family carers. Nine family carers joined in the interviews (Betty's (85) daughter and husband, Mary's (81) husband, Robert's (80) wife, John's (84) wife, Harry's (90) daughter, Hazel's (91) daughter, Elaine's (96) daughter and Patricia's (85) daughter).

All participants listed in **Table 16** were interviewed approximately two weeks after their discharge. Fifteen participants consented to be interviewed two months after their index admission (Betty, Mary, Hazel, Eleanora, Robert, Joan, Elizabeth, Ruth, Elsie, Winifred, Enid, Marie, John, William and Charles). All these participants, except Marie (81) and John (84) were interviewed for a final time, between four to six months later. Data were extracted from the primary care records of the 13 participants who were interviewed three times and used for triangulation. Two participants (Betty (85) and Ruth (90)) completed one or two entries in their diaries, which were used to support findings from their interviews. No other participant engaged with the diary. Despite recruitment from two hospital sites, no distinct differences were observed in how participants described their experiences or perceptions.

This study was designed to have a longitudinal element, so that changes over time could be identified. Coding of interviews at two and six months elicited no new themes. However, these further interviews did allow for clarification and expansion on previous conversations. As the participant-researcher relationships and rapport developed over time, participants were willing to provide more detail which indicated that they felt increasingly comfortable to discuss those more emotional aspects of post-discharge medicines management, such as the level of burden and frustrations with perceived care.

Whilst no new themes were coded within these longitudinal interviews, changes to medicines management capability and engagement with medicines over time were identified. In many ways, as evidenced by the thematic analysis, the hospital admission and subsequent changes to

medicines caused patients to lose confidence in their skills and knowledge. As a result, they, or their family carers, adopted different strategies until they could regain autonomy. This was most clearly identified in the following cases:

- **Winifred (78):** Following her index admission, she no longer felt able to manage her medicines herself. Prior to hospital stay, the pharmacy provided them in their original boxes and she administered each dose herself. Following hospital stay, Winifred's daughter and GP arranged for her medicines to be issued in a multi-compartment compliance aid (MCA). Winifred was able to continue to administer her own medicines. She described, during interview 2, how as she recovered she took on more responsibility for checking the MCA as soon as it was delivered. By the final interview, she had established further strategies to support self-management such as installing a whiteboard in her kitchen so she could write up reminders for herself, such as when to re-order her medicines.

- **Marie (81):** Prior to Marie's index admission, she used a MCA. Once she returned home, she found that even this was too much for her as she was confused and felt overwhelmed. During the first interview, she explained how her daughter would put all her medicines that she needed to take into two egg cups, one for the morning and one for the evening. She also needed a reducing course of steroids, which her daughter annotated on to the calendar. At the second interview, Marie explained that she had grown in confidence with her medicines and was administering them herself now.

- **Ruth (90):** Before admission, Ruth was very confident with her medicines routine and used a MCA. After her discharge, the decision was made to commence insulin. Ruth explained during the first interview that she was very scared of needles and did not like the thought of this. By the second interview, she had had discussions with the Diabetes Specialist Nurse and was going to try to use it herself under their supervision. This was reflected in Ruth's diary entries (**Appendix 9**). She described building confidence with the insulin administration. From Ruth's primary care records, it could be seen that she received daily support from the self-management care

team to build her skills and knowledge on the safe administration of her insulin. By the third interview, she was able to administer the insulin by herself and was no longer afraid of doing so.

In one case, Robert (80) was observed to become less engaged with his medicines over the course of six months. He described how he had unsuccessfully tried to gather information about the changes to his regimen from his primary care practitioners over a number of appointments. These experiences led to a negative perception of his healthcare professionals and caused great frustration for Robert. As a consequence he became disengaged with his medicines management:

> *"I don't know whether it was something personal with me…but she was very abrupt. When she said, "Come on now, you've had your ten minutes," I said, "Yes, but in ten minutes you still haven't told me why you stopped Metformin." I said, "I've asked many times and I'm not going to leave now until I know." "We were giving you too many." I thought that's the most feeble excuse. I didn't say anything. I just thought, "I'm not going to fight it anymore, that's it." ..[…].. I was going to say, I don't even bother looking now to see if they've crossed one off…. I know that if they stopped some tablets and I wanted to know why, it would be pointless asking them."* [Robert, 80]

5.4 Findings from the Framework analysis

Interview data were coded, sorted and categorised using the Framework method (Ritchie et al. 2014) as discussed in **Section 3.6.8**. Three thematic areas with nine subthemes were identified, as shown in **Figure 21**. Participants frequently described how a hospital admission and subsequent medicines changes (Theme: Impact of hospital to home transition) caused disruptions in their ability to manage their medicines at home. They described various activities and strategies that they used to mitigate against any gaps in medicines-related care (Theme: safety strategies). However, these were performed to different levels of capability depending on how the participant perceived their role within the overall management of their medicines (Theme: medicines management role). Each theme is presented in turn, supported by

verbatim quotes from participants and their informal carers and some photographs, where consent for their use was obtained. Data from the primary care record and participant diaries were used to triangulate interview data, adding robustness to the thematic framework. During the interviews, participants described occasions where incidents had occurred following their admission to hospital. These incidents are a key component of the patient experience and brief descriptions are presented within the sub-theme Safety Incidents. An in-depth exploration of these potential safety incidents follows in **Section 5.6.9**.

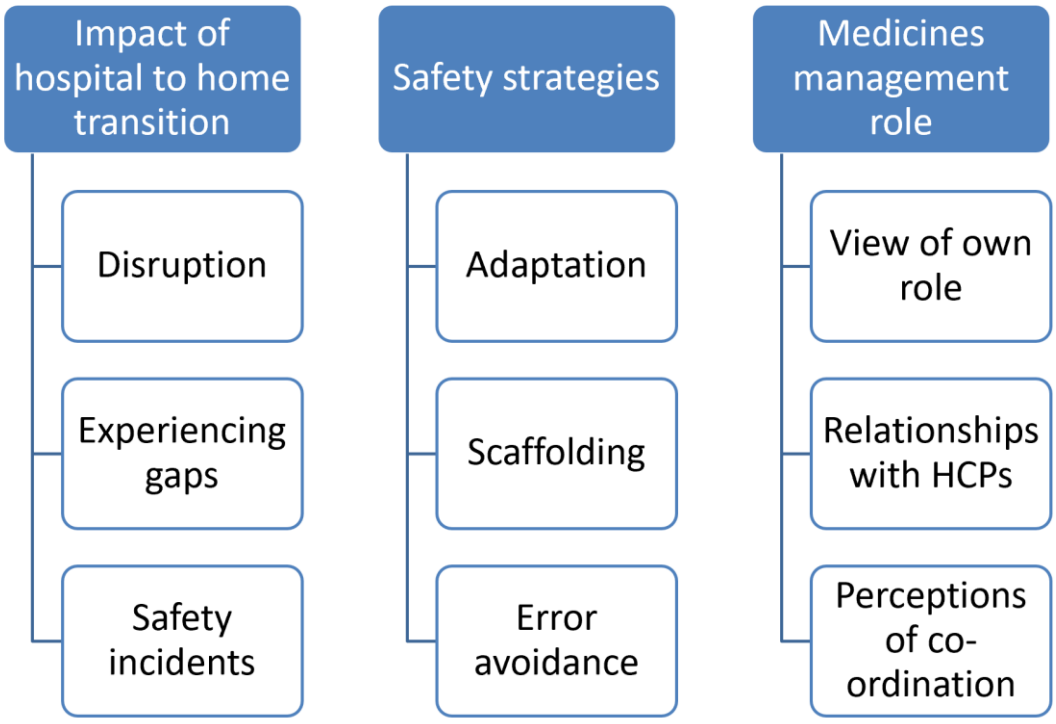


Figure 21: Framework analysis core themes and subthemes, modified from Tomlinson et al. (2020b) under the Creative Commons CC BY licence ©Health Expectations

5.4.1 The impact of the hospital to home transition

This first theme, which describes the participants' experiences of the care transition and the impact on their medicine's management, is presented in three subthemes: Disruption, Experiencing Gaps and Safety Incidents. The hospital to home transition was often experienced as a disruption to normal medicines practices (for example, participants' routines and their

responsibilities), which impacted on participants' knowledge of their medicines and their capability in managing the regimen. Participants also experienced gaps in their medicines-related care (such as problems obtaining supplies, lack of verbal communication or accessing follow-up in primary care), which sometimes led to physical harm and/or emotional distress.

Disruption

Hospital admission was experienced as a disruption to the participants' continuity of their treatment. This sub-theme highlights how this interrupted knowledge of their medicines, their regimen and routine, their capability and even their responsibility for their medicines; all of which impacted on their medicines management once they returned home.

During interviews, participants frequently reported a lack of understanding about which, if any, medicines were changed during their inpatient stay. Prior to admission they had established routines and knew which medication to take and when. Sometimes they observed a different number and colour of their medicines upon discharge, compared to what they were taking before admission, so inadvertently made assumptions that their regimen had changed:

> "…*but they have changed cause I know how many I used to take each morning and I know they're reduced but then with a few more later added on the day to what they used to be*." [Hazel, 91]

> "*I think some of them have changed but I'm not sure which*." [Nancy, 82]

> *"I think more or less the medicine, take out the chew tablet, I don't know."* [Eleanora, 83]

These changes and additions to established medicines regimens resulted in a lack of knowledge about what participants were taking, or why. This interruption to knowledge impacted on individuals' abilities to manage their own medicines when they returned home. Whilst some participants had been

responsible for, and managed their own medicines before admission, multiple changes upset the systems that had worked for them beforehand:

> "*I couldn't explain it to myself and I've always been good at working my… I've always done my own dosette box, always, but I thought 'ay, I don't know where to start here'."* [Betty, 85]

> "*because when we came home and we'd got all these boxes I said, "I can't cope with that," you know because I just didn't know what they were*". [Elizabeth, 87]

> *"I'm getting confused, I'm on that much medication and then I get used to that and then it's getting changed again…"* [Marie, 81]

Alongside this interruption to knowledge, participants described fluctuating levels in their personal health, deterioration and a recognition of prolonged recovery during the post-discharge phase. This disorientation appeared to impact on their medicine's management capability. For example, in the early post-discharge phase they often did not feel well, forgot to take their medicines or struggled to access them due to lower levels of mobility:

> "*But every day I knew I was getting a little bit better but I wasn't 100% the way I used to feel. It seemed as though it took ages this time to get myself pulled round properly."* [Betty, 85]

> *"The thing was, when I came out, I couldn't read them (medicines) for it to stay in, you know. And I could have been doing the wrong tablets at the wrong time. Because I don't think, when I came out, if it had said morning and evening or something like that, I don't think I would have been able to register it, if you know what I mean."* [Elizabeth, 87]

> "*when I got home I were thinking to myself I think they've let me out too early; I'm not ready, you know, because I didn't feel… I didn't feel as if I could cope, you know, with everything and I was forgetting my tablets and I were just more or less sleeping in here most of time, so I wasn't remembering anything."* [William, 79]

> *"Yes, I have to ask, if I need it, it's very sore is my foot now you see, but I ask if I can have my Co-codamol and they put a couple of tablets in my little pot that I have; it's in the kitchen at the moment."* [Elsie, 84]

Some participants voiced frustrations at a reduced ownership of medicines administration during their admission. This interruption in responsibility particularly upset Mary (81); *"I said 'Where's all my tablets gone?' and they said 'Oh we have to keep them and to give them you, you know'"*. Ruth (90) was only able to take paracetamol capsules as she struggled to swallow tablets. Despite taking in her own supply and explaining this to the nursing staff, they would not let her self-administer. Consequently, she had to go without her paracetamol for her arthritic pain during her admission, which she had taken regularly whilst at home prior to admission. She also described how her stronger pain relief medicine was taken away; "…*but then they took them all out and put them in a safety box. They wouldn't let me have my Tramadol, not unless I asked for it, and they only used to give me one, where I took two for pain."*

Experiencing gaps

A gap within healthcare is recognised as something that should have happened but it did not (Fylan et al. 2019a). This sub-theme describes where participants perceived their medicines-related care to be lacking, affecting the management of their medicines. Gaps were evident in conversations about medicines and post-discharge follow-up care, which led participants to make assumptions about their regimens, or onward treatment. In addition, many medicines continuity issues highlighted by participants, led to not only supply problems, but also errors in medication and gaps in day to day care.

A lack of quality conversations about medicines during inpatient stay was experienced by most participants. They expressed how they had not known what the medics were doing, and felt that they were withholding information or that their medicines had been changed behind their backs. Some family carers also felt that they were not being kept up to date with progress throughout the admission, resulting in a poor understanding of the participant's post-

discharge treatment. This gap was one of the main causes of deficits in medicines knowledge, emphasised in the previous sub-theme, disruptions:

> *"I accept when they tell me, what I don't like is doing it behind my back and thinking that an old codger of 80, he won't remember what his tablets were; I do."* [Robert, 80]

> *"Nobody explained anything. I didn't even know they took me off the rivaroxaban*." [Winifred, 78]

> *"…quite often the nurses didn't know or if they did know they weren't saying, you know, they probably thought they'd got to keep it confidential."* [Marilyn, 86]

> *"… they kept changing my tablets and that but nobody tells you what they're for or owt, you know."* [William, 79]

Where participants recalled speaking with a HCP during their hospital stay, e.g. ward pharmacist, they often could not remember the detail and described how they felt 'not with it' whilst in hospital or as though they had suffered with memory lapses. Conversations seemed to focus on whether they were taking their medicines and what they were taking, more akin to MR processes, than medicines information or advice. In a few cases, where participants had asked questions of the hospital staff, they found the answers disappointing or lacking in detailed explanation. Sometimes, this caused further panic, such as when Marilyn (86) was told she could not have a certain tablet that she had usually taken at night:

> *"When the doctor hasn't had time to write up your drugs and it comes to night time and you're due for a night tablet. That really is a bit upsetting..[…].. I mean obviously when somebody's written it for a night time tablet at home, you expect to go in and have it..[…].. I must admit I went in a panic, told the night sister..[…].. and 'yes, no, you couldn't have it'."* [Marilyn, 86]

> *"I did say to someone "Has my medicines changed?" and they said "We don't know" but they have changed."* [Hazel, 91]

Shirley (81): "They didn't say very much."

Researcher: "And did anybody have a conversation with you about your medicines for example?"

Shirley (81): No, 'are you taking your medicines?' 'Yes'.

Similarly, conversations at discharge were found to be insufficient. For example, Robert (80) had his new medicines delivered to him (by taxi) the following day, which meant that no one at all spoke to him about his treatment. Other participants were not provided with any explanation despite receiving their medicines on the ward:

"I was just given the bag of medication and that thing [discharge letter] I showed you". [James, 79]

"*when we got there they'd just gone for the tablets, so it's just like yeah, there's your tablets, off you go."* [Elaine's daughter]

"They didn't really discuss because he had his dosette box so they knew basically and your list what he was on. And the antibiotics that he was on, they kept him on them and what have you didn't they?" [John's wife]

"*She's been in and out of hospital for the last 20 years and this is the first time we've had anything like this, just a letter given to you as she came out, no explanation whatsoever."* [Betty's husband]

These examples of poor quality conversations about medicines left participants and their family carers with a number of unanswered questions about their conditions, why changes had been made, what they had to do once they had returned home, and importantly what side effects, if any, they might anticipate. Even more upsettingly, they had to guess or draw their own conclusions about the rationale for changes:

"But you still don't know why they took her in twice and why, you know, she's had the stopping of the cholesterol and the acid tablet, you used to take two and now they've changed that just to one." [Betty's daughter]

> "*It said something in the hospital notes about too much lactate so I assume that means lactic acid in the blood stream, something like that...[…]… It's just guesswork on our part but if it says that then you've got to guess haven't you that that's what they're meaning*." [Robert's wife]

Rationale for medicines changes were also lacking or confusing within primary care records. Joan (78), Charles (82), Robert (80) and Eleanora (83), for example, all had significant changes to their medicines during their hospital stay. Whilst discharge paperwork indicated that a change had been made, there was no clear reason why, nor was this followed up within primary care. Eleanora's (83) notes revealed confusing and contradictory information. Her discharge paperwork clearly stated that an item (atenolol) had been ceased. However, in the same document the comment, "BP low on admission; Prescriber happy to continue at 50mg" also appears. In some instances, a post-discharge medicines conversation had occurred with a member of the primary care team, e.g. community nurse, and this was coded within the record. Interestingly, no participants referred to these conversations within their interviews:

> *"Medication management assessment: family assisting/ patient is aware of medication name and why it has been prescribed. Compliance checked: patient feels medication is working." [Elizabeth's notes; four days post-discharge, Community nurse assessment]*

> *"Checking medicines adherence "able to read labels, able to open, remembers to take, knows names, knows when to take"" [Betty's notes; four months post-discharge, Care team manager visit]*

Despite an awareness of these gaps in discussions about medicines, participants appeared to rationalise that HCPs were too busy to talk to them, had no time to stop and had lots of other patients to see. Sometimes the staff were not visible enough to patients and family carers for them to ask questions, especially when carers came to visit:

"Well I don't see any reason why they can't ask questions really in a way, but they just seem as though they haven't a lot of time you see, you know to be answering… if they stopped at every bed they'd get nothing done really would they. Because they are shorthanded, I do know that, but I mean I didn't bother them, I just let them get on with it. I didn't bother them." [Ruth, 90]

"…people (HCPs) don't listen. That's the thing. People just you know, they're that busy writing down instead of listening to what your concerns are. They've got too many people to see in such short time." [Harry's daughter]

"I mean we were there nearly every day, it's not like they couldn't get in touch with us. We were, that week, that last week I were there every single day and nobody came and spoke to us at all. Even, I mean you don't like always asking because they're busy, there was never nobody about anyway…" [Elaine's daughter]

Others attributed the lack of discussions to ageism, where they felt they were treated as a 'geriatric' or as if they had dementia:

"I was in a bay with three other ladies and one definitely had dementia. One, I would have struggled to say whether she did or she didn't and the other lady was poorly so nobody seemed to treat me, nobody seemed to stay and talk. And nobody told me these sorts of things and I think they thought I was possibly in the same, I think I was categorised the same as what these other ladies were and I wasn't. In fact one doctor came in and said "Oh you're reading a book" and he was amazed that I was reading a book." [Hazel, 91]

"Added to which they'll decide that they'll give you what they want you to eat rather than take what you've written on the menu or not give you a menu at all and decide that you're a geriatric and you don't know what you're talking about, you can't read. So that's difficult." [Marilyn, 86]

"Just because you're getting on a bit or you're doing this, sort of, easily, doesn't mean to say you're a cabbage. You should be allowed to have some of the information." [Charles, 82]

Some conversations were, therefore, held between HCPs and family members, and thus, the participants relied on their family to relay key information to them. This was evident in Hazel's (91) case, where her daughter had been informed that Hazel had been diagnosed and treated for stomach ulcers, whilst Hazel herself had not been made aware of this:

Daughter: But they did find you've got stomach ulcers.
Hazel: Did they find I've got stomach ulcers?
Daughter: Yeah, yeah.
Hazel: Oh I didn't know that.
Daughter: Yeah you've got stomach ulcers.
Hazel: Oh I didn't know.
Daughter: Well you're taking medication for it.
Hazel: I've got medication but I honestly didn't know that. [Hazel, 91]

These gaps in discussions about medicines led to 'unknowns' and confusion about follow-up care and monitoring within the community: who was responsible, what action and when it would happen, and an assumption of why certain tests needed to be done.

"*I've looked at the discharge notes and it says something about to check her Us and Es or something, her blood pressure and her heart rate in, in a couple of weeks. I thought if that's the note for the GP but nobody's been in touch about that*." [Elaine's daughter]

"*I went to see a lady a couple of weeks ago..[…]..I've got to go and see her again on Valentine's Day, 14th. She got onto me all the time 'why are you going into hospital all the time? Why are you taking all these medicines?' And I don't think she was a doctor, she was some kind of doctor not a GP, and she said 'I've got to see you'."* [Shirley, 81]

"A check up, yeah you know, but you know I can't understand why nobody has been…" [Joan, 78]

Challenges within post-discharge follow-up were also observed in primary care records. Joan's (78) discharge paperwork asked her GP to review a number of items that she was taking, but a review never occurred according to her patient record. Similarly, Charles' (82) discharge instructions called for post-discharge review and education regarding his medicines, which once again was not evidenced in his notes. The time taken for letters to be processed and reviewed could also have impacted on follow-up care, with both Hazel (91) and Ruth (90) waiting three to four weeks for action to be taken after letters from the hospital were sent to their GPs.

Often hospital discharge was perceived as a last-minute decision, which resulted in gaps in the supply of take-home medicines supply which caused significant anxiety for patients and family carers. Some participants, such as Ruth (90), were frustrated that they did not have their own medicines returned to them or, like James (79), were given items that they had not taken for a long time. Marilyn (86) found it alarming when she did not receive all the medicines she was expecting. Shirley (81) did not receive any medicines to take home and this was a cause of great concern for her, especially as it was Christmas. Patricia (85) was supplied both new and old medicines at discharge, including some medicines that had been discontinued and were contraindicated:

> "…*one of the things that absolutely stunned me I have to say, she was given that carrier bag which is down there with her new medication in because they had made some alterations but alongside that they shoved in all the other stuff that she took in with her. So they also sent her home with the things that were no longer, that were not being used*." [Patricia's daughter]

Following discharge, patients encountered further issues not only with delayed supplies, or ordering new items, but also with the oversupply of things no longer needed as well as the incorrect packing of MCAs. Some were frustrated with the increasing amounts of medicines at home and appeared unclear on how to rationalise their supplies. One participant, Doris (88), was unclear whether some of her discharge items were to continue after she had finished the hospital supply:

"…and I says "Oh I haven't got any, you know if I am to have them, I need", you know I didn't know whether it was just you know like a week's supply and finish with them" [Doris, 88]

"I told them at chemist. I said, 'you see, I've been in hospital', 'oh, have you?' I said, 'yes'. I said, 'I've been in a month'. So, that put it all back. The tablets didn't come you know?" [Alice, 92]

""Mum," she said, "I don't think your dosette box is right, there's something short in them" […] so went back into the chemist and she said, "I didn't think you'd need that anymore, so I knocked it off."" [Hazel, 91]

"…every week I have to ring them up; you haven't given me this and you haven't… and this is short, I've got this one I don't want…" [James, 79]

Discontinuity of medicines supply was also evident within primary care records. Joan (78) and Elsie (84), for example, both experienced problems with obtaining their onward supplies and both contacted NHS 111 services to resolve this. From his notes, Charles (82) received a duplicate supply of acute medicines that he had received at discharge, due to the lack of clear instruction over who was to supply the items on the paperwork.

Safety incidents

This sub-theme describes the potential patient safety incidents (PSIs) experienced by the participants during their interviews. PSIs were categorised broadly into four areas, as described in **Section 3.6.8**, and each will be briefly explored in turn. A more detailed investigation of the potential impact of these PSIs on the participants' physical and emotional wellbeing is in **Section 5.6.9**.

Participants commonly experienced problems with obtaining their medicines; most often they ran short because the community pharmacy did not send the next supply on time or were sent in error. Other potential PSIs included the over-supply of medicines that the participant no longer used, or that left them unsure about what to do:

"Now this chemist down here messed up with my tablets two weeks ago. I went four days without a special tablet that should have been in my dosette box and wasn't. It was one for my blood, that one. So, I rang them up and I asked them why [….] and then it was two weeks after that and I said to my daughter I said, "There's another tablet missing out of here." So, she checked. She checks all my medication. I said, "[de-identified]" I said, "I'm not going mental" I said, "I know my tablets." So she rings the Chemist again. She said, "This is not on." Now this was one of my heart tablets." [Marie, 81]

"I just looked at it and there was stuff that they were giving me that I didn't need but that wasn't the pharmacy's fault, they could only give me what the doctors prescribed me and they gave me stuff that I haven't been taking for two years." [James, 79]

PSIs caused by problems with post-discharge communication, co-ordination of care, or medicines information were also regularly described by participants. These were often the cause of much confusion and anxiety for participants and their family carers, especially when they expected something to happen (such as a visit from the heart failure nurse, the restarting of temporarily withheld medicines or post-discharge blood tests) but it never did:

"Well the doctor has put it down, three times he's put it down for her (Heart Failure nurse) to come but they haven't been yet, so whether they're busy or whether it's because I haven't been in I don't know." [Dorothy, 82]

"I mean I've looked at the discharge notes and it says something about to check her U's and E's or something, her blood pressure and her heart rate in, in a couple of weeks. I thought if that's the note for the GP but nobody's been in touch about that." [Elaine's daughter]

Clopidogrel had been temporarily stopped for two weeks on discharge (index admission). This was not restarted in primary care. She was later admitted with acute coronary syndrome and the hospital pharmacist contacted the GP to find out why it had been initially stopped and not

restarted. It was then restarted, lifelong, during this later admission. [Observation from Hazel's primary care record]

Other potential PSIs were due to problems with taking medicines, where access to doses was hindered or overdose occurred due to confusion in medicines-taking regimen. A few participants also experienced side-effects from their medicines, the worst of which resulted in Betty's (85) readmission to hospital:

"It was 50 (mg of pregabalin) to start with, what you're on now. Then they upped it to 75, didn't they, 150 a day. Then it was gradually about 180. She was taking over 300 a day. It was only that paramedic, she put it up on her thing and she started reading it. She said, "Just have a look at that." Severe side effects are blurred vision, lack of coordination, the shakes. It explained the shakes, confusion, depression. If you have these side effects, immediately you must get in touch with your GP. But you'd been on them for about nearly two months." [Betty's husband]

"They said that's your warfarin and I said, "How much is it?" "One and a half," so they'd been giving me one a half Friday and this was Saturday, they were giving me another one and a half, I said, "No that's no good, I've got to be on eight and a half." So they slipped up there but they soon got over that, put me back on a higher level for a couple of days and then put me back to normal." [James, 79]

5.4.2 Safety strategies

The theme of Safety Strategies involves the self-management techniques and activities performed by patients and their carers to promote the safe use of medicines after hospital discharge. The three sub-themes of Adaptation, Scaffolding and Error Avoidance are presented.

Adaptation

The first sub-theme of adaptation includes the strategies that participants used to help them adjust to their new post-discharge medicines. Some of them also

changed their pre-admission medicines management activities into more suitable ones following discharge.

Adaptation strategies involved changes to regular routine, or to the home environment after hospital discharge, allowing participants to regain control and maintain responsibility for the management of their own medicines. Routine appeared important for patients, with many describing their adjusted post-discharge regimens in relation to their meals or personal milestones throughout the day:

> *"My first job in a morning is I always make a cup of tea and then the second job is take my sugars, I do my reading, you know, first one in a morning and then I come in here, and I bring my tea in and I sit here and I take my morning tablets then… And then them ladies (rehabilitation team) come about half past 11 to check on me, and then with them coming at five o'clock I always take my tablets, my evening tablets at that time. I've been… five o'clock I always just take my tablets and that then they're all finished with."* [William, 79]

> *"I've started to take my medication different now, different times. She wrote it all down what I've got to do. So I get up about half past six in a morning and take a cup of coffee, make myself a cup of coffee, and then just wait a bit and take another couple of tablets and then I take another one that leaves me two after I've had my breakfast. So that's what I do now; I take them two after I've taken my two tablets with breakfast at six o'clock or half past six, something like that. And I've had it all done by seven o'clock."* [Betty, 85]

Elaine's daughter described the effort she needed to put in to fit Elaine's (96) new routine around her own work and meals, which she felt was 'tiring'. Careful modification to the timings of Patricia's (85) trips out was needed to accommodate daily district nurse visits. Furthermore, Enid (81) explained how she worked hard to slowly adjust her medicines-taking routine, hour by hour each day, to suit her lifestyle at home:

"If I was at work, so on the morning do her breakfast, tablets then I go to work. Luckily she doesn't need one while tea time, but depending on my husband's shift pattern, like the other week he'll be here at dinner time to do her dinner. I come home at 4 o'clock, I'll give her tablets and do her tea and then I'll come back at 7:30pm and give her other tablet and she goes to bed. But when, yeah when my husband's on, sort of, later shift, so early mornings he won't be here at dinnertime, I'll have to make her a sandwich but she needs tablets at dinnertime so timing is good for tablets." [Elaine's daughter]

"Well I get upset love but I think I can't double up, I can't take double, and then I've got to get back into it gradually by saying 'oh I won't take that at four today, I'll take it at five' or below, whichever is nearest time and I have to bring it back down back myself…" [Enid, 81]

"At the moment we're trying to get out sometimes a couple of mornings a week to the shops or whatever but we're always sort of mindful that my mum's got to be back for about 2:30 every day." [Patricia's daughter]

Alongside these routine changes, some participants changed the way they performed their often complex medicines-taking behaviours. Since discharge, Doris (88) now preferred to sit at her armchair and work through her discharge letter, counting the required tablets into a lid. Enid (81) liked to set her daily medicines out on a circular tray, representing the hours of the day when she needed to take them (**Figure 22**). Joan (78) used to keep all her medicines in her bedroom but since discharge, she prefers to keep them all in just one bag by her armchair.

Figure 22: Enid (81) laid her medicines out each day in the face of the clock

Finally, participants and family carers explained that they had considered flexible action plans that they could feasibly carry out if certain problematic situations arose with their medicines. For example, some planned to contact their community pharmacy by telephone if their medicines were not delivered on time and felt confident in the knowledge that their relatives could visit the pharmacy for them if delivery were unavailable:

> *"That's why I rang 'cause if there's going to be any delay I'll just go and pick it up myself."* [Patricia's daughter]

> *"Yeah they said they're very, they usually come about 12 o'clock and she said, I've rung up the chemist and she said they're on their way."* [Hazel, 91]

> *"I'll give them till this… like tomorrow and if there's no reply by say Monday/Tuesday next week I'll ring them up and just say 'well what is the holdup', you know…"* [Betty's husband]

Scaffolding

This sub-theme describes how participants and their family carers supported the healthcare system to provide optimal care by carrying out activities that compensated for the gaps that they had experienced (O'Hara et al. 2019). Furthermore, examples of healthcare professionals providing temporary or impromptu support to the participant in the post-discharge period were also included.

In the immediate post-discharge period, participants carried out activities to ensure that medicines continuity occurred. For example, Betty (85) and Elaine's (96) daughter acted as conduits for information and took their discharge letters to the GP and/or community pharmacist as soon as possible after discharge. Alice (92) alerted the community pharmacist when she had been discharged, which prompted the delivery of her medicines supply to her home. Hazel (91) and Dorothy (82) went one step further and took their discharge medicines supply to the community pharmacist and showed them what their new medicines were:

> *"…when she came home […] I went down to the doctors with the discharge note…"* [Elaine's daughter]

> *"…They gave me some more to take (tablets) which I take to the chemist and let them know."* [Dorothy, 82]

> *"I actually told the chemist myself about it and I said to him "Yet again they've changed my tablets"…"* [Hazel, 91]

Temporary strategies, such as checklists and tick-sheets (**Figure 23**) were used to support safe administration of medicines in the early post-discharge period whilst participants continued recuperating. Marie's (81) daughter wrote on the calendar when doses were due to change and Betty's (85) daughter and Mary's (81) husband produced checklists to show what medicines should be taken and when. James' (79) daughter helped him to rationalise his bags of medicines and Elizabeth's (87) daughter set out her medicines in daily individual pots until she was used to the new regimen. Some patients, such as William (79) and Harry (90) made use of temporary packages of care provided by the Local Authority to help them with medicines administration:

"…my daughter was going through the bag last week and she said, "Dad do you take these?" I said, "No," "Dad what's these?" I said, "They're carbocisteine, put them in the bin, I'm not using them," and I'm not cluttering my flat up." [James, 79]

"My daughter's done all the calendar for me (highlighting dates of when to reduce steroid dose), because I'm getting confused…" [Marie, 81]

"…my daughter puts them out for me when she comes round in the evening, she puts them out for me then for the following day." [Elizabeth, 87]

"I had them people in that come and watch to make sure you can do what… make your own meals and have a shower and that, home help (including medicines administration), I had them in and they're just finishing today actually, they've signed up to say I can do it all myself, you know?" [William, 79]

Within primary care records, evidence of temporary support from healthcare professionals was also noted. Joan (78) had a home visit from a pharmacist, Ruth (91) was enrolled in a self-management service which offered a short package of support to increase her confidence with insulin administration, and Robert (80) had a post-discharge visit from a healthcare assistant:

"Meds discussed and education provided, has good understanding. Appear compliant. Initial confusion but this has resolved. Dosette declined. Still in pain, has not been taking Solpadol as was not on discharge letter – advised to take. Follow-up in 2/52" [Joan's notes, pharmacist visit, two weeks post-discharge]

"Self-management of insulin: Noted that she was forgetting to mix the insulin" [Ruth's notes, team visit, three months post-discharge]

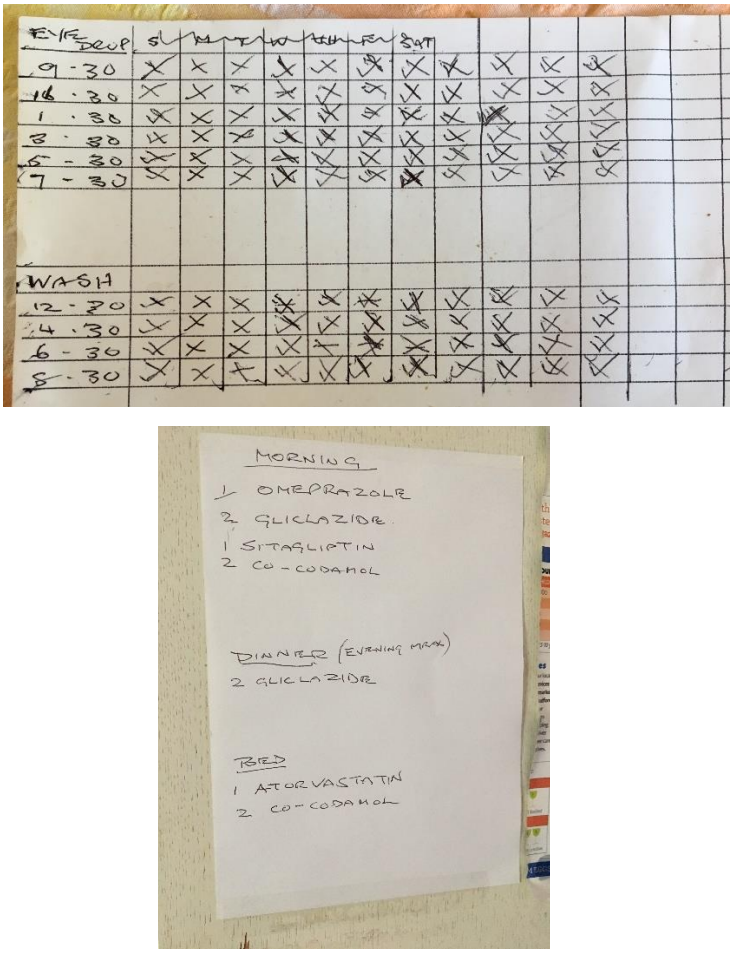


Figure 23: Mary's (81) tick-sheet and checklist to support administration

Participants recounted how they relied on their family carers to help bolster memory whilst recuperating, for example, when reminding them to ask particular questions during upcoming primary care appointments or to remind them to take their tablets with them if they are going out:

> *"Like when they say to me 'mum, do you want to go out?' or granddaughter's come, because they're all grown up, 'do you want to come with us, we're going so and so but don't forget your tablets', you know, they remind me if I forget…"* [Enid, 81]

> *Mary: He looks after me 100% , you know he really does, if it wasn't for him I wouldn't be able to cope on my own I don't think, it'd just drive me potty.*
>
> *Researcher: In what way?*
>
> *Mary: Remembering to keep my supply in; I'd start to panic.* [Mary, 81]

Daughter: So she's got an appointment to see the GP tomorrow afternoon, so I'm going in, but you still don't know why they took her in twice and why, you know, she's had the stopping of the cholesterol and the acid tablet…

Betty: But I want to know why they've stopped the cholesterol, you know, I've took it for years, a long time now.

Researcher: So is that something that you'll be asking in your appointment tomorrow?

Betty: Yeah, tomorrow, [daughter] is going in with us. [Betty, 85]

Other family carers were relied upon to co-ordinate care, to fully support the patient with all their activities of daily living, or to liaise with primary care HCPs directly. Robert (80) and his wife described her role as a "secretary", keeping notes of all appointments, important letters and medical information. Betty's (85) daughter kept a meticulous diary of important dates, such as when monthly medicines supplies were due and significant incidents such as readmission. She explained that this also provided the healthcare professionals with a record of important antecedents (**Figure 24**).

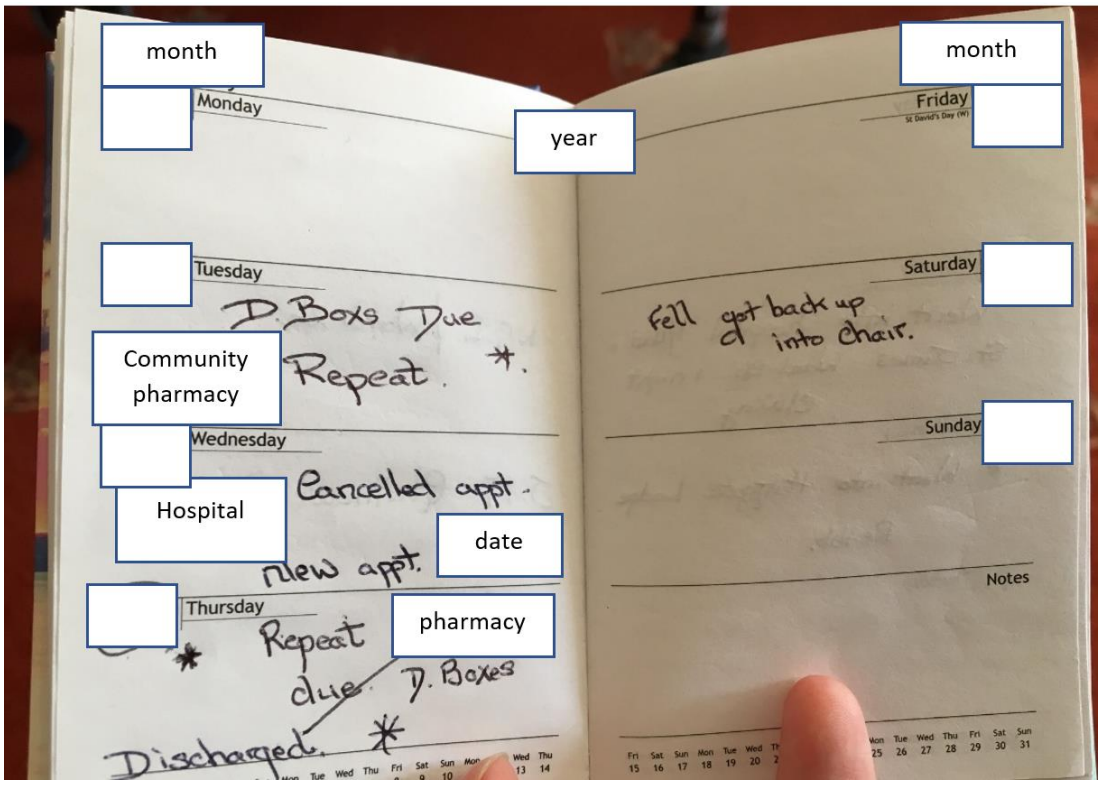


Figure 24: Betty's (85) diary (adapted to maintain anonymity)

Error avoidance

This sub-theme exemplifies the activities participants performed in order to help prevent medication errors. Strategies involved seeking information about their new medicines, the careful checking of dispensed medicines, meticulous stock control and having the foresight to anticipate and be in a better position to respond to potential post-discharge problems.

Some participants sought information about their changed medicines to learn more about them, or to identify any side effects, or contraindications that they may have to them. They took adequate time to study their new medicines to improve their confidence with them. They described reading the Patient Information Leaflets (PILs, included in all medicine packs), using the internet or asking their HCPs for further information. In addition, participants explained how they would read the discharge paperwork closely with the aim of understanding the medicines changes that had been made and so be able to identify follow-up plans. Some, such as Robert (80) and Ruth (90) also studied the medicines packaging and pharmacy labels or their new MCA instructions:

"On the paperwork [PILs], and then they send that for you […] and you can check it to make sure." [Winifred, 82]

"If there's any change I just read (PILs), you know because it explains how to take them and explains all the side-effects they can have on you." [Charles, 82]

"Either on internet or my brother works in a care home and he distributes tablets in the care home and I'll say to him, 'What's that?' 'That's a water tablet, that's for your heart.'" [Elaine's daughter]

"…my kidneys are damaged and ...[…].. when I first started taking it, nobody said to me 'this will damage your kidneys if you keep it over a length of time'. So that's now why I ask and I ask what's going to happen with them, you know?" [William, 79]

"The only thing I've looked at is, you know, reading them, reading about them, you know… because you see when I was taking that Methotrexate, when I first started and they put me on them I was taking six every Monday, then I found out I were losing my hair… I hope I don't start losing my hair again." [Ruth, 90]

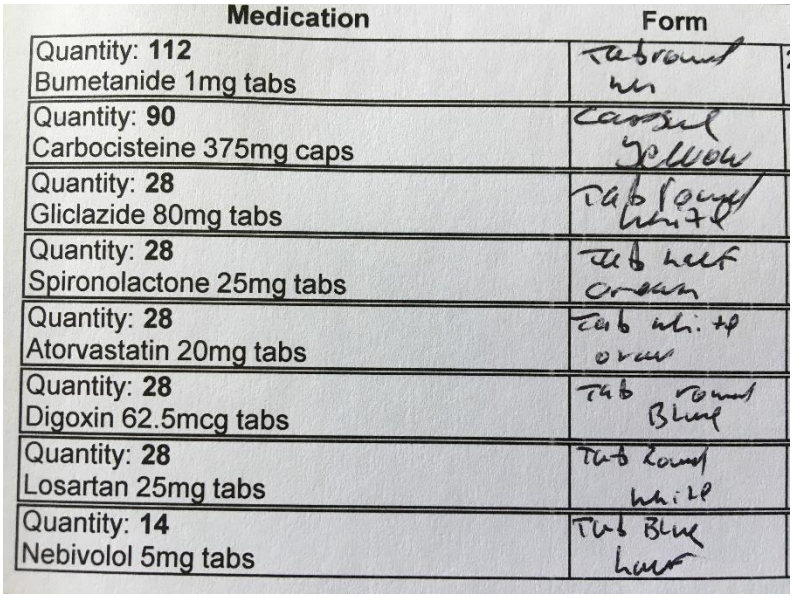
Robert's (80) primary care notes stated that he had contacted his GP four times within the six months after his discharge to seek information about his medicines. It could be seen that Ruth's son too took the time to contact her primary care practice regularly regarding her diabetes control over the course of six months. Betty attended her GP for regular monitoring tests to check that her new medicines were working for her (**Appendix 9**).

Checks and balances were carried out by participants and their families, similar to a MR process in practice. Enid (81) meticulously checked the contents of each newly delivered MCA by using the handwritten descriptions of the tablet shapes (**Figure 25**). Often, some participants tended to count how many tablets they were taking and spotted potential omissions or changes based on numbers of medicines. Marie (81) explained how she stringently questioned every unusual tablet during hospital medication rounds and how the nurses then explained to her what the medicines were. Primary care staff

were also consulted about the correctness of interpretations of discharge paperwork, or asked to check over medicines or strategies that had been implemented:

> *"Oh yeah, I'll show you (annotated calendar). My diabetic nurse said she's (daughter) done a good job."* [Marie, 81]

> *"Yeah and I checked with her (community nurse) that… I said 'I've gone back on', she said 'you did right'."* [Robert, 80]



Medication	Form
Quantity: **112** Bumetanide 1mg tabs	Tab round white
Quantity: **90** Carbocisteine 375mg caps	Capsule Yellow
Quantity: **28** Gliclazide 80mg tabs	Tab long white
Quantity: **28** Spironolactone 25mg tabs	Tab half cream
Quantity: **28** Atorvastatin 20mg tabs	Tab white film coated
Quantity: **28** Digoxin 62.5mcg tabs	Tab round Blue
Quantity: **28** Losartan 25mg tabs	Tab round white
Quantity: **14** Nebivolol 5mg tabs	Tab Blue heart

Figure 25: Enid (81) used the tablet descriptions to check the contents of her MCA

Another factor was that close stock control ensured that participants had enough medicines in hand to mitigate for any late deliveries. Mary's (81) husband made sure to have at least two months' of each medicine in stock, and carefully organised supplies at home (**Figure 26**). Robert (80) and Charles (82) separated out their discontinued medicines from their current supplies, with the intention of returning them to the community pharmacist. Others, such as Marie (81) and Jean (78) had too much stock at home due to oversupply from their community pharmacist and took conscious steps to reduce or put an end to this. Hazel (91) proactively returned her incorrect MCAs to the community pharmacy:

"And (daughter) and her husband and her took me to our own chemist and I took all the dosette boxes back because… they delivered it while I'd been away (in hospital), they delivered it next door. So I had six dosette boxes full of medicines to take back." [Hazel, 91]

"I have to ring them (community pharmacist); don't send me this and don't send me that, so now I'll ring them when I need it so, because a lot of things are just piling up and piling up." [Jean, 78]

Figure 26: Mary's husband maintains stock control in a special cupboard

Further to this, participants perceived primary care healthcare professionals to be mitigating against any potential errors. For example, community pharmacists, aided by alerts from participants about new items, amended incorrect medicines within MCAs, synchronising supplies or gathering information to ensure that the next post-discharge supply was correct:

"They kept changing the tablets so when they did that I had to send them all back and they (community pharmacy) had to do them again, you know?" [William, 79]

"He's (community pharmacist) asked me this morning, he says 'oh your doctor's put down gliclazide' …he said that we've got to put these in the box because it could be a while with the diabetes you've got." [Enid, 81]

Hazel: No they (community pharmacy) took a photocopy of the…

Daughter: You took the, you know the (take home) dosette box it had like a paper thing in the lid with all the medication.

Hazel: That's what he took a copy of. [Hazel, 91]

Finally, some participants and their family carers were able to anticipate potential gaps in onward care or had concerns about certain elements of post-discharge care prior to discharge and defended against them by asking specific questions. Participants' previous experiences of side effects with medicines, or challenges of dealing with medicines changes in the past, prompted them to further question their treatment. This enabled them to better prepare for post-discharge medicines management. Furthermore, their beliefs, such as Elaine's (96) daughter imagining that missing a single dose would result in negative effects for her mum, or Patricia's (85) daughter realising that injectable medicines would be required at home, provoked them to begin organising post-discharge care during admission. Betty's (85) daughter, an experienced carer, explained how she had a list of questions prepared in her mind that she knew she needed to ask about her mum's medicines:

"…I had a lot of this with my dad didn't I, he was in hospital an awful lot so I just over the years think oh well that's okay 'cause when he comes out I'll look in the dosette box, I'll see what he's on, I know what the list is and I'll find out and make sure he gets the right thing at the right time and that's what we've always done isn't it?" [Patricia's daughter]

5.4.3 Medicines management role

Participants appeared to assume a range of roles within their post-discharge medicines management. Linked to this, their perception of self and medicines, their relationship with their primary care HCPs and their perception of co-ordination all related to how participants adopted their role. Each of these sub-themes will now be described in turn.

The view of their own role

This sub-theme discusses the perceptions of participants in relation to their desire for knowledge, their level of expertise and their responsibility for their medicines. The role that they assumed within the management of their medicines, whether actively engaged or passive, was fluid i.e. dependent on task, stage of recovery and resource.

Knowledge about medicines was varied, with some such as Enid (81) and Ruth (90) being experts in their long-term medical conditions. These participants had lived with their respective conditions for many years, which prompted them to learn about the associated action on the body of what the medicines did and how they worked. They often prioritised certain medicines that were important to them (e.g. for heart and blood) and, therefore, could comprehensively describe any medicines changes that occurred with these. More emphasis with regard to the changes to these medicines was given during the interviews and they did not describe any other changes that occurred. For example, Patricia's (85) daughter focused solely on one new medicine during the interview (injectable medicine to prevent blood clots), rather than the seven other changes that had been made:

> *"Some medications I cannot miss. Some of them it's fine but some of them I just cannot miss them."* [Winifred, 78]

> *"I had this heart problem when she were born, my heart give way..[…].. And it made me learn to do things and I've always been interested in medicine, do you know what I mean?"* [Enid, 81]

> *"…it's the main ones that are for the heart and the blood that I have to watch, you know what I mean?"* [Enid, 81]

> *"So of course when they found out she's got an embolism and they had to give her blood they had to stop giving her the blood thickener and put her on a blood thinner."* [Patricia's daughter]

A few, such as James (79) and Marie (81) expressed that they had nothing more to learn about their medicines or could work out changes for themselves.

Moreover, they described not being afraid to tell someone if they were not happy about something related to their medicines and felt empowered to challenge where they felt necessary:

> *"… when you've been on the medication that I'm on and I've been on it like a good three and a half years, I don't need explaining to me how."* [James, 79]

> *"Oh I know what they're for, it's all to do with just take one puff in a morning and it goes down into your airways and one thing and another, so there's really nothing to explain about that, it's just the colour of the thing (inhaler) that's changed, that's all."* [Marie, 81]

> *"Like I asked about the leg; this is my leg not yours, so I don't care what you think about that, if I'm not happy about it I will tell you and I will ask you to see your superior."* [James, 79]

> *"I have no problem because I speak my mind anyway. The same as Doctor [de-identified], he's the heart surgeon, and he'll come and he'll sit and he'll talk with you and he'll say, "Now, do you understand that?" I said, "No," because they're talking medical. I said, "Talk layman to me" I said, "I don't know what you're on about.""* [Marie, 81]

Others, such as Mary (81), Nancy (82) and Hazel (91) were able to describe the types of medicines that they were taking but had adopted a more passive attitude to medicines because of the number of admissions to hospital, complexity of regimen and the subsequent changes to their medicines. Some, such as Barbara (91), Margaret (82) and John (84) admitted that they had limited knowledge of their medicines and just took what was given to them. Eleanora (83) described how her limited vocabulary hindered her from discussing the medicines in detail with healthcare professionals and, therefore, asked for all conversations to be conducted with her daughter instead:

> "*I tell my doctor call my daughter who understands more than me and more in English. Well understand medicine and you know, call my daughter who's understood more than me."* [Eleanora, 83]

"…every time I go in hospital some doctor or other changes some tablets. I think because they change every time you go, just take them, so that's all I do." [Hazel, 91]

"No, I just do as I'm told, stop them if they tell me to stop them and start them if they tell me to start them, so." [Mary, 81]

"I haven't a clue what the yellow one does or the red one does. I haven't a clue what they're doing to me, but faithful, I'll take them." [John, 84]

Despite the varying levels of knowledge about their regimens, most participants and their family carers explained how they wished to be fully informed about changes to the medicines they were taking and the rationale behind these. Whilst they desired to be involved with their medicines in this way, they were often hindered by a lack of discussion about them during the hospital stay, as described in **Section 5.4.1**:

"Well the medicines is, yeah it's a bit difficult isn't it, them not saying anything, I wish they'd have just spoke to us and just explained why the change." [Elaine's daughter]

"Well, I used to think sometime, 'well, what's it for?' you know? And I… I didn't get told you know. I felt like saying, 'well, what's this for? What's this for?' you know?" [Alice, 92]

"I'd like to have been told when you first start taking a tablet what the effects are on your body and that, you know, long-term." [William, 79]

"I think they (patients) should have somebody explain to them what to do and how to do it. Even if they want it writing on paper in bigger handwriting." [Enid, 81]

How participants felt about their level of responsibility within medicines management also ranged. Some participants preferred to maintain control by filling their own MCAs and organising supplies, whilst others such as Margaret (82), Harry (90), and Elsie (84) relied solely on their formal and informal carers for everything, including administration. They often rationalised this as a requirement due to their deteriorating memory or reduced capability after

discharge. They appeared to trust the system wholly to supply their medicines correctly and to deliver them on time. They did not check the medicines and took them without question. They perceived the physician to know best, and often just let them get on with it, without question:

> *"I thought 'well, I like take what you give me and that and that's the end of it' […] you'll do what you have to do. I said, 'look everything that you have to do, do it with my permission.'"* [Harry, 90]

> *"No I leave it [medicines] for the carers…[…]… It's something I won't be doing"* [Margaret, 82]

> "*No, I couldn't (look after my medicines) now, no, my brain's not there; half of it is missing."* [Elsie, 84]

> *"I take what is given me by the doctor. I don't know."* [Eleanora, 83]

Four participants (Joan (78), Shirley (81), Winifred (78), and Marilyn (86)) were retired nurses and explained that they were vigilant with their medicines, especially because they were aware that errors can and do happen. Their previous experiences had led them to retain as much responsibility for their medicines as they could:

> *"Yes because, as I say, a lot of things can happen in hospital and you always have to be careful what you're taking because sometimes they give you a prescription and the chemist sends you the wrong thing, you know. So, you have to know what you're taking and you have to know what the chemist sent for is the right thing. I've always done that. You have to know that, because you wouldn't believe the amount of times they give you the wrong thing."* [Winifred, 78]

> *"I know how to give medications out and you don't… say 'can we have more?' 'You can't have more, no'. I've never done that. I just take what I'm supposed to take and that's it."* [Shirley, 81]

> *"They don't have the same rapport that we used to have when we were training and I think it's lacking in some way in their education really*

because they're more or less wandering around the ward not quite knowing what's the matter with everybody." [Marilyn, 86]

Participants who were actively engaged in medicines management activities, often described the significant work they had to do. Interestingly, Alice (92) firmly believed that she should not have the sole active role for her medicines management. She was frustrated that she had to keep scaffolding the system to ensure she received her supplies on time:

"I mean I have to do it [medicines] all myself you see? And it's not right at my age." [Alice, 92]

"But it's like a job really, if you know what I mean? I know it's silly but it's like having a job, oh I've got to break off and do this [my medicines], you know?" [Enid, 81]

It is important to note that participants' perspectives of the importance of medicines knowledge and responsibilities appeared to shift depending on the task that they described and their current stage of their recovery. For example, whilst some participants described a passive role with their medicines management, they wished to be more involved in conversations to help improve their knowledge. As described in **Section 5.3**, a proportion of the participants became more actively engaged in their medicines management over time.

Relationships with healthcare professionals

This sub-theme relays participants' views of their relationships with primary healthcare practitioners. Whether they perceived valuable or inadequate interactions appeared to impact on subsequent medicines management activities.

Meaningful relationships and positive perceptions of primary care practitioners and community pharmacists were reported by few participants. Those who did describe more long-standing, positive relationships, such as Mary (81) and Hazel (91), trusted their pharmacist, for example, to explain things fully. They valued the service that they received and felt well looked after. Mary (81) and

her husband had an extremely high opinion of her HCPs so her perception of trust may have resulted in her taking a more passive role with her medicines. Where a positive relationship was described, participants sometimes took steps to involve primary care practitioners as part of their medicines management actions, such as pro-actively contacting them after discharge, to ensure they were kept up to date with information:

> *"He'll (community pharmacist) explain it you know, I just trust him as well… I think that's at one stage, I can't remember what it was for but as they changed her tablets and he phoned, he seemed to phone her up every couple of days to see how they were doing and effect on her you know so we thought that you know, they didn't just say 'Oh take that.'"* [Mary's husband]

> *"I mean the pharmacy has been brilliant, I can't knock them because when you ring they're willing to trotter about and go to the doctors for anything that they haven't got a prescription for or anything like that, they're quite willing to do anything for you."* [Elaine's daughter]

> *"I actually told the chemist myself about it and I said to him "Yet again they've changed my tablets"…"* [Hazel, 91]

> *"…it all went smoothly but that's because I deal with the chemist a lot…"* [Patricia's daughter]

> "*Well I think they're (community pharmacy) good because they messed about a lot with hospital, you know when they're changing them, I mean they've got to change all these dosette boxes and get them back to me and they don't complain; they get on with it and do it, you know, so they're pretty good."* [William, 79]

> "*Yeah, if you want anything, if he can, if he's got it in that day, he'll bring it, even if he's on his way home from work, you know. So, we're very lucky, in that sense."* [John's wife]

Those who commented on a more negative relationship with their healthcare professionals or primary care practices possessed a lack of trust in HCPs to

perform their role, or were left feeling that they could not call on them for advice. In some cases, these perceptions led to the use of the scaffolding and error avoidance strategies described in **Section 5.4.3.** This was particularly evidence in Elaine's (96) case, where her daughter had to bridge gaps in communication between the GP practice and the pharmacy, due to a perceived poor relationship. In others, it led to a lack of engagement with their medicines, and indeed their overall care, for example in Shirley's (81) case she felt that her HCP did not believe how unwell she really was. Many described a lack of easy access to their GP and felt that contacting them was a waste of time; either because they couldn't get through on the telephone or if a home visit was made, a proxy would be sent (which was considered "useless" by Marilyn (86)):

> *"And apparently the chemist that we use and the doctors; they don't really get on. That pharmacy thinks the doctor is really slow and not helpful with repeat prescriptions, so when I'd been in the doctors I went straight to the chemist as well and I give them a copy of the new tablets because I thought if I don't do it, nobody's going to do it."* [Elaine's daughter]

> *"Well I think unless you're actually on the dying list they don't bother with coming out, they just send these sisters out that… they can only write so and so, certain things, they can't make decisions on their own so it's pretty useless sending them."* [Marilyn, 86]

> *"No, no, nobody comes unless I phone them and then when I phone them I never get no b****y answers because she's like my b****y a**e her in reception, no, she's a waste of space in my opinion."* [Barbara, 91]

> *"Well, I never see the GPs. They always say the doctor's coming but when the doctor comes it's always a nurse and they don't say anything. I tell them everything. I go into detail but it's just sort of "Well, we all have to grin and bear it" sort of, you know. So they don't do anything."* [Elsie, 84]

Interestingly, within primary care notes, it could be seen that healthcare professionals often reviewed medicines post-discharge or conducted follow-up of results without the patient being present. Ruth's (90) GP, for example, would often review her diabetic treatment, but the GP relied on being tasked by other members of the team, such as the diabetes nurse, and never saw, or had a conversation with Ruth (90) directly. This was also the case with Robert (80). His GP reviewed his medicines without speaking to him, and incorrectly documented that he had stopped taking his metformin after discharge, which was not the case in reality.

Others simply described a less than optimal relationship. This was mainly evidenced in the case of community pharmacists, who were perceived to be the 'supplier' or 'dispenser' of medicines only. Participants explained how they would not consider asking them for advice or information, beyond this basic supply function. Marilyn had developed a particularly negative perception of her pharmacist after having some difficulty with supply issues:

> *"I think that was the pharmacist, they just chucked them and write their own idea of what they're going to give which was a pity because I was missing some of the drugs…"* [Marilyn, 86]

> "*Well no, I'd go to GP first… Err because he's the prescriber…. Err the what they call it is the dispenser, so I'd go straight to err the source*." [Harry's daughter]

> *"I think as long as you read the leaflets and explain what they are for you you're only going to get the same advice from the pharmacist I should imagine. If you're with the pharmacist I would imagine that's what advice you would get wouldn't you? More or less the same advice as on the leaflet."* [Charles, 82]

Perceptions of care co-ordination

This third sub-theme reports on how participants and their family carers viewed their post-discharge care co-ordination and the effect this had on their medicines management. Whether co-ordination was perceived as seamless

or chaotic, it prompted participants to be either passive or active in their medicines management.

Seamless care co-ordination was described by some participants, especially where they believed that information was transferred about their admission between the hospital, community pharmacy and their GP. Whilst they assumed this was the case, they could not explain how this might occur, they simply had faith in the system. Mary (81), for example, firmly believed that follow-up plans were in place and Joan (78) believed that important day-to-day information was passed between key individuals within primary care (e.g. her district nurse was passing information to the GP), although they had no evidence that this was the case. These participants did not appear to actively engage in scaffolding activities described in **Section 5.4.2**:

> *"No only when they change the tablet, hospital ring straight to my chemist and it carry on that way*." [Eleanora, 83]

> *"To be honest I don't know. I know that the doctor's always informed but who inform him I don't know…"* [Nancy, 82]

Other participants perceived their care to be disorganised, bordering on chaotic. Alice (92) and Elaine's (96) daughter, for example, felt that they had to take charge and co-ordinate care by themselves, especially as they described how they did not trust the system. They were frustrated at needing to continually follow things up and Betty's (85) husband described the extra burden that this added. Some perceived there to be poor communication between sectors which led them to believe that they must act as conduits. Betty's (85) daughter blamed the electronic transfer of discharge information to have resulted in a lack of verbal communication about her mother's medicines changes during her admission:

> *"It's all electronic isn't it now? They send the report straight from the hospital…[..]… so you don't really get to know anything what the doctor's said until you go tomorrow."* [Betty's daughter]

"Well you, you feel like you can't trust people don't you, to do their job and communicate… I mean it is just that annoying when you have to keep ringing and thinking why…" [Elaine's daughter]

"That (hospital appointment) was three or four weeks ago, about four weeks ago now. And I still haven't got my tablets through from the doctors…. Well it will be my doctors, who won't have prescribed it. You see, we get the letter and just leave it you know, I suppose it will come electronically won't it? It won't be posted I shouldn't imagine." [William, 79]

"The district nurse told me take it out and clingfilm the pack. But then when they (community care team) came and said you know, 'it's not acceptable'… 'where's he's tablets?'. 'All the tablets fell out'. And they said, 'whose told you to do this?'. I said, 'the [nurse] told me to do it'. 'Well, it's a bit silly, isn't it?'. I said, 'well, I'm only doing what I was told to do'. 'Why?'. 'Because I had to take the tamsulosin out because otherwise he'd take the tamsulosin'." [Harry's daughter]

5.5 Exploring potential patient safety incidents

This section explores the safety incidents described by participants in more detail. The methods are outlined in **Section 3.6.5** and these findings were presented at the Prescribing and Research in Medicines Management conference in January 2020 (Tomlinson et al. 2020c). Thirteen participants (48%) described twenty-five potential PSIs within the course of their interviews, all of which were rated. PSIs included examples of adverse drug reaction, delayed medication supply, incorrect medication supply and patient confusion resulting in overdose. For sixteen of the incidents all HCPs independently agreed that these were PSIs. In six of the potential incidents, one adjudicator disagreed that these were PSIs. Two raters thought that three of the incidents were not PSIs.

In the instances where only one rater did not class the incident as a PSI, their score was omitted and the mean was calculated based on the remaining three scores. In the instances where two raters thought it was not a PSI, an

additional rating was obtained from a moderator who is the Medication Safety Officer at LTHT. For these three incidents, the moderator classed two as PSIs, and subsequently their score was used to compute the mean. One incident was not classed as a PSI and was omitted from further analysis (**Table 17**).

All PSIs were categorised according to taxonomy, developed from the older patient perspective of MRPs (Nicosia et al. 2020): (1) obtaining medications; (2) taking medications; (3) medication effects, including side effects; and (4) communication and care coordination. Initially, the PCLSG representatives as a group and the researcher categorised the PSIs independently of each other. The PCLSG and researcher disagreed on the categorisation of 14 incidents, namely where the PCLSG thought the incident was a composite of multiple issues, and therefore could not choose just one. They also expressed that problems with communication underpinned all of the PSIs and, hence, should not be its own discreet category, but included as an element within all other MRPs.

Overall analysis of ratings resulted in the HCPs rating the potential harm caused by two PSIs as minor; 19 as moderate; and three as severe. PCLSG representatives felt that eight incidents could cause moderate distress, and 16 would cause severe distress to an older patient (see **Appendix 9** for full results). Interrater agreement was calculated as a percentage and found to be 41.3% for HCPs and 57.3% for PCLSG representatives.

Table 17: PSIs that required further adjudication*

Participant	Age	PSI detail	Severity rating: 0=no risk of harm; 10=death							Adjudication
			HCP 1	HCP 2	HCP 3	HCP 4	Mean	Median	Harm: <3 minor, 3-7 moderate, and >7 severe	
Dorothy	82	The GP has requested for the heart failure nurse to visit her three times now. They haven't been yet – this could be because they are too busy or maybe she wasn't in	4	7	Not PSI	Not PSI	5.5	Not PSI	Not PSI	Not PSI - we don't know what the GP has said or whether the nurse has turned up
		She was due her INR test last week but was away. She was supposed to them this Wednesday, but had forgotten	4	7	5	Not PSI	5.3	5	Moderate	
Elsie	84	Following discharge, Elsie was very immobile due to painful foot surgery and relies on her carers more for medicines administration. Whilst her carers were supposed to attend four times per day, their visits have become more sporadic and sometimes they only come twice a day. This has an impact on the number of times she can take her painkillers as she only has them when they are brought to her	5	5	Not PSI as only pain medicines missed	4	4.67	5	Moderate	
Marie	81	Her medicines are changing all the time and she's getting confused with what to take. She's overdosed by accident twice, so her daughter looks after the medicines immediately post-discharge	7	9	Not PSI	5	7	7	Severe	
		Her daughter has had to ring the chemist to tell them not to bring any more medication until Marie rings them – she has carrier bags full and is getting confused	4	7	Not PSI	1	4	5.5	Moderate	
Hazel	91	The hospital stopped lots of her medicines. She mentioned this to her GP at an appointment and the GP expressed her confusion. Hazel only has one kidney and the GP said she had to take certain medicines which had been stopped in hospital (furosemide and ramipril). The GP explained that some of the tablets she couldn't do without, and restarted them	5	8	7	Not PSI	6.67	7	Moderate	
		The chemist keeps sending her Gaviscon every month even though she doesn't want it. She has eight bottles currently. The chemist won't accept them back as they have left the shop	1	4	Not PSI	Not PSI	2	1	Minor	1
Joan	78	The chemist is supplying items that she doesn't need, she doesn't know what to do with it	1	5	Not PSI	Not PSI	3.33	4	Minor	4
		No one has reviewed her since discharge (2 months) when her blood pressure medication was stopped. Her blood pressure has always been high, now it's suddenly gone low – she can't understand why no one has checked it	5	5	4	Not PSI	4.67	5	Moderate	

*Coloured row indicates the incident that was later removed as it was not considered a PSI by the adjudicator.

HCPs and PCLSG representatives agreed in their severity ratings for 10 PSIs namely problems with: obtaining medications (n=2); taking medications (n=2); medication effects (n=2); and communication and care coordination (n=4).

The main disparity between severity ratings occurred for problems with obtaining medication (n=9), where HCPs scored these PSIs as mild or moderate whilst PCLSG representatives rated them as moderate or severe. This comparison, thus, illustrates that PSIs relating to post-discharge medicines supply (supply of medication no longer needed, tablets missing in compliance aids or delayed supply) can be perceived to be severely distressing for patients, yet in comparison only classed as causing minor or moderate harm by HCPs. The remaining five PSIs were rated as moderate harm by HCPs and severe harm by PCLSG representatives and were problems with: taking medications (n=1); medication effects (n=2); and communication or care co-ordination (n=2).

5.6 Discussion

This chapter has delivered the findings of a thematic analysis of patient and family carer perspectives of post-discharge medicines management using the Framework method (Ritchie et al. 2014). Interview data were triangulated with information extracted from primary care records and diary entries, to increase robustness. This analysis clearly shows that the participants experienced their hospital stay and subsequent transition back into their home as a disruption to their knowledge and skills, which impacted on their ability to manage their medicines. They described this as a challenging period, especially when they perceived gaps in care, which is echoed throughout international research spanning the last 20 years (Driscoll 2000; Arora et al. 2010; Eijsbroek et al. 2013; Knight et al. 2013; Andreasen et al. 2015; Eassey et al. 2016; Fylan et al. 2018).

Impaired medicines knowledge is a common finding throughout the literature. For example, Knight et al.'s (2013) qualitative study of 19 older patients found a mixed view of the quality of medicines information at discharge. A few patients were satisfied that they had received adequate information; yet some had to bolster this by asking further questions. Most patients reported little or

no provision of information about changed medicines, which left them feeling disappointed or confused when they were given their discharge medicines (Knight et al. 2013). In a larger study, the majority of recently discharged Australian participants reported a lack of medicines knowledge, which resulted in confusion about changed medicines (Eassey et al. 2016). This confusion has been shown to result in post-discharge medication issues (Eijsbroek et al. 2013). Obtaining an overview of prescribed medicines and discontinuity of post-discharge supply have been highlighted as significant challenges specifically for older people living with frailty (Andreasen et al. 2015). This previous study of 14 recently discharged patients illustrated the insecurities and frustrations they experienced, which resonates with the current findings (Andreasen et al. 2015).

Impaired capability after hospital discharge was recognised by Wong and Hogan (2016) in their study assessing continuity of care for older adults. The immediate post-discharge phase (30 days following discharge) is characterised as a period of increased vulnerability caused by significant deconditioning and stress associated with a hospital stay (Krumholz 2013). This phenomenon, known as post-hospital syndrome, can lead patients to more negative perceptions of their care transitions (Wong and Hogan 2016). The findings from the current analysis also underline the fact that participants perceived that they had fewer medicines responsibilities whilst in hospital, which may have contributed to a decline in their skills. When medicines ownership was returned to them at discharge, their capacity for self-management may have been impaired. Deferring responsibility for administration to someone else in the post-discharge phase is the patient's way of coping with their lack of confidence in their skills (Andreasen et al. 2015).

Findings from the longitudinal interviews within this study have further shown that capabilities can change over time. This implies that medicines management needs are dynamic and should be reassessed over time, taking into consideration that the way the patient presents in hospital is not always a true reflection of how they are, or how they will be, in their own home after discharge. Enid (81) expressed this plainly and precisely: "*They've got to go*

over it with you and see what you're like taking, they don't live with you, so they don't know."

Involving patients throughout their journey to resolve any knowledge and skills deficits is one way to ensure that they, and their family carers, have the tools to adopt and perform the self-management of medicines. This could enhance 'patient activation', defined by Carman et al. (2013) as an "individual's knowledge, skills and confidence for managing their own health." Encouraging involvement by increasing knowledge, and patient activation by increasing skills and confidence, could lead to better participation in medicines self-management behaviours.

5.6.1 Increasing knowledge through information

Information exchange is key to patient participation (Bugge et al. 2006). Most medicines-related problems are related to poor communication (Forster 2006; Kripalani et al. 2007b). A study of 31 adult patients demonstrated that a range of information needs to exist for patients at discharge, such as the name of their medicines, the indication and the dose (Borgsteede et al. 2011). Older patients, though, expressed no need for further detailed information as they felt that their doctor knew best. Duggan and Bates (2008) found that medicines-related informational needs decreased with age, meaning that older patients did not desire medicines information. What these patients did want, however, was pre-emptive advice i.e. what to do if, and when, certain situations arose. Being informed of potential post-discharge problems has previously been shown to be a key gap within current methods for discharge preparation (Driscoll 2000). Within this present study, participants displayed a range of information requests, such as Robert (80), Betty (85), and Ruth (90), who were interested in the rationale for medication changes, William (79) who wanted to be told about side effects, and Mary (81), Elizabeth (87) and Alice (92) who did not want to know any specific details.

Wong and Hogan (2016) point out that hospital discharge is a time of fear, confusion and worry. The day of discharge is, therefore, not optimal for learning (Cain et al. 2012). Very few participants within this study mentioned conversations at discharge, and yet "discharge counselling" is a term that

appears widely throughout the literature and within good practice guidance. At discharge, patients are supposed to be offered information about medication changes. Whether they had simply forgotten, due to this being a stressful time, or whether it did not happen, participants did not feel they had experienced quality conversations at discharge. Data extraction from the primary care record also revealed that participants failed to recall a number of conversations with healthcare staff. Specific medicines-focused conversations were coded within some participants' records (Elizabeth (87) and Betty (85)) as part of post-discharge assessment. No recall of these events may indicate the participant's perceived importance, relevance or quality of these conversations.

In a study focusing on the quality of discharge information, there was broad variation in the content of conversations (Wright et al. 2017). For example, only 58% of patients were counselled on how to obtain further supplies after discharge, which was a significant source of frustration within the present study. Borgsteede et al. (2011) also found that patients value both oral and written information. This would ensure the patient has something to refer to later once they have returned home. In this study, oral information appeared lacking and participants recounted spending time trying to interpret the written discharge letter to understand what has happened to them and their medicines. The participants commented on how these documents often contained conflicting information, were written in complex medical terms or simply were not understandable. This, and a general lack of information during inpatient stay, is a missed opportunity to help prepare patients for medicines management after discharge.

5.6.2 Increasing activation through capability

Participants within this study expressed how they did not have the opportunity to administer their own medicines during hospital stay, and often despite them bringing in their regular supply. This was a source of tension for some patients, who would have preferred to maintain their own routines. This reduced ownership and responsibility for medicines management during hospital stay could have accounted for reduced capability. Elizabeth (87) related to this

during her interview, where she explained that because she was not administering her own doses, she did not know what medicines she was taking. As a result of this her confidence diminished and she could not cope with administering her own medicines in the post-discharge phase. In a study conducted by Manias et al. (2015b), participants expressed that self-administration of medicines helped them increase their autonomy and allowed staff to redirect resource to other areas, e.g. patient education. Another beneficial feature of self-administration is that of allowing patient knowledge to be demonstrated to staff. This is important when considering if a patient is approaching discharge and what kind or level of support they are likely to need at home. Current local hospital policy does not appear to encourage self-administration practices, because of the requirement of daily patient assessment and its associated paperwork to be completed. It is also the case that some patients, such as Winifred (78) and Margaret (82), may prefer to hand over this responsibility to healthcare staff, especially those who are very unwell or have additional support needs (e.g. patients living with dementia).

5.6.3 Self-management and safety strategies

Whilst the experiences within this study are similar to those from the international literature, explored in **Section 2.6.2**, the participants also communicated numerous activities and strategies to help with medicines management in the post-discharge period. This is a novel topic as previous literature has highlighted that whilst older patients living with frailty would like to be more involved in their care, authors were not sure what they are able to do (Ipsos Mori for Age UK 2014). This analysis has shed light on what these more vulnerable patients and their family carers do to ensure safety and continuity of medicines management.

Activities undertaken by patients and carers are often carried out at home and rarely seen or acknowledged by HCPs. This mirrors the ‘invisible work’ required of patients to adhere to their medication schedules described by McCoy (2009), Jowsey et al. (2016) and Huyard et al. (2019). These strategies involved significant burden, frustrations and challenges that the participants had to overcome. May et al. (2014) describe this within their Burden of

Treatment Theory, which hypothesises that as demands on patients to manage their conditions through pro-active work increase, they can become overwhelmed. This results in poorer healthcare outcomes, including non-adherence, increased service utilisation and financial cost (May et al. 2014). Huyard et al. (2019) remark that the burden and negative emotion felt by patients and carers is often the result of a learning process, especially when long-standing routines are challenged, such as when medicines are changed. Jowsey et al. (2016) also acknowledge that crafting plans to ensure care co-ordination presents a time burden to patients as well as an emotional one. Additionally, patients and their family carers must make significant effort to re-build and maintain their new post-discharge schedules (Huyard et al. 2019). This is a demanding process, in particular when medicines regimens are complex or patients lack the skills or resources to carry out associated tasks.

The thematic analysis has demonstrated that older patients and their carers are able to design and take part in activities that support not only their own medicines management, but which also scaffold or safety net the healthcare system. Patients' and carers' methods of reaching into the system to support care, such as by acting as an information conduit, promote resilience (Fylan et al. 2018; O'Hara et al. 2019). Resilience strategies are thought to help avoid error and improve performance (Furniss et al. 2014). In Fylan et al.'s (2018) study of cardiology patients, participants displayed resilience strategies when managing their medicines by identifying system vulnerabilities and taking steps to overcome gaps in care. For example, seeking information to close gaps in knowledge, organising medicines supplies, and implementing prompts, such as checklists were all strategies employed by participants. They also demonstrated self-management strategies, such as post-discharge learning, adaptation and implementation of adherence cues (Fylan et al. 2018). The strategies of adaptation, scaffolding and error avoidance identified within this study correspond with those of cardiology patients of a range of ages (Fylan et al. 2018), thereby demonstrating that older patients and their family carers can also be a source of system resilience. In another study, patients creatively overcame gaps in their care by facilitating communication and keeping their own audit trails (Jowsey et al. 2016). The authors

acknowledged that the development of these strategies depended on the patient's capacity to recognise a gap in care and their ability to develop a tailored solution to the problem that they would be able to perform within their capabilities (Jowsey et al. 2016). The ability to do this relies heavily on knowledge, skills and resources. It is perhaps those who lack these that are the most vulnerable and at highest risk of harm.

No one was reported to have prepared the participants for the significant 'work' that they had to put in to managing their medicines, and some, such as Alice (92) were frustrated about the amount of effort she needed to expend on medicines related tasks, such as organising her medicines deliveries. Forster (2006) argues that more could be done to better prepare patients for the role they may have to play after discharge. However, it is clear from the analysis that not all participants wanted to be engaged or participate in these tasks, and their level of engagement with their medicines is an important consideration for intervention design.

5.6.4 Levels of engagement and participation with medicines management

Better involvement through increased knowledge and activation through skills and confidence, as referred to above, are thought to increase a patient's level of engagement with their own care (Carman et al. 2013). Within the present study, a range of roles associated with medicines management were identified. From those passive participants, who simply did as they were told, through to those who requested an active role in shared decision making, there are implications for healthcare practice and indeed intervention design in terms of the type of support that is offered to patients and, just as importantly, how much.

Patient and carer engagement to improve medicines safety requires HCPs and families to work in active partnership (Kim et al. 2018). Patient engagement is crucial to care as it has been shown to foster better patient-centred outcomes, especially significant since low levels of participation are associated with an 8% to 21% higher healthcare cost (Hibbard et al. 2013). Engagement can be

illustrated by how much information flows between patient and provider and how active a role the patient plays in decisions (Murray et al. 2019). A framework for engagement (**Figure 27**) currently exists and indicates progression from consultation to partnership and shared leadership (Carman et al. 2013). Current practice appears to be at the consultation level. HCPs and patients need to be encouraged to work together as partners and move towards the higher levels of partnership to empower patients to self-manage their medicines. Patients and staff will require appropriate resources to do this. It cannot be assumed that every patient wants this higher level of engagement. Mohsin-Shaikh et al. (2014) identified that individuals over 65 years of age wanted less involvement in their own care whilst in hospital. In an American study (Levinson et al. 2005) of 2765 participants, 96% wished to be offered choices and to be engaged about their preferences. However, 52% preferred to defer the final choice to the HCP, with 44% trusting the HCP implicitly, therefore not seeking information themselves. Active roles were associated with younger more healthy women and the desire for participation decreased after the age of 45 years. Flink et al. (2012) found that patient characteristics, such as female gender and younger age, and attitudes or empathy from HCPs were enablers to patient engagement. Whilst this may be true for some older patients, it is difficult to agree with this finding entirely as this study's thematic analysis has revealed a range of preferences for engagement and, therefore, for each patient their level of need and desire should be established. Willingness to participate is also dependent on the task at hand (Belcher et al. 2006). Eassey et al. (2016) argues that it is the responsibility of HCPs to assess their patient's preference for level of engagement. However, there are limited validated strategies available to do this. Furthermore, May et al.'s Burden of Treatment model (2014) demonstrates that when more 'work' is passed on to patients, their capacity to self-manage can be overwhelmed. Some participants, such as Enid, already viewed her medicines management as 'a job'. Care, therefore, needs to be taken to ensure that increasing involvement and engagement with medicines management does not overburden the patient or family carer.

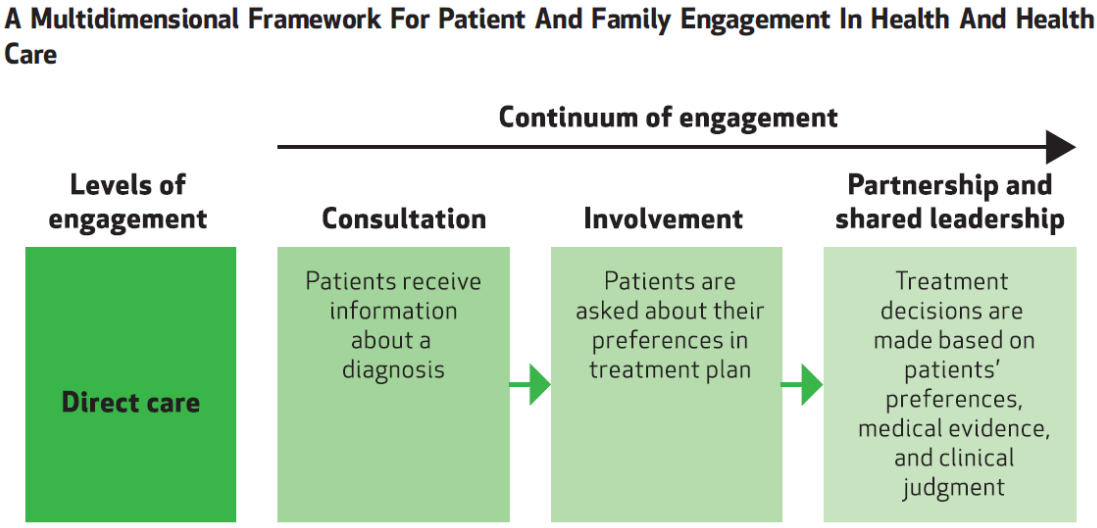


Figure 27: A framework for patient and carer engagement reproduced with permission from Carmen et al. (2013) ©Health Affairs

If HCPs are supposed to support engagement of patients and family carers, then how do they achieve it? Flink et al.'s (2012) work confirmed that conversations were key. However, these were not in evidence amongst this study's participants. Patient and carer beliefs, experiences and misconceptions all influenced participation and their previous experiences taught them how to interact and communicate with the healthcare system (Flink et al. 2012). For example, past poor experiences motivated them to get involved next time. There is a gap perhaps in educating patients and carers in how they can participate in their care. In their study of medication decision making, Belcher et al. (2006) identified three categories of older patient: those who do not want to participate; those who cannot; and those who can and should participate. There are parallels here to the current study, where a similar range of roles in medicines management were found. The difference in this current work is that the roles were not found to be static, and participants moved from 'cannot' to 'can' once they had invested in their confidence and capability. It must not be assumed that patients will always occupy one role, and similarly any interaction with the system must identify the current role, and the desire to move on (Carman et al. 2013).

Whilst not solely focusing on medicines, Murray et al.'s (2019) 'state-change model' (**Figure 28**), developed through systematic literature review, conceptualises older people's involvement as a "dynamic, interactional and

complex process". They are clear that engagement is a changeable way of being, which can be influenced by various factors. Contrary to previous work, Murray et al. (2019) suggest that there is no hierarchy or levels within their model, especially when some patients, as was the experience in this present study, did not desire to be 'autonomous acting'. This new way to conceptualise involvement is important primarily because it will enable HCPs to more carefully identify where and how to position their efforts, when encouraging patients and their family carers to self-manage their medicines. What it does imply, however, is that patient involvement is mediated through HCP engagement only, when other patient-related factors, such as available social support or level of health literacy, can also influence patient involvement.

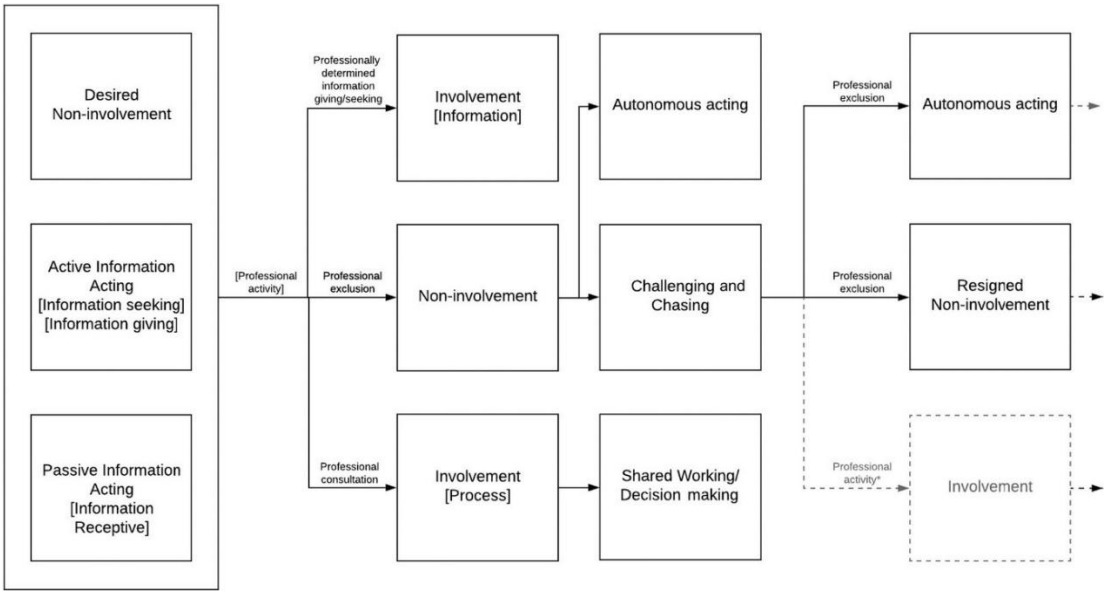


Figure 28: The state of change model, reproduced from Murray et al. (2019) under the Creative Commons CC BY licence ©Health Expectations

Whilst there were clear benefits to involving family carers within medicines management, there were some challenges because of the involvement of multiple people, for example in the case of Ruth's son. It was observed in her primary care records that they often had opposing views, especially related to the management of her insulin. Ruth (90) had explained that she now felt confident and competent to deliver her own doses and this was observed by the self-management team (**Appendix 9**). Ruth's son, on the other hand, felt

that she could not manage and repeatedly enlisted the district nurse to trigger more support, which was considered unnecessary by the self-care team.

5.6.5 Improving engagement

Increasing patient engagement and participation in care has been linked to increasing patient safety (Longtin et al. 2010). Participation is known to reduce stress and anxiety too (Sahlsten et al. 2008). In a UK questionnaire study (Mohsin-Shaikh et al. 2014), patients and HCPs were supportive of hospital inpatients becoming involved in their medicines management as a safety role. Three main areas were identified where patients felt they could participate: I would like to look at my drug chart, I would like to administer my medicines, I would like to ask questions (Mohsin-Shaikh et al. 2014). There was a gap, though, between desire for participation and actual experience. This is evidenced within this present study, with many participants having unanswered questions at discharge and being offered no opportunity for self-administration during inpatient stay. A further important point is that, data from primary care records signalled more missed opportunities for patient engagement. For example, post-discharge medicines review was noted and coded within all cases. Unfortunately, this took place without the patient. The consequences of just using the patient notes to complete the review were poignantly illustrated by Robert (80), where his discharge information stated he was to cease his metformin, nevertheless he continued taking it. This was not identified and resolved until two months after discharge.

In their questionnaire study, Eldh et al. (2010) found that most participants regarded ‘participation’ as being listened to by HCPs. This interaction was considered highly important by their participants, as well as having knowledge (this is described as being different to ‘being told’). They, then, concluded that being informed is an essential attribute to participation, also echoed by Sahlsten et al. (2008). This goes hand in hand with ‘being heard’ in terms of preferences, values and experiences. It is interesting to note that many of the processes developed to enhance continuity of care within current practice (e.g. electronic transfer of discharge documentation, shared care records,

electronic prescribing) were perceived by participants within this study to result in less face-to-face interaction.

The role of the family carer also requires consideration as the analysis revealed a range of engagement from the carer perspective. For example, Hazel's daughter tried to ascertain information related to the medicines changes but appeared to gain only the basic details from the nurse. Contrasted to this is Patricia's daughter who seemed very experienced in her role as family carer and who described how she would ask specific questions to different members of the care team to ensure that she could prepare for her mother's discharge. This difference in engagement could be due to prior experience (Patricia's daughter had already been carer for her father) or confidence in navigating the healthcare system or feeling empowered to participate. To elaborate the point further, Driscoll (2000) found that when carers were present during conversations between patients and hospital clinicians about post-discharge care, there was a decrease in anxiety and fewer problems occurred after discharge. Manias et al. (2015a) conducted 40 interviews with carers and showed that they unfortunately participated in a passive way (where the HCPs made all decisions), rather than in a 'shared' or 'active manner'. Those carers who were active, became extensively involved, and yet it is unclear what the significant factors were that drove such a level of engagement. If the factors had been elicited, then could carers be trained (i.e. offer the knowledge and skills) to encourage participation? Manias et al. (2015a) stressed that it is the responsibility of the clinical team to make sure that carers are actively engaged, but it remains unclear whether current processes allow HCPs to do this. Ward rounds often take place in the morning, with carers visits in the afternoon. This dramatically reduces the opportunity for active engagement between carer and HCP. Within this present study, family carers expressed that they had difficulties seeking doctors to speak to and that they (the carers) were not 'heard'. For example, Elaine's daughter explained that she had not spoken to a doctor in the week leading up to her mother's discharge. Whilst verbal information was given in some instances within Manias et al.'s study (2015a), the carers mainly desired comprehensive written reports about medication changes, not just at discharge but throughout

the hospital stay. Again, within this study, it was evident that some carers and participants put in a significant effort to try to understand the discharge letters, which were often jargon-heavy or difficult to interpret (**Figure 29**).

Changed Medication

Medication	Status at discharge	Changes/comments
atorvastatin 20mg Tablet	Changed	Meds On Adm Frequency In the Evening
chlorhexidine gluconate 4% Topical Liquid	New	Inpatient Duration of 1Â dose(s)
chlorhexidine gluconate 4% Topical Liquid	New	Inpatient Duration of 10Â day(s)
ciprofloxacin Tablet	New	Inpatient Duration of 3Â day(s)
diclofenac diethylammonium 1.16% Gel	New	
fluticasone furoate 27.5microgram Nasal Spray	Changed	Meds On Adm Route Both Nostrils Meds On Adm Frequency When Required
NASEPTIN nasal cream	New	Inpatient Duration of 10Â day(s)
nitrofurantoin 100mg Modified Release Capsule	Ceased	
omeprazole Gastro-Resistant Capsule	Changed	20-40mg on admission as per medicines reconciliation documented in notes
valsartan 160mg Capsule	Changed	Meds On Adm Frequency At Night

Figure 29: Example of discharge document excerpt that Betty (85) and her family struggled to interpret

5.6.6 The power of relationships

The analysis suggested that relationships between participants and HCPs may have an impact on the level of engagement that a participant had with their medicines. Participant's perceptions of their relationships with healthcare professionals and with care services either enhanced or negatively affected their relationship with their medicines. As Bugge et al. (2006) comments, patients who have untrusting relationships with their HCP, may be less inclined to disclose necessary information, e.g. to support medication change decisions, which can result in negative outcomes for the patient. In this study, those who had poorer perceptions of their healthcare professionals (e.g. Barbara (91) and Charles (82)), or the care they were receiving may have withheld information, or not contacted the most relevant person. William (79) explained, for example, how he preferred to wait until he saw his diabetes

specialist doctor if he had any concerns about his general health because he could never get in contact with his own GP and believed the diabetes doctor would be the one to get the job done quicker. This lack of easy access to primary care providers was also a focus for Parekh et al. (2018b) and is thought to limit the perception of quality communication and level of involvement in medicines-related decisions.

Healthcare professionals may also consciously or sub-consciously withhold information (Bugge et al. 2006) due to reasons of attitude or the patient's portrayal of 'self' i.e. HCPs may overlook patients who appear to look fine and are functionally able (Bowles et al. 2003). Difficult or non-adherent patients might also be overlooked by HCPs due to perceptions of workload and staffing difficulties. Interestingly, in Bugge et al.'s study (2006), patients who were not counselled very well did not find the experience unsatisfactory, as long as they felt the physician took them seriously. Feeling connected to HCPs was identified as a crucial element of quality communication by Cain et al. (2012). A lack of connection can also be detrimental, with staff easily overlooking opportunities to engage with patients, as highlighted by the participants within this study. Therefore, the relationship between HCP and patient should not be underestimated. In this present study, many patients felt that staff were too busy to talk to them and often reported that conversations were rarely had. Non-information transfer may be a sign of concordance with patient wishes (Duggan and Bates 2008). However, in this study only a few patients explicitly said they did not want information.

Some participants who described challenging relationships with their healthcare provider became motivated to do more to overcome the gaps that this created (e.g. Betty's husband, Elaine's daughter). Both family carers described less than optimal relationships driving them to increased effort whilst trying to resolve issues themselves. This is resonant of Murray et al.'s (2019) 'challenging and changing' status of their model of involvement, where patients and carers become involved as a result of professional exclusion.

Besides this, a reliance on hope and trust in their HCP may have led participants into passivity. In the current study, for example, Mary (81) trusted

that follow-up plans were in place, and Joan (78) hoped her pharmacy would send her items on time. These participants described a ‘wait and see’ approach to their medicines management and appeared to wholly trust that the system would provide. Flink et al. (2012) found that patients who perceived care to be co-ordinated (i.e. transfer of information was provided across organisations) interacted less with the system and volunteered less information. Conversely, a lack of trust in the system to deliver effective cross-sector communication was felt by some participants not only in this study but also in that of Andreasen et al. (2015). This lack of trust impacted on participants’ perception of ‘proper and professional care’, which was regarded as ‘unsafe’ and ‘dangerous’ (Andreasen et al. 2015).

Despite the current drive for person-centred care, a paternalistic patient-provider relationship (Longtin et al. 2010) appeared to be present throughout many participant interviews. Participants were often dissatisfied and frustrated with what they perceived to be ageist care. As discussed in **Section 5.6.5**, HCPs should support beneficial engagement and empowerment of patients to self-manage their medicines. Patients need to be given the choice as to whether to participate in their care and with the risks clearly explained if choose otherwise (Duggan and Bates 2008). In this present study, no participant reported being given the choice. This may be to do with HCP’s assumptions about older people, paternalistic models of care or even some other factor such as ‘collective jeopardy’. This latter scenario relates to working in a team which assumes shared responsibility and, consequently, no one does it because you all think the other person will do it, i.e. the doctor thinks the pharmacist will speak to the patient, the pharmacist thinks the nurse will speak to the patient and so on.

5.6.7 Perceptions of processes

Understanding processes (e.g. how cross-sector communication works, why patients are asked to bring their current medicines into hospital with them) may help better manage patient’s expectations of post-discharge care and reduce unnecessary burden and frustrations experienced by the study participants. Many participants lacked an understanding of key processes with their

medicines, which sometimes led to negative perceptions of the system, or HCPs. An example of this is when Marilyn (86) did not receive the medicines she was expecting at hospital discharge. She incorrectly perceived the pharmacist to have undertaken the prescribing for her, and thrown away medicines that she needed:

> *"I think that was the pharmacist, they just chucked them and write their own idea of what they're going to give which was a pity because I was missing some of the drugs that I brought in."*

Numerous key performance indicators and process targets exist within current healthcare systems. One such target is that of MR on admission to hospital and on transfer back to primary care after a hospital stay. Admission reconciliation should occur within 24 hours, whilst post-discharge reconciliation is completed within seven days (National Institute for Health and Care Excellence 2015a). This intense focus, as evidenced within this analysis, may be at the wrong point in the system. For example, much emphasis and associated workload is geared towards ensuring MR is completed within the first 24 hours of admission. This priority may mean, therefore, that conversations about medicines throughout the rest of the hospital stay are limited, as there is no 'target' for this. Similarly, the pressure to review medicines within the seven days post-discharge, may be the reason why only medical notes are used and patients are often not involved, evidenced in the primary care data extracts, as this would require time and workload planning. Interestingly, it was also noticed within the primary care extracts that the testing of targeted factors, such as HbA1c, were requested far more than necessary. Mary's (81) primary care data, for example indicated that she had had her HbA1c tested three times in six months. Again, this time and focus could be better utilised elsewhere.

Lastly, whilst some participants perceived there to be little or no cross-sector communication, analysis of primary care records showed significant contacts between primary care and the hospital, particularly when trying to problem-solve. Examples of hospital pharmacists contacting practices for further information about medicines changes, hospital pharmacists contacting

community pharmacists about supplies and GPs contacting hospital professionals were all evidenced within the primary care data. The challenges of communicating across different sectors were observed, often by several failed attempts at making any contact and subsequent notes relating to the individual's frustrations. Once again, a significant amount of time appears to have been spent on unsuccessful communication attempts and on documenting this within the participants' notes, no doubt time that could have been better spent.

5.6.8 Learning from potential patient safety incidents

The analysis of potential PSIs raised serious concern that they may cause moderate to severe harm and significant distress to older patients. In this study, approximately 50% of participants experienced a PSI. However, current literature estimates that MRH affects approximately 33% of older adults (Parekh et al. 2018a). This over-representation within the sample could be due to the types of PSI that were considered. Problems with medicines supply were included, based on their importance to older people as identified by the taxonomy of MRP (Nicosia et al. 2020), where they may not have been classified as MRH producing incidents within the original study. Parekh et al. (2018a) defined MRH as, "an adverse drug reaction or harm arising from a failure to receive medication owing to non-adherence." It is unclear, by this definition, whether failures to receive medication as a result of problems in obtaining the medicines would have been recorded, or those PSIs that caused psychological harm or distress. Non-adherence is often a patient-focused behaviour, whilst problems with obtaining supply could stem from either the patient or healthcare system. Therefore, the use of Nicosia et al.'s taxonomy (2020) may have encouraged the identification of wider PSIs than those cited in Parekh et al. (2018a).

PSIs relating to obtaining medications were the most frequently described difficulties by participants in this study (n=11), rather than issues with communication (n=7), medication effects (n=4) or taking medicines (n=3), and are, therefore, clearly important to patients. Supply issues may not be considered to cause physical harm to the patient, nonetheless, they are

severely distressing. This is demonstrated by the findings, with HCPs scoring these PSIs as mild or moderate and PCLSG representatives as moderate or severe. This discrepancy has general implications for how HCPs perceive 'harm'. Physical harm may be considered as more pertinent to HCPs. However, psychological harm is also important to consider, mainly in terms of the emotional distress for the patient. Hence, the distress experienced by older patients may not directly map onto the potential physical harm caused to them by the PSI. Healthcare professionals, thus, need to be much more mindful of the wider impact of their actions for patients and have an awareness of how problems in the system affect patients.

Whilst the PSI may have manifested itself within the hospital setting (e.g. the temporary suspension of certain medicines), often the ramifications were not felt by the patient until later, once they had returned home (e.g. when medicines were not restarted in the community as expected). In such circumstances, it could be challenging for the participants to know who to speak to in order to resolve the problem. Even more concerning is the fact that, due to organisational specific incident reporting systems, it is unknown how and if PSIs that occur across transitions are captured. PSIs reported within community settings may not be shared with hospital colleagues to support cross-sector learning and vice versa.

None of the participants within this study identified their problems as PSIs and certainly none described officially reporting them. Involving patients in the detection and reporting of PSIs may help increase their role within their own and others' safety. Organisational incident reporting systems often rely on the HCP inputting data on the behalf of the patient. Reporting systems have been criticised for being time-consuming, too brief to allow learning and expensive (Stavropoulou et al. 2015), meaning that they are often underutilised. A way to engage patients in this process, perhaps by developing a more patient-friendly and accessible reporting mechanism and empowering them to complete the report, may overcome some of these barriers.

It is known that patients and their carers can and do implement their own systems and strategies to bridge gaps arising from potential PSIs. It is also

known that supporting upstream functions (e.g. inpatient education, appropriate supply from hospital) have the potential to create improved outcomes for patients after discharge (O'Hara et al. 2020). Therefore, it is worth considering how HCPs and organisations can support and equip patients with the appropriate skills to resolve any MRPs that they may experience in the future.

5.6.9 Quality of the study

This is the first analysis to explore in-depth experiences of post-discharge medicines management, over the course of six months. The analysis also raised greater awareness of the types of activities that older patients living with frailty perform, after returning home from a stay in hospital, and with medicines changes. Further investigation of potential PSIs also allowed for the illustrative mapping of harm and emotional distress, which has offered new insights into how patients and HCPs may perceive these events.

One of the strengths of this study was that recruitment occurred from two hospitals, which allowed for comparison and demonstrated that no significantly different experiences were held. Patients were recruited using a maximum variation sampling technique (Davis et al. 2009) which permitted a diverse range of medicines support needs to be observed. It must be noted that these two hospitals were chosen based on their size and number of wards available, as well as their willingness to take part. This may, therefore, limit the transferability of these findings to other hospital sites and settings.

Following recruitment, 50% of the total sample was retained at the end of the study. This had been predicted at the outset, due to the nature of research with older people living with frailty (Davies et al. 2010). Half of the participant sample took part in longitudinal interviews. Whilst no new themes arose from the second and third interviews, these were felt to help build rapport and participants continued to add further noteworthy details about their emotions and the consequences of post-discharge medicines management within these later conversations.

Qualitative thematic analysis is inherently subjective (Silverman 2016). However, use of the Framework method (Ritchie et al. 2014) has added robustness because a transparent audit trail of movement from transcripts to themes is available. A quarter of all transcripts were independently coded by a supervisor, allowing for fair comparison to be made. Transcripts were also triangulated with data from the primary care records, which helped to further clarify specific themes, complemented the knowledge of why and how things happened or contributed to a fuller understanding of the participant experience. Essentially, it allowed for the full experience to be considered, where participants failed to recall certain events, such as contact with NHS 111 or emergency department visits.

Finally, the PCLSG were integral to all parts of this study, as outlined in **Chapter 3**. Their involvement in data analysis was particularly valuable since their interpretations of transcript excerpts prompted new lines of analysis, such as exploring the level of carer involvement.

5.6.10 Limitations

This phase of work used semi-structured interviews, triangulated with data extraction from the primary care records and participant diary entries wherever possible. Observations of medicines-related activities (administration routines, safety strategies, problem-solving tasks etc.) would have been also a valuable method of such triangulation. Despite this, it was felt that it was difficult to conduct this in a satisfactory way that did not influence behaviour or interfere in recuperation, given the ad hoc nature of medicines management-related behaviours. Given the range of safety strategies used by patients, further study could also be conducted using additional photo elicitation methods (Lang et al. 2015) to identify the tools that participants use.

Despite introducing the diary to all participants and being co-designed with the PCLSG, only two participants Betty (85) and Ruth (90) used it, completing three entries each, instead of the suggested one per week. Their entries offered additional insights into Ruth's (90) thoughts about her newly prescribed insulin and Betty's (85) follow-up monitoring and were valuable for data triangulation. Unfortunately, other participants did not readily offer

explanations about why they did not engage with this tool, and it remains unknown exactly how it could be improved. Diaries have been used with varying degrees of success as data collection tools in previous studies (Daker-White et al. 2014; Waring et al. 2014; Fylan et al. 2019b). One possible explanation for their underuse in this study is that it was too burdensome in the immediate post-discharge phase, or forgotten about in the face of other priorities.

The sample was limited in its ethnic diversity and, hence, does not represent the wider population of the UK. With this in mind, it is unclear whether the findings are transferrable to other patient groups and to the population as a whole. BAME communities are often under-represented within health and social care research (Smart and Harrison 2017) and barriers to their participation include: language, socio-cultural factors, lack of knowledge about research, mistrust towards others, stigma associated with specific health conditions, and practical issues (Jutlla and Raghavan 2017). Despite significant help during recruitment from an Urdu-speaking research nurse to overcome any language and cultural barriers, it remained difficult to recruit people from a wider range of ethnic backgrounds to the study.

The sample included more women than men; nevertheless this is representative of the older home-dwelling population. Participants also included four retired nurses, which appears to be an over-representation, regardless of which has not impacted on the analysis due to the range of other perspectives included. There was also an imbalance in the number of recruits from both sites. Approximately two-thirds of participants were recruited from SJUH, with only a third from BRI. This is reflective of the greater number of wards available for recruitment at SJUH (six, compared to two at BRI), and consequently the larger pool of potential participants.

PSIs were independently rated by four HCPs and four PCLSG members. They were presented with a restricted amount of information (supported by verbatim quotes) but not able to seek further details, clarification nor clinical notes. Their rating relied heavily on their ‘gut instinct’, which is usually informed by their clinical experience, interpretation of the presented PSI and perceptions of

harm. This may explain why inter-rater agreement was only 41.3% for HCPs and 57.3% for PCLSG representatives.

5.6.11 Implications for intervention design

Findings from Phase 2 suggest that intervention modelling should:

1. Provide tools to increase knowledge about medicines changes that occur during hospital discharge.
2. Improve awareness of the patient's role within medicines safety and encourage a minimum level of engagement with medicines management activities for everyone.
3. Signpost patients and family carers to the relevant HCPs after discharge and promote the role of their community pharmacist in helping to solve post-discharge MRPs.
4. Consider the burden that any additional medicines management activity may place upon the patient or family carer, especially the potential negative consequences of this e.g. non-adherence, carer strain (May et al. 2014).

5.7 Chapter summary

This chapter has presented the results of a qualitative analysis of 27 interviews conducted with older people and their family carers. A Framework analysis of the participants' experiences of post-discharge medicines management pointed towards significant deficits in care, whilst at the same time identified things that worked well for them. Participants described the gaps that they had experienced in conversations about medicines, which impacted on their abilities to manage their medicines once they had returned home. They revealed the problems that they had had whilst navigating the complexities of the healthcare system, some of which could have potentially caused severe physical harm and distress.

The experiences and range of self-management strategies employed by participants confirms that post-discharge medicines management is complex. Following discharge, they were required to expend significant effort and 'work' at their medicines management, due to the disruptions and gaps that their

hospital stay had caused. Wider involvement and engagement of patients and their carers within medicines management activities throughout hospital admission and into the post-discharge phase may help bridge these issues. In the next chapter, these findings will be further explored, along with the results of the systematic review (**Chapter 4**) to identify components of a potential intervention. First, interview findings are used to develop an understanding of the barriers and enablers to enacting medicines management behaviours, which then underpins theory-based intervention modelling. Expert consensus is sought to ensure that selected components have validity and are likely to be effective and acceptable in practice.

Chapter 6: Intervention modelling

6.1 Introduction

This chapter outlines the work completed during Phase 3 of this study. It will describe how potential intervention components were identified through expert consensus, whilst being grounded firmly within the patient experience (Phase 2) and underpinned by synthesis of best evidence (Phase 1). The methods that were followed are described in detail in **Section 3.7.3** and illustrated in **Figure 13**. Briefly:

- Findings from the framework analysis of patient interviews were categorised into barriers and facilitators of post-discharge medicines management behaviours.
- The results where then mapped firstly to the TDF to situate the determinants within the key domains affecting behaviour, and, secondly to the BCTT resulting in a list of potential BCTs.
- This pool of BCTs was narrowed, ranked and refined through: i) expert panel debate, ii) consensus survey, iii) consideration of the APEASE criteria, iv) and then reviewed in the context of the originally mapped TDF domains as well as Phase 1 findings.

The results are presented in three parts: the identification of barriers and facilitators to post-discharge medicines management behaviours; mapping of the BCTs; and consensus building. The chapter ends with a discussion of the key points arising from this work.

6.2 Findings

The intervention modelling phase first drew on the inductive framework analysis conducted in **Chapter 5** to identify the behavioural determinants of post-discharge medicines management. These were then mapped to the TDF V1 and BCTT using the methods described in **Section 3.7.3** to identify all possible valuable BCTs. The findings from each of these steps will now be presented in turn.

6.2.1 Identification of barriers and facilitators

The inductive framework analysis of the 27 participant interviews was scrutinised, and the barriers and facilitators to post-discharge medicines management were identified. A total of 47 participant behavioural determinants were found within the data and were classified as barriers, facilitators, or both, depending on the findings. Each determinant was supported by verbatim quote(s).

Once all barriers and facilitators were identified from the framework analysis, they were deductively mapped into 11 of the 12 domains of the TDF V1 (**Table 18**) and are presented in **Appendix 10**. The 12th domain (nature of behaviour) was not included in this step (**Section 3.7.3**) because it relates to the key characteristics of the behaviour of interest as opposed to potential mediating mechanisms or influences (Dyson et al. 2013; Cadogan et al. 2015).

An example of a behavioural determinant of post-discharge medicines management identified within the framework matrices was: extent of knowledge about which medications have been changed and why. The information that participants had been given about their changed medicines impacted on whether they took the right medicines after discharge, such as in Patricia's case:

> *"So of course when they found out she's got an embolism and they had to give her blood they had to stop giving her the blood thickener and put her on a blood thinner"* [Patricia's daughter].

In other examples, the extent of their knowledge impeded effective medicines management because the participant was unsure exactly which medicines to take or the correct doses, as was well described by Marie:

> *"No, he did change one of my tablets, did the heart specialist. I don't know what he changed. I'm on that much medication I don't know what amount I have to take"* [Marie].

This determinant was therefore categorised as both a barrier and facilitator to post-discharge medicines management, because the post-discharge

medicines management appeared to depend on the extent of the participant's knowledge of their medicines.

On review of the TDF, this particular determinant fit well within the domain of knowledge and was mapped accordingly.

Table 18: The number of barriers and facilitators mapped to each TDF domain

TDF V1 domain	**Number of behavioural determinants**
Knowledge	4 (2 barriers, 1 facilitator, 1 both)
Skills	4 (1 barrier, 1 facilitator, 2 both)
Social /professional role and identity	7 (2 barrier, 0 facilitator, 5 both)
Beliefs about capabilities	2 (1 barrier, 0 facilitator, 1 both)
Beliefs about consequences	6 (1 barrier, 3 facilitator, 2 both)
Motivation and goals	4 (1 barrier, 0 facilitator, 3 both)
Memory, attention, and decision processes	5 (5 barrier, 0 facilitator, 0 both)
Environmental context and resources	6 (3 barrier, 1 facilitator, 2 both)
Social influences	2 (0 barrier, 1 facilitator, 1 both)
Emotion	4 (3 barrier, 0 facilitator, 1 both)
Behavioural regulation	3 (0 barrier, 3 facilitator, 0 both)

6.2.2 Mapping of the BCTs

Once all behavioural determinants had been mapped to the TDF V1, the process outlined in **Figure 13** was undertaken so that all possible BCTs that could promote behaviour change within each domain could be identified (**Appendix 10**). **Table 19** illustrates an example of the mapping that was

conducted using the two published mapping exercises; Michie et al. (2008) and Cane et al. (2015).

Table 19: An example of mapping the TDF domains to the BCTT

Example TDF domain	**Target BCTs**[Δ]
Memory, attention and decision processes	1. Self-monitoring* 2. Planning, implementation* 3. Prompts, triggers, cues*
Environmental context and resources	1. Environmental changes* 2. Restructuring physical environment^ 3. Discriminative cue^ 4. Prompts/ cues^ 5. Restructuring social environment^ 6. Avoidance/ changing exposure to cues for behaviour^

[Δ]Michie et al. (2008)* & Cane et al. (2015)^

Fifty discrete BCTs were identified and considered to be valuable when designing an intervention to promote post-discharge medicines management. A description of how each BCT could be potentially used within practice was developed by the researcher, in collaboration with the supervisory team (**Appendix 10**). To identify the most beneficial and noteworthy BCTs for intervention modelling, the next step of consensus building was performed.

6.2.3 Consensus building

Expert panel

A panel of experts was formed consisting of two pharmacists, one with hospital and primary care experience, one with community experience, two health services researchers experienced in the topic, a social work academic and a patient representative. Together the panel were asked to agree on any BCTs that they deemed inappropriate. A meeting was held during which the merits of each BCT was discussed in turn, and a consensus was reached as to whether to take the BCT forward to the larger consensus survey. As a result

of this work, 15 BCTs were removed leaving 35 potential BCTs for the next round of consensus, which involved surveying target population judges and ranking of the remaining BCTs. The rationale for each BCT's removal is presented within **Table 20**; the most common reasons related to a difficulty in applying the BCT directly to the context of post-discharge medicines management (such as body changes, anticipated regret), as well as the BCT being unacceptable to older people or unethical (e.g. threat, social reward).

Stakeholder survey

During this stage, the remaining 35 BCTs were developed into an online survey, which asked respondents to rate each discrete BCT across three factors; acceptability, effectivity and possible unintended consequences. Forty stakeholders were invited to take part in the survey, including pharmacists, psychologists, medics, patients and family carers and health services researchers. The survey was sent via email, with a follow-up reminder dispatched after two weeks. A total of 25 (62.5%) responses were collected, however no personal information was recorded, so it is unknown which of the 40 stakeholders took part. The findings of the survey are presented below.

A total score for each BCT was calculated based on the number of respondents who rated it as i) effective, ii) acceptable and iii) unlikely to cause any unintended consequences for the patient. Each BCT could score a maximum of 75 points. Percentages of the maximum score were calculated and the BCTs ranked in order from lowest to highest scores (**Table 21**). The lowest scoring BCT was the provision of rewards or incentives to promote behaviour change (score = 34/75) and the highest scoring BCT was the provision of practical social support (score = 73/75).

Table 20: Discounted BCTs and justification

BCTs removed	**Comments from panel**
Antecedents^	The panel was unsure how to deliver this effectively in practice and how reliably it would promote behaviour change, especially as the antecedents would be general, rather than personalised for an individual.
Biofeedback^	Difficulties in practicalities of delivering this BCT due to multi-morbidity. May also lead to obsessive monitoring which can be dangerous.
Body changes^	Difficult to define for this context.
Covert sensitization^	Unethical and not appropriate.
Anticipated regret^	Difficult to define for this context.
Social and environmental consequences^	May result in unintended negative consequences e.g. avoiding appropriate contact.
Vicarious reinforcement^	Not appropriate for this context.
Threat^	Unethical and not appropriate.

Covert conditioning^	Unethical and not appropriate.
Contract*	Unsure how this would be received by the patient, may feel like a threat and is overly formal.
Discriminative cue^	Difficult to define for this context.
Avoidance/ changing exposure to cues for behaviour^	Presupposes negative behaviour/ bad habits which may impact on relationship with patient.
Social comparison^	May result in unintended negative consequences e.g. avoiding appropriate contact.
Identification of self as role model^	The panel felt that this may be burdensome for older patients.
Social reward^	May lead to unintended negative consequences e.g. patient feeling judged.

Further refinement

Working backwards, the highest-ranking BCTs were mapped onto the TDF using validated sources. The top-scoring eight BCTs were found to link with ten of the 11 domains (**Table 22**). The 11th domain, behavioural regulation, has only previously been mapped to one BCT (self-monitoring of behaviour) (Cane et al. 2015), which was ranked 31st out of 35 BCTs. This showed that the eight highest scoring BCTs covered the majority of the TDF domains that were mapped to the determinants of post-discharge medicines management. Following visual inspection of the BCT ranking, discussion of the TDF domain coverage and the Phase 1 findings with the expert panel, a final selection of eight BCTs was agreed. These BCTs were highly rated as most likely to be acceptable and effective in promoting post-discharge medicines management by the survey, had resonance with Phase 1 findings, and mapped to the vast majority of TDF domains. The final BCT list comprised of: social support (practical), goal/ target specified, prompts, triggers or cues, social processes of encouragement, pressure, support, motivational interviewing, rehearsal, review goals and comparative imagining or future outcomes.

Table 21: Survey results

BCT*	Effectiveness (max score 25)	Acceptability (max score 25)	No side effects (max score 25)	Total score (max 75)	%
Rewards, incentives	11	11	12	34	45.3
Graded tasks, start with easy	17	14	6	37	49.3
Homework	21	18	16	55	73.3
Emotional consequences	19	19	18	56	74.7
Self-monitoring	24	22	11	57	76.0
Focus on past success	18	18	21	57	76.0
Increasing skills; problem solving, decision making	21	20	18	59	78.7
Perform behaviour in different settings	19	22	18	59	78.7
Salience of consequences	21	20	18	59	78.7

Information regarding behaviour, outcome	24	24	12	60	80.0
Habit reversal	23	24	13	60	80.0
Demonstration by others	22	21	18	61	81.3
Feedback on behaviour	23	19	19	61	81.3
Pros and cons	22	19	20	61	81.3
Environmental changes	24	22	16	62	82.7
Monitoring	23	20	19	62	82.7
Reduce negative emotions	22	22	18	62	82.7
Verbal persuasion	22	22	18	62	82.7
Information about other’s approval	21	21	20	62	82.7
Goal setting	22	21	20	63	84.0
Habit formation	23	24	17	64	85.3

Social support (emotional)	24	24	16	64	85.3
Information about health consequences	23	22	19	64	85.3
Restructuring social environment	22	22	20	64	85.3
Action planning	23	21	20	64	85.3
Self-talk	21	20	23	64	85.3
Persuasive communication	21	22	22	65	86.7
Comparative imagining of future outcomes	23	22	21	66	88.0
Review behaviour/ outcome goals	22	22	22	66	88.0
Rehearsal	22	22	22	66	88.0
Motivational interviewing	24	23	20	67	89.3
Social processes of encouragement, pressure, support	22	23	22	67	89.3
Prompts, triggers, cues	24	24	21	69	92.0

Goal/ target specified: behaviour or outcome	25	25	20	70	93.3
Social support (practical)	25	25	23	73	97.3

*Coloured rows are those BCTs selected for final inclusion

Table 22: The highest ranking BCTs mapped backwards to the TDF

Rank	BCT	Mapped TDF domains
6th	Comparative imagining of future outcomes	Beliefs about consequences
6th	Review behaviour/ outcome goals	Motivation and goals
6th	Rehearsal	Skills, Beliefs about capabilities
4th	Motivational interviewing	Beliefs about capabilities, Motivation and goals
4th	Social processes of encouragement, pressure, support	Social/ professional role and identity, Beliefs about capabilities, Motivation and goals, Social influences
3rd	Prompts, triggers, cues	Memory, attention and decision processes, Environmental context and resources
2nd	Goal/ target specified: behaviour or outcome	Knowledge, Skills, Motivation and Goals
1st	Social support (practical)	Social influences, Emotion

Intervention development

As a final step to further ensure the content and face validity of these eight BCTs, the merit of each individual BCT was next judged by the expert panel. Each highly rated BCT was assessed against the APEASE criteria (Michie et al. 2014) to ensure effectiveness, deliverability (assessed as affordability and practicability) and acceptability (including equity and unintended consequences) in practice. All panel members were aware of the findings from Phase 1 and were asked to consider the acceptability and effectiveness of the BCTs in light of these. Intervention examples from the literature were also used

to inform key decisions and comments or considerations from the panel (**Table 23**). Following joint discussions, each criteria was given a 'yes' (or a tick in Table 23) if the BCT was considered that it met that criteria, or a 'no' (a cross in Table 23) if it was felt that it did not. There were instances where the content and context of implementation would need to be further investigated in order for a definitive decision to made, and these were given both a 'possibly yes and possibly no' (a tick and a cross in Table 23). For example, practical social support was considered possibly affordable, equitable and it may cause some unintended consequences, depending on how it was delivered. If older patients had no social network to rely on for the delivery of this BCT, the panel felt that others, such as a formal buddy scheme, could offer this practical social. This may however, come at a financial cost and not be equitable, depending on the patient's circumstances. Unintended consequences may also present themselves depending on the level of reliance on the supporting peer, and whether the older patient might become excluded from their own medicines management if they have cognitive impairment for example.

All BCTs were considered effective following APEASE assessment and when reviewed in light of the Phase 1 findings as well as wider literature. Phase 1 identified that interventions which bridged the transition and included self-management advice, follow-up or medicines reconciliation were valuable. The selected BCTs were thought to reflect these recommendations, especially if components were commenced during hospital admission and continued into the post-discharge phase.

In addition, all BCTs were considered acceptable to older people, with the exception of motivational interviewing. The panel reflected that this BCT involving multiple in-depth counselling sessions aimed at resolving ambivalence about health behaviours (Miller and Rollnick 2002) could be too burdensome for older people in the immediate post-discharge phase. However, the literature and Phase 1 findings demonstrated that some older people would engage and respond well to this BCT, so it was given a mixed result. Generally, all other APEASE criteria received mixed results since it would depend on how the BCT was implemented and the patient's preference. This reinforced the importance of personalising the choice of BCTs to the

individual to ensure acceptability, equity and minimal unintended consequences, as well as local tailoring or adaptation of the intervention to fit within current service provision to maximise affordability and practicality. Hence, at this stage, all BCTs remained eligible for inclusion within the final intervention.

Once the final selection of BCTs was established, the target determinants identified within step 1 were reviewed to help suggest content ideas for each BCT (**Table 24**). The content was tailored to the BCT, TDF domain and behavioural determinant, aiming to overcome identified barriers and enhance the facilitators. In some instances, determinants could be modified through various BCTs, for example, intrinsic motivation driven by beliefs about the system was linked to four BCTs; review behaviour/ outcome goals, motivational interviewing, social processes of encouragement, pressure, support, and goal/ target specified. This is because the TDF domain of motivation and goals, which this determinant is mapped to, is mediated by all of these four BCTs.

Table 23: APEASE criteria assessment

BCT	Affordability	Practicability	Effectiveness & cost effectiveness	Acceptability	Unintended consequences	Equity	Comments
Social support (practical)	✓/×	✓	✓	✓	✓/×	✓/×	Social support has been shown to have strong effects on treatment outcomes (Cushing and Metcalfe 2007) and is associated with better diabetes self-management behaviours (Rosland et al. 2008). Encouraging family and friends to offer practical support could promote post-discharge medicines management. However careful consideration of equity is required to ensure support is widely available (in cases of people with limited social networks) and affordability if a more formal buddy system is required (e.g. training and facilitation costs). Careful considerations of whether the peer can do this appropriately without excluding the patient (Garfield et al. 2016), particularly in more challenging contexts such as in moderate to severe cognitive

							impairment or where English is a foreign language, is required to avoid unintended consequences.
Goal/ target specified: behaviour or outcome	✓	✓/×	✓	✓	×	✓	Goal setting encourages shared decision making with older people (Schulman-Green et al. 2006) and has been found useful by patients with T2DM (Sprague et al. 2006; Naik et al. 2011). Appropriate training may be required. However, it may be possible to establish acceptable goals with the patient either at hospital discharge or soon after discharge, in the context of post-discharge medicines management. It is unclear how practical this would be to deliver within current workload and is likely to require close teamwork between secondary and primary care. Care continuity for follow-up after the goal has been set is also required.
Prompts, triggers, cues	✓	✓	✓	✓	×/✓	✓/×	Triggers or cues to prompt the behaviour are likely to be highly effective. However, the PCLSG advised that most older patients may already do this activity (albeit to varying degrees). Consideration would need to be given about the consequences of changing any already established prompts/triggers/cues and any examples would need to be highly personalised to the individual and, hence, equitable. The intervention would, therefore, need to emphasise the importance of learning from what patients currently do. It would also need to offer advice around small incremental changes that could be made to enhance medicines management, through conversation about everyday life.

Social processes of encouragement, pressure, support	✓/×	✓	✓	✓	✓/×	✓/×	Similar considerations to social support (practical). However, this BCT would enhance processes of emotional and verbal support to promote positive attitudes towards medicines.
Motivational interviewing	✓/×	✓/×	✓	✓/×	✓/×	✓/×	Motivational interviewing has been successfully used in interventions to support care transitions for older people (Ahmad et al. 2012; Ravn-Nielsen et al. 2018) and has been shown to be cost-effective. However, it requires significant training and resourcing to deliver at scale (Cook et al. 2010; Benzo et al. 2013). Retention rates of older people throughout the whole motivational interviewing course vary, which may in part be due to the acceptability of the BCT (Cook et al. 2010; Kiyoshi-Teo et al. 2019), possible patient burden or the amount of time required to take part. Delivery considerations are important to ensure equity (e.g. for patients who are housebound and who may not be able to attend a clinic setting for follow-up).
Rehearsal	✓/×	✓/×	✓	✓	×	✓	Rehearsal of behaviour has been shown to be useful in other contexts, such as inhaler technique, and may help promote independence and knowledge of own medicines in the context of self-administration whilst an inpatient (Richardson et al. 2014). Uptake of self-administration in hospital can be poor due to resource implications. Nevertheless, older people could be prompted to rehearse other medicines management behaviours (e.g. checking of medicines, stock control, problem solving) in the post-discharge phase (Coleman et al. 2006). This BCT is likely to require repeated administration

							however, which may have resource implications. Any follow-up element relies on HCP team work and care continuity across the transition.
Review behaviour/ outcome goals	✓/×	✓/×	✓	✓	×	✓/×	Goals could be reviewed at follow-up appointments which gives an opportunity to adapt to the changing needs of the individual. This could have implications for resourcing unless tagged on to already existing post-discharge services/ follow-ups. Careful consideration of equity to ensure that all people have appropriate access is required. Additionally, this would dictate good communication across the transition and HCP team working.
Comparative imagining of future outcomes	✓	✓/×	✓	✓/×	×/✓	✓	BCT would likely need to be tailored to individual patients as the imagining and comparing of future outcomes of changed versus unchanged behaviour is likely to vary between individuals (Cadogan et al. 2015). This may therefore be impractical to deliver. Furthermore, delivery would need to imagine consequences from the patient's perspective which would be challenging to ensure that all options are considered, and a comparative option might cause unintended consequences e.g. anxiety/ worry.

Table 24: Example content that could be delivered by each BCT

Rank	BCT	Mapped to TDF V1 domains	Determinants	Example content delivered by BCT
6th	Comparative imagining of future outcomes	Beliefs about consequences	Anticipating gaps in care (facilitator)	Ask patients to anticipate the medicines management problems they may have when returning home as well as the impacts of this and consider how pro-active steps can be taken to prevent gaps from occurring vs. no action
			Beliefs about missed/ incorrect doses (facilitator)	Prompt patients to consider their beliefs about missed or incorrect doses as well as potential impacts and consider how pro-active steps can be taken to prevent this from occurring vs. no action
			Trust and faith in the system (barrier & facilitator)	Explore patients' expectations of the system and consider how pro-active steps can be taken to prevent medicines-related problems vs. no action
			Perceptions about quality of post-discharge care (barrier & facilitator)	Engage patient in a discussion about their perceptions of post-discharge care and consider how pro-active steps can be taken to overcome gaps vs. no action

Rank	BCT	Mapped to TDF V1 domains	Determinants	Example content delivered by BCT
			Perceptions about lack of easy access to the GP (barrier)	Ask patients to anticipate the medicines management problems they may have when returning home and consider how pro-active steps can be taken to overcome GP access issues vs. no action
			Previous experience in context of post-discharge meds management (facilitator)	Ask patients to consider their previous experiences and explore how pro-active steps can be taken to prevent problems vs. no action
6th	Review behaviour/ outcome goals	Motivation and goals	Lack of curiosity in medication: “I just take what’s in the box” attitude (barrier)	Explore with the patient their thoughts about their medicines and their own role, review the goals that were set around medicines management and adapt as appropriate at follow-up appointment
			Intrinsic motivation driven by beliefs about the system (barrier & facilitator)	Ask the patient about their thoughts about their medicines and encourage reflections about how their beliefs about the system may impacted on this, review the goals that were set around medicines management and adapt as appropriate at follow-up appointment

Rank	BCT	Mapped to TDF V1 domains	Determinants	Example content delivered by BCT
			Prioritisation of certain medicines (barrier & facilitator)	Engage patient in discussion about their medicines and their perceptions regarding the relative importance of each, review the goals that were set around medicines management and adapt as appropriate at follow-up appointment
			Perception of importance of medicines (barrier & facilitator)	Explore the patient's thoughts about how important their medicines are, review the goals that were set around medicines management and adapt as appropriate at follow-up appointment
6th	Rehearsal	Skills	Level of mobility limits access to medicines	Ask patients to try suggested medicines management activities and to report what they are unable to do. Work with patient to modify activity to accommodate for mobility constraints
			Skills to interpret discharge paperwork (barrier & facilitator)	Discharging HCP to explain discharge paperwork with patient/ carer prior to discharge (a minimum of two occasions)
			Work done to ensure correct medicines administration (e.g. stock control, medicines reconciliation) (facilitator)	Rehearse with the patient steps to take to ensure correct medicines administration prior to discharge, and at follow-up appointment

Rank	BCT	Mapped to TDF V1 domains	Determinants	Example content delivered by BCT
			Willingness to ask questions (barrier & facilitator)	Identify unanswered questions and practice or role play asking them with the patient/ carer
		Beliefs about capabilities	Perceptions of fluctuating health and prolonged recovery (barrier)	Rehearse medicines management activities in the pre-discharge phase e.g. medicines administration, who to ask for help etc. Identify work arounds with the patient for those times when they feel less capable
			Confidence to resolve problems (barrier & facilitator)	Explore strategies to resolve common problems with the patient and encourage them to practice or role-play the situation in order to gain confidence
4th	Motivational interviewing	Beliefs about capabilities	Perceptions of fluctuating health and prolonged recovery (barrier)	Explore the patients' perceptions of their recovery and prompt patient to reflect how realistic they are.
			Confidence to resolve problems (barrier & facilitator)	Role play of scenarios to build confidence in resolving common medicines related problems or coaching the patient to enable them to resolve their own problems
		Motivation and goals	Lack of curiosity in medication: "I just take what's in the box" attitude (barrier)	Engage patient in a discussion about their medicines behaviours, especially their motivations for taking their medicines and checking their doses

Rank	BCT	Mapped to TDF V1 domains	Determinants	Example content delivered by BCT
			Intrinsic motivation driven by beliefs about the system (barrier & facilitator)	Ask patient to consider their beliefs about the system and how this impacts on their medicines management behaviours
			Prioritisation of certain medicines (barrier & facilitator)	Coach patient to consider their beliefs about their medicines and how this impacts on their medicines management behaviours
			Perception of importance of medicines (barrier & facilitator)	Ask patient to consider their beliefs about the importance of their medicines and how this impacts on their medicines management behaviours
4th	Social processes of encouragement, pressure, support	Social/ professional role and identity	Belief that HCPs will relay any important information (barrier)	Peer champion/ pharmacist/ etc. encourages patient/ carer to ask questions and advise of a minimum dataset that they should know at point of discharge
			Unwillingness to 'bother' HCPs (barrier)	Peer champion/ pharmacist/ etc. prompts patient/ carer to engage with HCPs to seek further information and provides reassurance that this is acceptable
			Previous career (e.g. retired nurse) (barrier & facilitator)	Work with the patient to explore their expectations and encourage reflection on the relevance of

Rank	BCT	Mapped to TDF V1 domains	Determinants	Example content delivered by BCT
				previous experiences to the current context. Promote appropriate actions
			Paternalistic culture (e.g. the doctor says I have to take them so I do) (barrier & facilitator)	Peer champion/ pharmacist/ etc. discusses beliefs about care decisions and prompts patient/ carer to challenge or seek further information from HCPs
			View of own responsibility for medicines management (barrier & facilitator)	Discuss with the patient their thoughts about their medicines and their own role and responsibilities with their management
			Perceptions of relationships with healthcare professionals (barrier & facilitator)	Work with the patient to explore their expectations and encourage reflection of the relevance of previous experiences to the current context. Promote appropriate actions
			View of self as 'expert' (barrier & facilitator)	Explore the patient's perceptions of their role and encourage reflection about the impacts of this on their medicines management

Rank	BCT	Mapped to TDF V1 domains	Determinants	Example content delivered by BCT
		Beliefs about capabilities	Perceptions of fluctuating health and prolonged recovery (barrier)	Discuss with patient/ carer the expectations of recovery and support them to consider what is realistic in their context
			Confidence to resolve problems (barrier & facilitator)	Provide patient with verbal encouragement and reinforcement to resolve problems
		Motivation and goals	Lack of curiosity in medication: “I just take what’s in the box” attitude (barrier)	Encourage patient to reflect on their motivations for taking their medicines and support them in discussions of what matters most to them
			Intrinsic motivation driven by beliefs about the system (barrier & facilitator)	Discuss the patient’s beliefs about the system and support them to consider and reflect upon their previous actions based on these beliefs
			Prioritisation of certain medicines (barrier & facilitator)	Work with the patient to explore their beliefs about their medicines and provide further encouragement about non-prioritised medicines where appropriate
			Perception of importance of medicines (barrier & facilitator)	Encourage patient to reflect on their motivations for taking their medicines and support them in discussions of what matters most to them

Rank	BCT	Mapped to TDF V1 domains	Determinants	Example content delivered by BCT
		Social influences	Practical input from informal carers (facilitator)	Encourage patient and carer to consider what practical support will be required and suggest actions that can be performed
			Support from healthcare professionals (barrier & facilitator)	Discuss with the patient the different types of support that is available from HCPs and prompt them to seek help when necessary
3rd	Prompts, triggers, cues	Memory, attention, and decision processes	Changes to routine disrupt pre-admission established daily patterns (barrier)	Work with the patient to identify new daily pattern and provide written checklist as appropriate
			Memory lapses affect knowledge and capability (barrier)	Identify what information the patient would like about their medicines (minimum dataset for all) and provide this verbally, as well as written/ in a suitable patient-friendly format
			Forgotten medicines related questions by the times medics were present or appointments occurred (barrier)	Advise patients to document queries as and when they arise and provide handy format (written or app etc.) that can be used
			Drawing assumptions after discharge (barrier)	Prompt patients to recall what they already know and correct any misconceptions. Provide safety

Rank	BCT	Mapped to TDF V1 domains	Determinants	Example content delivered by BCT
				netting by prompting them to telephone the appropriate HCP if anything is unclear
			Medicine regimens are complex (barrier)	Work with patient to identify new daily pattern and provide written checklist as appropriate
		Environmental context and resources	Multiple different medicines within the home causes confusion (barrier)	Prompt patient/ carer to rationalise medicines in the home as soon as possible
			Delayed or over- supplies within community (barrier)	Prompt patient/ carer to rationalise medicines in the home as soon as possible. Trigger appropriate actions to resolve any delays in medicines supply
			Haphazard attendance of formal carers or community health care professionals (barrier)	Prompt the patient to contact the appropriate HCP if things do not happen as expected
			Adaptation of physical layout of medicines at home (facilitator)	Work with patient to identify new daily pattern and suggest personalised adaptations e.g. different storage locations, as appropriate

Rank	BCT	Mapped to TDF V1 domains	Determinants	Example content delivered by BCT
			Use of practical physical resources (e.g. handwritten checklists, MCAs) (barrier & facilitator)	Discuss with patient those prompts and cues they currently use. Provide advice around resources as appropriate.
			Clarity of written information (barrier & facilitator)	Patient-friendly discharge letter to be provided that clearly specifies what has happened and the treatment plan to be followed
2nd	Goal/ target specified: behaviour or outcome	Knowledge	Extent of knowledge about which medications have been changed and why (barrier & facilitator)	Advise patient of medicines changes, both verbally and written in a format that is patient-centred. Discuss new daily regimens.
			Confusion about indications and dosages (barrier)	Provide patient with information about indications and dosages (both written and verbally)
			Unanswered questions about side effects and monitoring (barrier)	Provide patient with expected monitoring and potential side effects, and advise on what to do if these are experienced or monitoring doesn't occur
			Support from others to fill knowledge gaps (facilitator)	Help patient to identify who is able to help them when there are unknown features of their medicines

Rank	BCT	Mapped to TDF V1 domains	Determinants	Example content delivered by BCT
		Skills	Level of mobility limits access to medicines	Help the patient to set goals related to the circumstances when they would either arrange for help, or reorganise their home environment
			Skills to interpret discharge paperwork (barrier & facilitator)	Patient-friendly discharge letter to be provided that clearly specifies what has happened and the treatment plan to be followed
			Work done to ensure correct medicines administration (e.g. stock control, medicines reconciliation) (facilitator)	Help patient to identify relevant and personal key goals focused on their post-discharge medicines management
			Willingness to ask questions (barrier & facilitator)	Support patient to identify who is able to help them when there are unknown features of their medicines
		Motivation and Goals	Lack of curiosity in medication: “I just take what’s in the box” attitude (barrier)	Explore with the patient their thoughts about their medicines, their role and their motivations for taking their medicines, work together to set appropriate objectives around medicines management to achieve personalised goals

Rank	BCT	Mapped to TDF V1 domains	Determinants	Example content delivered by BCT
			Intrinsic motivation driven by beliefs about the system (barrier & facilitator)	Explore with the patient their thoughts about the system and its impacts on their medicines management, and work together to set appropriate objectives to achieve personalised goals
			Prioritisation of certain medicines (barrier & facilitator)	Work with the patient to verbalise their thoughts about their medicines and their perceived importance, and set appropriate objectives around medicines management to achieve personalised goals
			Perception of importance of medicines (barrier & facilitator)	Explore with the patient their thoughts about their medicines and their own role, and work together to set appropriate objectives around medicines management to achieve personalised goals
1st	Social support (practical)	Social influences	Practical input from informal carers (facilitator)	Ensure each patient has the details of a peer contact (informal carer or via formal peer support service) that can provide practical support, at the point of discharge and that they know when/how to contact them

Rank	BCT	Mapped to TDF V1 domains	Determinants	Example content delivered by BCT
			Support from healthcare professionals (barrier & facilitator)	Provide meaningful opportunities for HCPs (community/ PCN pharmacists) to offer patients co-ordinated practical support. Other appropriate options may include reablement services or other similar POCs.
		Emotion	Frustrations over reduced ability to self-manage medicines (barrier)	Provide opportunities for patients to self-manage their own medicines as appropriate once approaching the date of discharge
			Frustrations over perceived lack of continuity/ follow-up (barrier)	Trained individual (pharmacist/ peer champion/ care co-ordinator etc.) helps patient/ carer identify specific worries or concerns and provides practical strategies to manage the situation
			Concern when unexpected medicines were supplied (barrier)	Trained individual (pharmacist/ peer champion/ care co-ordinator etc.) helps patient/ carer identify specific worries or concerns and provides practical strategies to manage the situation
			Worries/ anxiety about onward medicines management (barrier and facilitator)	Trained individual (pharmacist/ peer champion/ care co-ordinator etc.) helps patient/ carer identify specific worries or concerns and provides practical

Rank	BCT	Mapped to TDF V1 domains	Determinants	Example content delivered by BCT
				strategies to manage emotions and overcome problems

6.3 Discussion

The final phase of the study aimed to combine the findings of Phase 1 (systematic review) and Phase 2 (primary research of the patient experience of post-discharge medicines management) in order to model the potential components of a complex intervention. The intervention supports post-discharge medicines management by promoting behaviour change linked to specific behaviour change techniques (BCTs). Eight individual components for inclusion in a complex intervention have been identified that are underpinned by best evidence synthesis of: systematic review findings, patient lived experience, theory-based analysis, and stakeholder consultation. These components were assessed for content and face validity and considered against the APEASE implementation criteria, which found them to be effective and mostly acceptable options. Suggestions for the content of the final BCTs was created by the panel, however, wider implementation considerations are required before further modelling can take place. These are presented below along with a discussion of the behavioural determinants and the most important BCTs.

6.3.1 The barriers and facilitators of post-discharge medicines management

Post-discharge medicines management is a complex behaviour that requires many decisions or actions in rapid order or simultaneously (American Psychological Association 2020). It includes many interacting and synergistic elements, as identified from Phase 2. Some examples are: supply management, seeking support, monitoring for side effects, checking for errors, and adherence. In this study, the complex behaviour was not broken down into its key constituents, meaning individual interventions targeting specific, individual behaviours have not been developed. This can, to a certain degree, explain why numerous barriers and facilitators to post-discharge medicines management behaviour were identified within the current analysis, resulting in the selection of multiple BCTs for inclusion. Whilst this study did not consider the individual specific behaviours, there is a benefit to identifying and defining the behaviour as fully as possible. This ensures that the identified barriers and

facilitators are precise enough to target the defined behaviours and that any resultant intervention based upon them is likely to effect change. If the behaviour is not defined clearly enough, it can be difficult to mediate change, as it is unclear what mechanisms (i.e. barriers and facilitators) are at play and how they can be appropriately modified (Michie et al. 2014). Ultimately, this means that developed interventions may not actually result in the behaviour change they were intended to target. Furthermore, identification of the particular actors linked to the behaviours is also an important aspect of the development of the barriers and facilitators. Providing unambiguous detail of who is involved further helps intervention developers to explore the roles and relationships that could impact on the interventions' effectiveness in practice and who the stakeholders will be for implementation. Whilst this study has gone some way to uncovering this detail, it is still unclear exactly what the specific behaviours of post-discharge medicines management are and the key actors involved. This work has, however, identified potential elements of the behaviour (as described above) and highlighted a range of HCPs and non-professionals involved in post-discharge medicines management to be engaged as stakeholders in intervention modelling. Further research is needed to further explore COMM as a complex behaviour and identify the key elements.

Previous studies have identified patient barriers and facilitators linked to medicines communication during transitions of care (Knight et al. 2013; Manias et al. 2015b; Eassey et al. 2016) and the discharge process taken as a whole (Hesselink et al. 2014). These studies, however, failed to fully elicit all possible behavioural determinants because they were not underpinned by any theoretical framework. Daliri et al. (2019) conducted three patient focus groups to identify the barriers and facilitators to medicines use following the hospital to home transition. They identified three main barriers: a lack of personalised care, insufficient information transfer, and problems in the organisation of healthcare. These three themes, again not underpinned by any theory, encompass many of the behavioural determinants identified within this analysis. For example: clarity of written information identified as a patient barrier within this current study (links with insufficient information transfer),

frustrations over perceived lack of continuity/ follow-up (link with problems in the organisation of healthcare), and unanswered questions about side effects and monitoring (link with lack of personalised care) were all mutually evidenced issues.

Other studies that have used an underpinning theoretical framework, such as the TDF, have also considered complex behaviours. Reported in the work of Patton et al. (2018) are mapped patient-reported barriers and facilitators to adherence in polypharmacy and in that of Cadogan et al. (2015) are mapped determinants to ensuring the prescribing and dispensing of appropriate polypharmacy to older people. This is a particularly useful method specifically because it considers all possible determinants of behaviour, rather than simply those that are seemingly obvious to intervention designers, such as knowledge (Michie et al. 2014). Both studies also mapped determinants to all domains of the TDF. Given that these studies all focused on complex behaviours too, this seems appropriate. This was also shown within the systematic review (Phase 1), wherein which most of the domains were mapped within the complex interventions, illustrating the fact that they are all equally important.

Within this current analysis, the domain social/professional role had the most barriers and facilitators mapped to it. Therefore, when considering intervention design, it was regarded as important to give due consideration to the impact of others on medicines management behaviour and how patients view their own role. Previous studies have shown that carers, for example, could have important roles within medication safety and that a relationship with a HCP can either help or hinder patient involvement (Mohsin-Shaikh et al. 2014; Garfield et al. 2016; O'Hara et al. 2019). This present study has identified specific social/professional role barriers to post-discharge medicines management relating to healthcare professionals: an inherent belief that HCPs will relay important medicines information to the patient, an unwillingness to bother HCPs, a paternalistic culture and perceptions of relationships with HCPs. These crucial factors have previously been identified within the literature and have been linked to poor patient involvement and engagement and lower patient satisfaction, as well as potential threats to patient safety.

Those barriers linked to the patients' view of their role within medicines management include: their previous career, the perceptions of their own responsibility and the view of themselves as an 'expert'. Sometimes their perceptions held from their career as a nurse, for example, or the belief that they are not allowed to manage their medicines because they have a formal carer, acted as a barrier to post-discharge medicines management behaviours. Often, however, these factors also functioned as facilitators depending on the patient and the context, prompting them to take action when something went wrong, or if they did not understand something. It is, therefore, clearly important (within any intervention) to consider how the patient views their own role, and that of others, and how this can be modified or positively exploited to encourage safer and more beneficial medicines management behaviours.

The domains of knowledge and skills were extensively mapped in all interventions within Phase 1's systematic review. However, in this analysis, other domains are mapped more frequently such as: belief about consequences; memory, attention and decision processes; and environmental context and resources. Patient education and providing medicines information is often a mainstay component of any complex intervention (Garcia-Caballos et al. 2010; Spinewine et al. 2013). If behavioural determinants are not correctly identified prior to intervention design, study components are often created based on the assumption of what the patient needs, or the 'ISLIWAGIATT' method (It Sounded Like It Was A Good Idea At The Time) (Michie et al. 2014). This can lead to intervention failure as the components do not appropriately match the behaviours that the intervention is targeting. This of course does not mean that knowledge and skills are not important. The Phase 2 analysis demonstrated that lack of knowledge and reduced capacity both negatively affect medicines management. Intervention developers must, therefore, target all relevant behavioural domains, not simply only the traditional components of knowledge and skills.

6.3.2 Identifying the most important BCTs

The BCTT mapping exercise identified 50 discrete BCTs that had previously been linked to the TDF domains through consensus exercises (Michie et al. 2008; Cane et al. 2015). Whilst some of the included studies within the systematic review (Phase 1) had used upwards of 40 discrete BCTs (Ahmad et al. 2012; Chan et al. 2015; Ravn-Nielsen et al. 2018), the average number of BCTs per intervention was 17. Very complex interventions, such as those used by Ravn-Nielsen et al. (2018) were resource intensive, delivered multiple times over a long follow-up period and included multi-faceted techniques such as motivational interviewing. To ensure that this study resulted in a manageable intervention that would not fail to be implemented in the longer term, the list of BCTs needed to be streamlined.

Some researchers, such as Patton et al. (2018) combined similar BCTs with the aim of reducing the number they had to work with. For example, in their intervention design, they chose to combine social support (practical) and social processes of encouragement and support. After group discussion within the supervisory team, it was agreed that these were distinct, since practical social support (such as collecting a patient's medicines for them) could be offered to a patient, without verbal encouragement. Therefore, all identified BCTs were included in the consensus stages of the intervention design. Following group discussion, 15 BCTs were later removed because they did not fit within the context of post-discharge medicines management.

The BCTT was created from BCTs that had been identified within public health interventions; smoking cessation or weight management initiatives being examples of this (Michie et al. 2013). Whilst it can clearly be seen how some of the BCTs, for instance body changes (example: prompt strength of relaxation training (BCTT v1)) and anticipated regret (example: ask the person to assess the degree of regret they will feel if they do not quit smoking (BCTT v1)) could be operationalised within a public health intervention, when applied to promoting post-discharge medicines management this is less obvious. Others, like threat or vicarious punishment were considered unethical in the

given context, and some, such as social reward, could have had unintended consequences for the older person population.

When undertaking intervention development work, it is important to ascertain who the key, primary and secondary stakeholders are, their relevance to the study and their importance, or level of influence (Department for International Development 2003). Overall, 25 respondents took part in the survey. Due to practical constraints, no demographic data was obtained from these individuals and it is therefore unknown which stakeholder groups took part. This should be borne in mind when considering the final selection of the BCTs. As a result of the COVID-19 pandemic, stakeholders were pragmatically recruited through convenience methods, and secondly through snowball sampling (Davis et al. 2009), whereby those who took part were also asked to forward the survey to interested colleagues. Again, it is unknown if the snowball sampling resulted in any participants and what their role or interest was. Therefore, it is unclear as to the appropriateness of all the survey respondents. On reflection, a more structured stakeholder analysis, using a stakeholder matrix for example, at the outset of this work would have identified the most important and influential individuals to target for this consensus study. It would also be prudent to obtain basic demographic details of respondents (e.g. profession) to ensure that all key stakeholder groups have taken part, and to facilitate further recruitment of target populations where necessary.

Following the survey and subsequent ranking of BCTs, visual inspection showed that the lowest scoring BCTs (<80% score) could be perceived as too burdensome for older people to engage with. The middle ranking BCTs (80-85% score) were considered as perhaps more challenging to operationalise within current practice. Those low ranking BCTs, homework, graded tasks and increasing skills for example, all require the patient to carry out a greater level of work. In the immediate post-discharge phase, Phase 2 illustrated that a prolonged recovery and perceptions of fluctuating health acted as a barrier to medicines management behaviours. This may, therefore, also influence their interaction with any intervention requiring substantial effort from the patient themselves after hospital discharge and could account for their low-ranking acceptability and unintended consequences scores.

Some of the middle-ranking BCTs identified in Phase 3 had been the most frequently used within the literature identified within Phase 1. BCTs involving feedback, action planning, information on the behaviour and health consequences, as well as persuasive communication had all been well represented within the studied interventions. In this consensus survey however, they were not highly rated as effective or acceptable to older people. Survey participants may have found it difficult to consider how these middle ranking BCTs could be delivered. This may be because participants were confined by the scope of their own professional practice, local context or knowledge of the patient experience.

Phase 1 further highlighted the popularity of practical social support, prompts, goal setting and review within complex interventions. All of these BCTs were included in the final selection of the components by participants and were highly ranked. This is because they are highly practical in nature and already well embedded within healthcare norms. For example, Phase 2 demonstrated how patients and their carers regularly enlisted the use of prompts and cues or practical social support to help manage their medicines. HCPs involved in long-term condition management will also be familiar with goal setting practices and this could possibly explain to some extent why these were so highly rated.

Whilst there are some similarities between these eight BCTs identified within **Section 6.2.3** and the Phase 1 findings, there is also some apparent mismatch. For example, within Phase 1, information giving was one of the most common BCTs identified within each intervention, whilst this did not translate through to the final component selection in Phase 3. The ability to give information to patients is often a core component within HCP education and training and therefore it is perhaps not surprising that this features predominantly within the Phase 1 interventions, which were often delivered by HCPs. However, in Phase 3, when intervention development was considered from a patient behaviour change perspective and involved stakeholders wider than HCPs, different BCTs were prioritised. Furthermore, when designing the intervention in this study, all possible BCTs that could result in the intended behaviour change outcome were considered. The Phase 1 theory-based

analysis also relied on extraction of the descriptions of the intervention components from the publications, which were often scant and open to interpretation. This may have resulted in a narrower identification of BCTs. Finally, it is unknown how the Phase 1 interventions were designed and developed, which may have further resulted in the mismatch. The approach taken by this study has hence allowed the exploration of a variety of different components that may not have been tried before within a medicines management context.

6.3.3 Refining of the BCTs into intervention components

After the selection of the final BCTs, APEASE criteria were applied and backwards mapping to the behavioural determinants was completed to ensure that any component would be fit for purpose. This led to in-depth deliberations about how practical it would be to deliver these components within current workloads, which individual or professional group was best placed to deliver them and how feasible they would be now, in light of COVID-19.

Many commissioned services, such as the NMS and MURs, currently exist to support patients after discharge with their new medicines. This study has regrettably demonstrated deficiencies within the system for engagement with these. The APEASE assessment indicated that the implementation of any newly designed service, or asking current HCPs to do more, would be costly, less acceptable and resource intensive. Therefore, rather than combine the components and suggest a brand-new service, further work should be done to identify all existing services that support COMM, explore how they are orientated within the patient pathway and where the gaps are, explicitly underpinned by patient experience. By modifying certain processes that do not add value to the patient's hospital to home journey, gaps could be resolved by implementing more appropriate intervention components that this study has uncovered. Of course, the anticipated Discharge Medicine Service and other locally trialled interventions, pharmacist-led medicines optimisation clinics for instance (Odeh et al. 2020), may go some way to doing this. The benefit of these intervention components however, is that they are underpinned by behaviour change theory and most importantly the patient experience. Hence

the eight components should be thoroughly considered in the design and implementation of any new complex intervention targeting post-discharge medicines management for older people.

Furthermore, Leykum et al. (2007) reinforced the importance of considering how interventions will be specifically applied within complex healthcare organisations. They postulate that dynamically designed interventions, which capitalise on the characteristics of complex adaptive systems (agents who learn, interconnections, self-organisation, co-evolution), will produce better outcomes. In addition, Penney et al. (2018) demonstrated that successful interventions align with the uncertainties and contextual differences that patients face. Care transitions interventions that encouraged patients to both self-organise and learn, hence, significantly reduced the rate of hospital readmissions (Penney et al. 2018). These elements are clearly important within the post-discharge phase, especially around medicines management, as they help patients respond to any problems that may arise. The content of the recommended BCTs should therefore be further developed with these key characteristics in mind.

The COVID-19 pandemic has offered service commissioners and organisations an important opportunity to review activities that are performed within everyday healthcare that often do not benefit patients. This may provide additional areas where the intervention components could be placed, adding increased benefit for patient outcomes. Decommissioning or the de-implementation of long-standing processes within organisations is challenging (Norton and Chambers 2020) and requires careful management. Changes to services have been performed rapidly with minimal consultation and have neglected to consider patient and public opinion. Given the benefit and value of PPIE within service design, opinion must be sought from the target patients in the development or modification of any new intervention. Therefore, older patients with experience of post-discharge medicines management could provide enormous insight into the future implementation of this intervention through their direct involvement in it.

6.3.4 Implementation considerations for the future

This study has identified eight potential BCTs which will help older people better manage their medicines in the post-discharge phase. These BCTs, however, now require further development of the specific content to be delivered, required resources, and target timeframe for implementation within the patient pathway, in order to produce a final complex intervention that is ready for trial. This work is beyond the scope of this thesis, but is currently underway as part of the larger NIHR funded study (PB-PG-0317-20010) that this thesis forms part of. Further considerations for implementation of the BCTs within a complex intervention, including how to test or measure outcomes and the target recipients, are now discussed.

Firstly, whilst the BCTs give indication as to the key components of the intervention, they do not offer suggestion as to the content i.e. what will actually be delivered. As highlighted in **Section 3.3.1** MRC guidance recommends that interventions are designed in collaboration with key stakeholders and are underpinned by patient perspective (Craig et al. 2019). Co-production or co-design, which allows key stakeholders to work with researchers as equal partners to explore ways in which care pathways or services can be improved, is a hugely valuable method. Co-design prioritises the sharing of varied perspectives in order to understand current practice and to generate innovative ideas that better match stakeholder (e.g. patient and HCP) needs (Steen et al. 2010). Important next steps for the development of this intervention, therefore, are to share these BCTs, along with Phase one and two findings, with groups of older patients, as well as family carers and HCPs, and undertake work to co-create the content with them. This would ensure that the final intervention will be more likely to improve the experiences of those who will use and deliver the components. Co-design with patients and HCPs would also make sure that important local adaptation and tailoring would be possible.

Whilst we know the BCTs that are likely to be effective, it is important that the intervention remains flexible. Personalisation and local tailoring is important when implementing successful interventions (Steinmo et al. 2016; Dixon-

Woods 2019). Thematic analysis demonstrated that patients have different relationships and levels of capability with medicines management. Thus, they will likely require different components of the intervention and varying degrees of intensity, specific to their needs. This has implications for testing the intervention via trial, because everyone could in theory receive variations of the same complex intervention, affecting the replicability and fidelity. By eliciting the key processes or functions of the components (i.e. by firstly identifying the mechanism of action via the BCTs), fidelity can be maintained despite any tailoring or adaptation (Bonell et al. 2012). Complex social interventions are different to pharmacological ones, because complex interventions interact with context and exert their effects via extended causal pathways (Bonell et al. 2012). Therefore, other trial types, rather than traditional RCTs should be used to test the success of interventions such as the one designed within this study. A process evaluation should be conducted as a minimum to help identify which components are key to promoting the target behaviour change (Bonell et al. 2012).

As described in **Chapter 4**, traditional RCTs are useful for investigating if an intervention works, however, they offer researchers little evidence about which contexts they work best in and experimental designs need to be improved to better evaluate complex interventions (Marchal et al. 2013). RCTs for complex interventions are limited by their ontological and epistemological positions (Marchal et al. 2013) and many argue that they are not appropriate for testing social interventions. Therefore, this intervention could be tested using more realist methods. However, both types of trial aims are important i.e. finding out if something works along with for whom and in which contexts (Bonell et al. 2012). Marchal et al. (2013) called for the use of theory-informed RCTs, but another consideration is a pragmatic trial (Haff and Choudhry 2018) which tests the intervention in the real-world setting. Some have argued that RCTs can have a realist dimension (Bonell et al. 2012; Jamal et al. 2015), however, others argue that the underpinning assumptions are, and cannot ever be, realist (Van Belle et al. 2016). Furthermore, RCTs tend to focus on clinical outcomes (e.g. mortality and readmission rates), but with interventions striving to change behaviour, more proximal measures should be identified and

measured (Oliveira et al. 2019). Patient reported outcome measures (PROMs) and patient reported experience measures (PREMs) should be developed (The Patients Association 2020) focusing on empowerment with medicines as an outcome and/ or process. Theorising about potential benefits of the intervention and identifying ways to measure those e.g. knowledge, attitude or behaviour (Chin et al. 2016) is also useful.

Further work also needs to be done to understand who should receive which particular elements of the intervention, since the most effective interventions target those patients at higher risk of poor medicines management (Spinewine et al. 2013). Whilst this intervention has been designed with older people, specifically keeping those living with T2DM and frailty in mind, components undoubtedly have the potential to be beneficial to other patient groups. The 'pick and mix' nature of the anticipated intervention design means that patients and their carers could choose, along with their HCPs, those BCTs which they felt would contribute to substantial improvement in their post-discharge medicines management behaviours. Multi-factorial, holistic assessment of the patient's needs would indicate the potential medicines safety risks the patient may face upon returning home, and would support further personalisation of the intervention. To guide this process, further additional research could explore the development of a taxonomy of possible patient personas. These personas (Sheard and Marsh 2019) would draw together specific higher-risk patient characteristics, for example living in isolation, and link the persona to a suggested range of targeted components that would make up a tailored intervention for that individual.

In the current context of practice, careful thought must also be given to the delivery mechanisms for these components. Face-to-face healthcare services have significantly reduced during the COVID-19 global pandemic and it is unclear when and to what level this type of working will resume. Of greater assistance is the knowledge that the intervention components identified within this study are flexible enough for delivery to be modified to suit the individual. This means that the components could either be implemented through face-to-face interaction or via remote consultation. Many services have become virtual in 2020, which has offered some benefits. For example, during remote

video consultations, HCPs are offered a unique insight into the patient's home environment, which may provide supplementary important clues about how they are coping generally. Whilst this is clearly of value, careful consideration of this intervention's target population's technological skillset is necessary to avoid digital exclusion. If these intervention components were to be delivered remotely, a thorough needs analysis must be undertaken on an individual basis so that patients are in no way disadvantaged. Those delivering the intervention components may also need to undergo further training to ensure key messages are well communicated in an effective manner, whilst using a virtual mode of delivery.

Older people living with frailty have worse experiences than other patients after leaving hospital (Care Quality Commission 2020). The Phase 1 systematic review revealed that interventions that bridge the care transition and continue into the post-discharge phase improve clinical outcomes for this patient group. Implementing a new complex intervention, across settings, within busy healthcare organisations, is challenging and often met with resistance to the necessary change, or barriers such as limited time and funding. To promote the uptake of any new intervention, the removal of unnecessary jobs, or those tasks which do not add value, is useful. For example, within the hospital setting there are targets for MR and much more emphasis and priority is therefore given to this task. This may then impact on the time that is spent with the patient, focus the conversation more towards information gathering (rather than shared decision making) and result in a missed opportunity for an informative quality conversation with the patient. In primary care, inspection of the Phase 2 data extracted from participant records illustrated a tendency to focus on obtaining and repeating blood measures, such as Hba1C, and the documentation of every interaction for audit trail purposes. If organisations focused on reviewing and streamlining these processes, precious time could be saved and energies more appropriately spent elsewhere.

Finally, future implementation work should explore who is best placed to deliver the intervention components. As demonstrated within Phase 2 and 3, a trusted source of advice and support is more likely to encourage post-discharge medicines management behaviours. Whilst HCPs could deliver

certain elements, patient peers or skilled volunteers may also have a role to play. Some participants within this study described how they would enlist the help of other non-professionals and future work should explore how these individuals could be enlisted and upskilled to deliver some of the more practical components.

6.3.5 Quality of the study

This phase of the study aimed to identify components of an intervention that had content and face validity within the context of post-discharge medicines management for older people.

This study has shown that medicines management is a complex behaviour. As described in **Section 6.3.1**, there is a benefit to identifying and defining the specific target behaviours as fully as possible as opposed to a non-specific collection. Michie et al. (2014) advocate that behaviours should be broken down as much as possible during intervention design to ensure that specific targets for change are identified. Others have used intervention design methodologies successfully with complex behaviours, as in 'medicines adherence' (Patton et al. 2018; Easthall et al. 2019) and 'prescribing and dispensing appropriate polypharmacy' (Cadogan et al. 2015). Hence, following discussion with an expert health psychologist, medicines management was not separated into each element of the complex behaviour. Since the participants did not break down medicines management into individual components within their mind, and if elements are synergistic, it would have been incredibly challenging to identify which element of the behaviour to target first and potentially detrimental to intervention efficacy.

By using this systematic, theoretical approach to intervention design, all barriers and enablers to post-discharge medicines management of behaviour are likely to have been detected. This includes those linked to emotions and beliefs about capabilities which are strong determinants of behaviour but are less likely to be discussed in participant interviews without prompts nor are they acknowledged within the literature (Easthall et al. 2019). All mapping was subject to professional second opinion by a health psychologist with expertise in the TDF to ensure robustness.

Unfortunately, by retaining the complex behaviour as a whole, this study found that all TDF domains could be extensively mapped, making it difficult to isolate and focus on the development of a single mechanism of action for the intervention. From the literature it is observable that usual methods of intervention design firstly identify the dominant TDF domains and then pinpoint the targeting BCTs (French et al. 2012; Little et al. 2015; Sinnott et al. 2015). However, all domains appeared equally important in this study, hence a different approach was required as advised by the health psychologist colleague. This study's pragmatic philosophy and Michie et al.'s (2014) intervention design methodology are well-known for their flexible methods of application, meaning that methods could be appropriately adapted. Therefore, instead of identifying which TDF domains were crucial to target, the method was revised to identify those BCTs which were relevant, taking advantage of the breadth of use of BCTs across the domains and their impacts. In this way, all potential BCTs across all TDF domains were considered for inclusion, then mapped backwards to ensure good coverage of domains, APEASE ratings and behavioural determinants. This resulted in the selection of eight BCTs that spanned 10 of the 11 TDF domains.

It is worth remembering that these BCTs are designed to influence an individual's behaviour within a complex system. Whilst the theoretical framework used within this study is useful for identifying individual determinants of behaviour, it often gives less insight into the organisational behaviours which could act as barriers to intervention implementation. Individual behaviour change is often nested within the boundaries of organisational processes and therefore the next stage of intervention development must take into consideration the key organisational factors that may affect wider implementation. Within this study, which has used theory to identify the BCTs useful for promoting individual behaviour change, all components are generally available within healthcare organisational norms, thus requiring minimal organisation-level changes. Next steps will therefore consider the context in which the intervention is to be delivered and how the system might need to change to enable individuals to deliver and receive the intervention. This ensures that the new intervention will not come up against

organisational barriers which can often halt the progress of innovation. A real-world example of this is shown in **Figure 29** (**Section 5.6.5** Betty's electronic discharge paperwork). Whilst an electronic intervention had been designed to improve the content and readability of the paperwork, when implemented, the organisation's IT system did not respond as predicted and produced inappropriate text with jargon and symbols. Had these organisational factors been fully considered at the outset of implementation then this could have been avoided.

Importantly, the survey was completed by 25 target population judges and experts in the field, ensuring relevance and validity of the selected BCTs. These judges were a selection of older patients, who were able to consider whether the BCTs would be acceptable to older people, and HCPs who were best placed to make decisions about the implementation and delivery of these BCTs. Consequently, the final selection of the BCTs following the survey has content and face validity. In addition, APEASE assessment and careful mapping of content back to the original determinants of the behaviour allowed for affirmation that these BCTs were appropriate.

6.3.6 Limitations

Mapping to the TDF was met with challenges, and frequent conversations with an expert health psychologist were needed to support and strengthen the quality of this work. It was difficult to identify the most appropriate domain in some instances because it was unclear if the determinant was the process of behaviour change or the output. For example, how the participants viewed their role within their medicines management impacted on their motivation to perform the behaviour. Since the determinants were not discrete entities, in this case it was felt that the determinant 'view of own responsibility for medicines management' could be coded either to the domain motivation and goals or to that of social role and identity. Careful deliberation over whether it was actually the role or the motivation acting as the underpinning mechanism for any behaviour change was taken. In this instance, it was decided that it was the role impacting on motivation, which, in its turn then impacted on medicines management behaviour. Therefore, the decision was taken to map

this determinant to social role and identity. This process of mapping is highly subjective and difficult for a novice researcher, and thus some determinants may be misrepresented.

In addition, it was decided not to code to the 12th domain of nature of behaviour and hence some determinants may have missed. It was intended, however, that any habitual processes that would have been coded under this domain would be modified indirectly by targeting other aspects of the behaviours (i.e. the other key domains) using the selected BCTs.

A further limitation was the difficulty in defining the BCTs in the context of this study. The BCTs stem from public health interventions and as such it was sometimes challenging to adapt them to post-discharge medicines management. An example was provided within the survey to help respondents understand how the BCT might be applied in practice. However, this may have restricted their imagination and they may have based their score on the example, rather than the potential of the BCT itself.

As described in **Section 6.3.2**, it is unknown which stakeholder groups took part in the survey and as such, the integrity of the responses may have been affected. Whilst every effort was made to identify relevant HCPs and patient representatives, due to COVID-19 constraints, pragmatic convenience and snowball sampling methods, as well as a reduced timeframe, limited the range of stakeholder groups taking part. Furthermore, the lack of demographic data collection impaired the knowledge of who took part. Therefore, the respondents may not accurately reflect the population who will engage with the intervention, hence affecting the quality of the overall findings. The final number of respondents to the survey was 25. This allowed for calculation of average scores and ranking of the BCTs. A natural cut off point was not easily identified and had to be discussed with the expert panel. Extra measures, such as mapping BCTs back to the TDF to ensure coverage of all domains had to be conducted. Whilst this study did not seek to identify any statistical significance, nor was it powered to do so, a higher number of respondents may have resulted in larger differences between the rankings and have offered a more natural cut off point for the final selection of the BCTs.

6.4 Chapter summary

During this phase of work, the identified barriers and facilitators to post-discharge medicines management behaviours were mapped to the TDF. From this, systematic and thorough collaboration with the BCTT has identified eight BCTs that are likely to be valuable when combined within a complex intervention to support post-discharge medicines management for older people. Consensus gave rise to prioritisation, including content and face validity checks, of all relevant BCTs that were likely to be effective, acceptable to older people, both practical and cost-effective to deliver within current healthcare organisations These BCTs are:

- Practical social support
- Goal/ target specified
- Prompts, triggers or cues
- Social processes of encouragement
- Motivational interviewing
- Rehearsal
- Review goals
- Comparative imagining of future outcomes.

Further assessment of the final BCT selection was conducted using the APEASE criteria and backwards mapping to the identified behavioural determinants. An opportunity for careful consideration of wider factors and recommendations for future implementation and trial within current complex healthcare systems was an additional outcome.

Chapter 7: Recommendations and conclusions

Previous **Chapters 4, 5** and **6** have described the work conducted in each of the three phases conveyed in **Section 3.3**. In addition, each chapter has presented a discussion of the ideas arising from the findings which emerged therein.

This chapter aims to discuss the overarching themes captured from all three pieces of work involved in this thesis, namely: engaging patients in conversations about medicines; involving patients in medicines management; post-discharge service provision; self-management; and system complexity. Each of these key themes will be explored in turn alongside recommendations for practice and further research. The chapter concludes with reasoned observations of the overall strengths, limitations and reflexivity related to this body of work as a whole.

7.1 Key theme 1: Engaging patients in conversations about medicines

Chapter 4 illustrated that educational activities, such as advising the patient about their medicines changes, were common to many complex interventions. However, this activity did not reach statistical significance for reducing the rate of hospital readmission. Furthermore, all interventions within the systematic review targeted the knowledge domain of the TDF, showing that this is a well-implemented strategy for behaviour change.

Chapter 5 demonstrated that patients experienced gaps in the quality of conversations about medicines whilst in hospital and many were unsure of the changes to their regimens. This affected their knowledge and/or capabilities with their medicines, and subsequently they had to assume the role of detective to try to identify what had changed, or relied on others (family carers or community pharmacists) to prepare their doses correctly.

Chapter 6 identified numerous barriers to post-discharge medicines management behaviours, including: a lack of knowledge about which medicines had been changed, confusion about indications and dosages, unanswered questions, an unwillingness to ask questions whilst in hospital, and difficulties in interpreting discharge letters.

This study has clearly illustrated that a better level of communication about medicines changes and indeed 'medicines orientation', including improving patient's wider capabilities, their confidence and positive cognition surrounding medicines (Fylan 2015: 219-222), is required to help patients and their carers prepare for post-discharge medicines management. This is certainly not a new

priority and has been defined within the literature as a significant barrier to successful care transitions for decades (Kripalani et al. 2007b; Witherington et al. 2008; Frydenberg and Brekke 2012; Manias et al. 2015a). Even with significant investment in the implementation of newer electronic systems assisting better quality discharge letters and technology for seamless information transfer to occur, communication still remains a serious concern for transitions of care and medicines safety.

This study has also shown that older people have varying information requirements (see **Section 5.6.1**) and the challenge for HCPs is to identify not only those helpful details the patient needs but also when, and how that information can be adapted to meet the needs of the patient (Bostrom et al. 1994). Furthermore, patients and their carers need to be recognised as an untapped resource for key medicines details. There is so much that HCPs can learn from patients about their personal barriers and facilitators to medicine management, from the contexts surrounding how they administer them to their emotional attitudes. However, how HCPs gather, make sense of and utilise this type of information from the patient requires further investigation because there is limited evidence to suggest that this is done well within current practice.

Whilst patients have different information and engagement preferences, it is highly important, from a medication safety perspective, that they are made aware of, as a minimum, those changes which have been made to their medicines (Bagge et al. 2014; Capiau et al. 2020). As far back as 2001, changes to the then current medicines management practices were advocated in the ‘Spoonful of Sugar’ national report (The Audit Commission 2001) driving forward the prioritisation of the safe use of new medicines. This document voiced the need to foster higher quality communication with patients. Verbal and/or written information prior to discharge has become the ‘standard procedure’ of medicines communication (Al-Rashed et al. 2002; Pharmaceutical services Negotiating Committee 2005) with little emphasis on medicines conversations throughout the entire admission period as a whole. Shared decision making is a key concept within medicines optimisation policy (National Institute for Health and Care Excellence 2015a). However, as

revealed in this study and in other literature, it is still not routinely practiced with older people (Bunn et al. 2018). Many of the participants, mentioned in **Chapter 5,** perceived that they were not being given any information either because they were 'old' or because the staff were just too busy. This then begs the question as to whether conversations about medicines were not held firstly due to a well-intentioned assumption that the HCP may confuse the patient, or because of time and resource constraints, or because there is not a defined person/ role to do this, or even simply because we, as HCPs, have not really thought in much depth about this. HCPs may also believe that the discharge letter contains all key medicines information. The literature does demonstrate that younger patients, more so than older patients, generally, prefer control over their own healthcare, clear involvement in any decision making, and to gather as much detailed information as possible (Jung et al. 2003). It is also suggested that older patients may value a more traditional, paternalistic relationship where their HCP alone makes the decisions (Duggan and Bates 2008; Mohsin-Shaikh et al. 2014), although this was not the case for many participants in this study. Therefore, this notion of ageist perceptions, compounded by resource limitations, may be a contributory factor to a lack of medicines conversations and much fewer attempts at shared decision making.

Most examples of medicines counselling interventions within the literature relate to the one-way transfer of important medicines-related points (Capiau et al. 2020), such as indications of medicines or doses. However, if the patient is not engaged in meaningful conversations about their wider medicines-taking behaviours, habits, and motivations, HCPs can miss important opportunities to add value to their interactions with patients. Discharge is seen as a time of great hurry to get the patient ready to go home and to free up bed space for the next unwell patient. This may in some respects help to explain why conversations at discharge tend to focus on medicines supply (focused on 'have you got the supply of medicines you need to go home?'), rather than a more in-depth consultation of medicines management capabilities and behaviours once at home. The use of checklists by discharge personnel, whilst considered good practice in some documents (Pharmaceutical services Negotiating Committee 2005), gives a sense that this medicines conversation

is often more of a box-ticking exercise at the end of an organisational process, rather than something much more meaningful. Without engaging with and asking the patient about how they feel about their medicines, one has to assume that they are treated as passive recipients of care. Furthermore, whilst much research has been conducted into discharge counselling, research findings included in **Chapter 4** have shown that medicines education, which is repeated over time, is more likely to be effective. Discharge is a notoriously challenging time for patients and can provoke involuntary anxiety and stress. Therefore, it is not always a conducive opportunity to learn and absorb new information (i.e. about medicines changes) or, indeed, having meaningful conversations (Sandberg et al. 2012; Slater et al. 2017). Medicines communication, therefore, needs to be undertaken throughout the patient journey, not only at multiple time points to reinforce key messages (Svensberg et al. 2020), but also more readily reflecting the needs of the patient at that time. For example, informational needs at admission will be different to those during stay, those at discharge and in the post-discharge phase. Therefore, further work should identify what information is required and when.

Many HCPs are present throughout the patient journey and could, reasonably, hold these important medicines conversations collectively at key milestones throughout the admission and into the post-discharge period, instead of relying on the traditional discharge conversation. Research has shown that the safest transitions of care are facilitated when HCPs spent time getting to know and to understand their patient's holistic care needs, bridging gaps within the system and knowing other healthcare teams across the transition (Baxter et al. 2020). Deeper knowledge about the patient was critical to: making certain that tailored support packages were put in to place, building trust and rapport, and identifying risks which could then be mitigated prior to discharge (Baxter et al. 2020). This, however, requires adequate time, skill and resources, and can often be overlooked by HCPs or de-prioritised in the light of other competing workplace pressures. In addition, whilst many HCPs are available during patient admission, they become less visible to them after discharge. Once home, older people may be unaware of who is available to speak with

them about their medicines, how to contact them or even that it is permissible to contact someone for follow-up support.

Where training in shared decision making and person-centred approaches has been implemented, evidence demonstrates a positive effect on patient engagement and HCP skills (Bunn et al. 2018). Fundamentally, there is a clear need to encourage patients and their carers to expect more from their care, to support them to directly challenge when they are not receiving the expected level of involvement with their healthcare team and seek further help or advice when things are not clear. A study of 80 surgical patients found that participants were willing to question HCPs about factual things relating to their care but did not feel able to challenge them (Davis et al. 2008). This could be due to a paternalistic culture or because the patient does not want to challenge the HCP's abilities as they hold control over treatment. What this study did show, however, was that in cases where a HCP instructed the patient to ask challenging questions, the patient was more likely to do so (Davis et al. 2008). Phase 2 of this current study, however, has shown that patients are often unclear about the discharge process and what experiences they can expect from the post-discharge phase. Without a defined patient-centred medicines management pathway and without clarification of what should happen, patients will not know what to expect and, therefore, will not be able to subsequently check and, more importantly, challenge the process.

7.1.1 Recommendations

For policy

Policy makers should redefine targets around medicines reconciliation at admission and hospital discharge. Hospital encounters must be seen instead as a wider opportunity for medicines optimisation throughout and conversations need to take place with patients and family carers throughout their admission, where this is appropriate.

A patient-centred medicines management pathway that spans the transition ought to be made available so that HCPs and patients are all aware of the expected standards of care and their responsibilities within it.

For practice

Conversations about medicines must be held with patients and/or their family carers at multiple points during admission and into the post-discharge phase to reinforce messages. Conversations should include, as a minimum, details of what changes have been made and which HCPs are available for post-discharge support and how they can be contacted.

Patients must be empowered to ask for these conversations if they do not occur. Investment is required to build the skills of patients, carers and HCPs in order for this to happen.

For research

More intensive exploration of why shared decision making is not widely practiced is required to understand the barriers to its inclusion within everyday medicines interactions.

Work should be conducted to investigate the minimum medicines-related information that older people require when changes are made, to identify who should offer this advice and at which time points it should be delivered. It is worth noting that this study has not focused on people who live with dementia or those who lacked capacity. Therefore, an alternative solution will be required for this patient cohort and future work should seek to understand the experiences of these individuals and their families.

7.2 Key theme 2: Involving patients in medicines management

Chapter 4 concluded that longitudinal and repeated support (such as education during inpatient stay and follow-up over a period of 90 days after discharge) was linked to better patient outcomes. Despite this, patients and their carers were most often engaged to support information-gathering exercises, for example, to help with medicines reconciliation. There was also little involvement of family carers in the majority of interventions.

Chapter 5 also demonstrated that older patients are sometimes treated as passengers in their hospital to home journey and are left on the periphery of their own care. Whilst some felt reasonably happy to be a bystander, others felt left-out of important conversations, or they were unaware of what had happened to them during their acute admission.

Chapter 6 identified barriers and facilitators to patient involvement. A paternalistic culture and the patient's own view of their responsibility for medicines management acted as barriers. Facilitators included positive relationships with their HCPs and anticipating gaps in care.

The literature advocates the benefits of learning to self-care (Allen et al. 2018), shared decision making (Cushing and Metcalfe 2007) and taking more ownership over one's own care (Avery et al. 2002). However, some older people may not think it is acceptable to ask direct questions of their HCPs or are reluctant to seek help (Bagge et al. 2014). This has been further compounded by the media's long-standing portrayal of the NHS in crisis, with many participants in this study stressing how important it was to save the NHS money, or how they did not want to burden overworked and short-handed

clinical staff. In a study of 233 GPs in 11 countries, Wetzels et al. (2004) asserted that barriers to engagement for older people include the patient's lack of experience at being involved, their respect and trust in their doctor and a lack of time during consultations. More needs to be done to upskill these patients so that they are confident to take an active role in their care. Evidence suggests that when we work with patients to improve their communication skills, they feel more supported which leads them to empowerment (Bunn et al. 2018). In this present study, patients often perceived HCPs to be too busy to talk to them. Work needs to be done to raise the expectations of our patients, to know that they have a right to seek help and know what kind of questions to ask. Besides this, some patients felt that the digitalisation of processes, such as electronic prescribing and online transfer of information to primary care had been the cause of reduced patient engagement. HCPs must consider these factors in their everyday practices and make certain that their new ways of working, whilst beneficial in some aspects, do not act as a barrier to, or replacement for, direct patient contact.

Missed opportunities for improving patients' medicines knowledge, their satisfaction and skills of error detection are well documented (Willeboordse et al. 2014). Given the various ways that older people and their family members pro-actively reach in to scaffold the system (Fylan et al. 2019a; O'Hara et al. 2019), organisations should identify how they can better engage with their patients so that this is done in a more supported way. A broader in-depth exploration of how organisations can work in partnership with patients to deliver a safer system is much needed. Some evidence exists to show that patients can effectively support medication safety on admission to hospital by providing the organisation with patient-held medicines lists (Garfield et al. 2020). In addition, the supply of medicines labels and information leaflets by organisations allows patients to identify risks with their medicines (Phipps et al. 2018). What is still unknown, though, is how patients and organisations can pro-actively work together to promote medication safety, particularly across the hospital to home transition.

Whilst some patients and carers employ their own safety strategies, it is unclear what the system can and should expect patients to be doing in terms

of medicines management. In one study, Notenboom et al. (2014) found 184 unique medicines management strategies used by patients, some of which were very complex and may have, in fact, jeopardised safety. Whilst this present study has tried to identify what patients and their carers actually 'do' in terms of post-discharge medicines management, it is still unclear what the key behaviours are. All aspects of medicines management are intimately connected, and patients might not compartmentalise each element as much as researchers or HCPs do. Medicines-taking tasks and behaviours are a normalised part of the patient's everyday routine and are highly individualised. Therefore, it is very difficult to make standard recommendations about who should be doing what. What is unique, however, about the intervention arising from this study is that there is an opportunity for personalisation and tailoring. Patients and their family carers could be empowered and encouraged to decide for themselves, through informed shared decision-making conversations, what help they need with their post-discharge medicines management and ultimately which intervention components, as well as to the degree of these, they might choose. This is much more in line with the person-centred care agenda outlined within The NHS Long Term Plan (2019), where expanded choices, support for self-management and shared responsibility for health should become the norm.

7.2.1 Recommendations

For policy

Make visible the invisible work of patients to demonstrate to organisations and HCPs the significant role patients and their carers can play in their own medicines safety, with an aim to reduce any age-associated stigma within the system.

Policy makers must be mindful that new digital innovations (such as e-prescribing or electronic information transfer) do not become a barrier to or replacement for patient-to-HCP interaction. Best practice guidance for maintaining patient engagement in the digital world is required.

For practice

Encourage patients, where appropriate, to have an active role in medicines safety.

HCPs ought to engage patients in conversations about the individualised medicines management strategies they use at home to ensure recommendations can be made to uphold safety.

For research

Further research would consider how older people can be upskilled to take an active role in their medicines care.

7.3 Key theme 3: Post-discharge service provision

Chapter 4 showed that interventions which commence during admission and bridge the transition by including an element of follow-up in the community are important for better clinical outcomes, such as reducing hospital readmission. Telephone follow-up was a particularly successful component when included in interventions.

Whilst this is known to be effective, some participants within **Chapter 5** experienced gaps in their post-discharge care which impacted on their clinical and psychological well-being. Problems with obtaining medicines supplies or discontinuities in primary care follow-up were common. Patients and their family carers had to bridge these gaps by employing their own strategies to ensure medicines safety. There was very limited evidence of engagement with services commissioned specifically to support patients with medicines changes. For example, no participants described engaging with the New Medicine Service or discharge MUR service provided by their community pharmacist.

Chapter 6 further illustrated that a lack of continuity or follow-up caused significant frustrations and that delayed onward supplies as well as having to make assumptions after discharge were barriers to post-discharge medicines management.

This study has shown that there is a clear missed opportunity for follow-up support from the community pharmacy after hospital discharge. It is unclear whether this is due to a lack of referral and signposting, a poor perception of the pharmacist's role or a lack of pro-active service offering. Furthermore,

community pharmacy services (such as MURs) often rely on an opportunistic interaction with the patient, for example, when they collect their medicines. Many of the participants in this study had their medicines delivered and, thus, did not have the opportunity to see their pharmacist nor to engage in services that are traditionally delivered in the pharmacy. Housebound patients or those who use internet medicines supply services will also have limited opportunities for engaging with their community pharmacy. The current decommissioning of MURs to better target high-risk areas, such as urgent care referrals, could therefore negatively affect the patients that may have benefitted from a medicines review. This is especially so, given that the current discharge MUR service in Wales (combining medicines reconciliation with review) has recently been associated with a significantly reduced risk of hospital readmission within 40 days of discharge ($p<0.001$) (Mantzourani et al. 2020). However, this shake-up of community pharmacy could also be an advantageous opportunity to deliver better value services to those who need them the most. For example, the new community pharmacy Discharge Medicines Service (Pharmaceutical Services Negotiating Committee 2020a) is clearly an ideal opportunity to put some of the things this work has highlighted into practice. At present, it is unclear how this service will work however. Essentially it needs to integrate the patient at its core, especially, in particular, those who are housebound. If pharmacists continue to be restricted when conducting telephone reviews (as they currently are with the MURs), housebound or isolated patients will continue to be disadvantaged. In addition, these conversations supported by this service need to echo the medicines-related content discussed in key theme 1 and support the patient in asking questions. Essential training may be required to upskill pharmacists to do this and carefully considered Service Contracts should be developed that avoid the closed question, checklist format of the MURs or New Medicines Service (**Figure 30**). Careful evaluation of this new service roll out is also required to ensure it is sufficiently meeting the needs of older people and their family carers, not just facilitating the measurement of superficial performance targets (Berwick et al. 2003; Dixon-Woods 2019).

NMS intervention questions for pharmacists
1. Have you had the chance to start taking your new medicine yet?
2. How are you getting on with it?
3. Are you having any problems with your new medicine, or concerns about taking it?
4. Do you think it is working? (Prompt: is this different from what you were expecting?)
5. Do you think you are getting any side effects or unexpected effects?
6. Have you missed any doses of your new medicine, or changed when you take it? (Prompt: when did you last miss a dose?)
7. Do you have anything else you would like to know about your new medicine or is there anything you would like me to go over again?

Figure 30: NMS intervention questions for pharmacists (Pharmaceutical Services Negotiating Committee 2013)

A further point is that primary care needs to consider how valuable it is to conduct medicines reviews without the patient, a matter frequently identified in a number of data extraction cases. Often decisions were made that should have included the patient, or that the patient could have given more details about to provide a quicker resolution. In 2011, the then Secretary of State for Health, Andrew Lansley, coined the phrase “nothing about me, without me”, but as yet this ethos of shared decision-making is still not widespread (Coulter and Collins 2011). In addition, Medicines Optimisation guidelines suggest that the patient must be involved in order to reach an agreement about their medicines (National Institute for Health and Care Excellence 2015a). Since policy and evidence advocate for patient involvement in medication review, only individual HCPs can decide whether to change their behaviour and consultation style, as well as identify and fulfil any training needs, in order to create shared decision making into a reality within their practice.

July 2020 marked one-year since the introduction of PCNs across England. These PCNs aimed to overcome the historic divide between health services and to reduce health inequalities. Therefore, they are one of the greatest opportunities available for improving medicines safety at care transitions (Pett

2020). There remains some concern, however, that the PCNs do not include secondary care and, consequently, there is still a gap to be bridged. There has been a drive to recruit pharmacy professionals (pharmacists and technicians) into extended clinical roles through the PCN, by means of such mechanisms as the Enhanced Health in Care Homes, the Structured Medication Review (SMR) and medicines optimisation directed enhanced services. SMRs are different to the traditional MURs, as they focus on a comprehensive clinical review of a patient's medicines, delivered by facilitating shared decision-making conversations (Pett 2020), rather than a conversation concentrating on the patient's administration of their medicines. More to the point, the PCN pharmacist is fully integrated within the primary care team and has full access to the patient medical record, unlike their counterparts in community pharmacies. This may specifically help in improving medication safety following hospital discharge primarily because the SMR service targets older people living with frailty who have recently been in hospital, and, thus, the PCN pharmacist is very well-placed to engage with the patient as part of the wider multi-disciplinary team.

The SMR specification reinforces that the consultation should be personalised, give appropriate consideration to the individual's health literacy and to their holistic needs. The recruited PCN pharmacy professionals will have variable experience and whilst they are enrolled on suitable training courses, they can often take 18 months to complete. It will take time for professionals to become competent and confident in the SMR. Furthermore, to overcome silo working, it is important that the PCN pharmacy professionals function collaboratively with the multi-disciplinary team and other pharmacy staff working in the community. Again, this will take time and formal communication channels will need to be developed.

In addition to pharmacists, Phase 2 findings revealed that participants were supported by various other HCPs, such as GPs or district nurses, and these individuals could further be engaged to reinforce important messages about medicines in the post-discharge phase, or pro-actively highlight those individuals who require further follow-up from the PCN pharmacy team. As new professional roles become utilised more widely within primary care, e.g.

physician associates, organisations should explore potential supportive roles that these HCPs could have with post-discharge medicines management.

Work during the COVID-19 pandemic has also encouraged fast-paced change and new ways of working, since face to face hospital inpatient communication has been suspended or significantly reduced. Pharmacy and other healthcare teams have rapidly changed their ways of working and provided more services over the telephone, or via online networking platforms such as ‘Skype’. These innovative ways of working during the crisis have again delivered an opportunity to provide responsive services when required, and the learning from this should be used to inform how post-discharge medicines management can significantly improve. Regardless of this opportunity, these decisions to change practices were made with very little or no wider consultation, and may, subsequently, not revert back to the more ‘usual care’. It is imperative that careful consideration about how to deliver medicines care in the COVID-19 world occurs to ensure that those isolated older people or those with physical, mental or cognitive conditions are not negatively affected and digitally excluded (Almathami et al. 2020; Christensen et al. 2020). Good practice recommendations to optimise remote consultations for older people living with frailty include: prioritising those most in need, considering the consultation process (including the technology requirements), and a focusing of medicines optimisation activities on urgent issues (British Medical Association 2020; Car et al. 2020). It is not known, at the current time, how older patients feel about this type of service delivery and it is likely that some will engage with and benefit from remote consultations, and others will not. Clinical experience highlights that a ‘one size’ approach can never suit all, and the value of face-to-face consultations, especially in the home, where the HCP can also observe the patient’s environment, must not be overlooked.

7.3.1 Recommendations

For policy

Post-discharge services should be underpinned by patient experience and must make the needs of all patients central in their design. Not involving the

patient or their carer as an active participant in the service (as in primary care medicines review) must never be an option.

A review of the PCNs ought to be conducted to consider how secondary care can be encouraged to contribute to multi-disciplinary working, to reduce system silos.

For practice

Organisations must work to remove unnecessary tasks or delegate to another suitably qualified person, in order to free up time to deliver meaningful post-discharge services.

Making appropriate use of new and existing professional roles to deliver follow-up services, such as PCN pharmacists and technicians or physician associates, is a priority. Training will be required to upskill these HCPs to deliver better conversations with patients.

HCPs must ensure that new methods of remote working do not encourage the digital exclusion of older people, especially those living in socially deprived areas.

For research

Research needs to explore why post-discharge community pharmacy services are underutilised by older people, in order to inform the design of the new Discharge Medicines Service.

The benefits and challenges of remote consultations for older people should be studied and used to make informed decisions about service provision.

7.4 Key theme 4: Is self-management an answer?

Given the current pressures within the NHS, resource limitations and the increasing demands of the ageing population, more could be done to address any limited patient skills and encourage them to self-manage their medicines. The current study has shown that there are numerous behaviours that could support self-management of medicines, such as organising medicines supplies, checking medicines, monitoring for side effects and seeking information about medicines. **Chapter 5** also explored a number of contextual factors that affected the patient's capabilities and willingness to engage with these behaviours. It is therefore clear that the self-management of medicines is a complex set of behaviours. Exactly what it entails is still yet undefined, and how it can be measured also remains unknown. From the work conducted in this study, self-management appears to be much more than adherence or administration behaviours. However, adherence is perhaps the most commonly studied behaviour within the literature (Cross et al. 2020). Other possible aspects of self-management include: medicines supply management, checking and error resolution, seeking support, monitoring of effects, and developing a thorough understanding of the medicines. More work needs to be conducted to really understand what this complex behaviour of self-management not only looks like, but how patients enact it, together with just how far current post-discharge services go towards promoting it.

In addition, Medicines Optimisation guidance promotes the use of self-management plans as a method of improving patient empowerment and involvement with medicines in chronic condition management (National Institute for Health and Care Excellence 2015a). This guidance stipulates that self-management plans should be individualised, used in multiple settings and can be patient or HCP-led. Documented plans should include which medicines are being taken, when and where to seek help and the responsibilities of both the patient and HCP. This resonates strongly with the information needs of older patients within this study, and, therefore the co-creation of a plan may be a useful adjunct to medicines conversations whilst in hospital and could be used to guide post-discharge follow-up. Within the current study, no patients described having a medicines self-management plan and no documentation

was available from the data extraction to provide evidence that plans had been created. This may be due to: a lack of awareness of the need to create a plan by the HCP, unclear ownership about who initiates the conversation with the patient, an assumption that older patients do not want to or cannot self-manage their medicines or lack of time and resource. A further consideration is who would be best placed to follow-up a plan within primary care that was implemented within secondary care. HCPs may also have concerns about creating work for colleagues, or not fully understanding the remit of professional roles, on the other side of the transition. Thus, exploration of whether self-management plans for medicines are utilised within practice and identification of the barriers to their use warrants further research.

Furthermore, this study has shown that patients report varying levels of engagement with their medicines, and so it is seen as beneficial that to encourage every patient to take some steps towards self-management warrants exploration. Given the drive for personal health improvement and wellbeing in the COVID-19 world, as well as consumer demand for better quality care, deference to paternalism may be reducing. As the next generation of people become older, different attitudes to self-care and involvement may become apparent; meaning that self-management of medicines becomes the norm, rather than the exception. In order to prepare for this, the time to teach the public about the importance of the wider self-management behaviours as well as the potential barriers (Xiao et al. 2019), and to share strategies which help them to perform these in their own contexts is right now.

One concept that may be helpful here is that of ‘activation’. ‘Activation’ enables patients to make informed choices to manage their health (Greene and Hibbard 2012) and relies on their level of motivation, knowledge, skills and confidence. Improving levels of activation in patients with long-term health conditions has been linked to better health outcomes (Greene and Hibbard 2012), care experiences (Hibbard and Greene 2013) and an increase in positive self-management behaviours, such as better diet, more exercise and adherence to medicines (Hibbard et al. 2007). Further research should explore whether these chronic care activation principles can be extrapolated to medicines self-management to develop a deeper understanding of how older

patients can become ‘activated’ and encouraged to take a pro-active self-management role with their medicines after hospital discharge.

7.4.1 Recommendations

For policy

Make available clearer guidance on who is responsible for the initiation and follow-up of a self-management plan, as advised in the Medicines Optimisation guidance (National Institute for Health and Care Excellence 2015a). Further promotion and detail around the value and content of the plans would be beneficial in increasing their use.

For practice

HCPs should explore how self-management plans could be incorporated into medicines conversations during hospital admission and post-discharge follow-up.

For research

Further research is required to explore the concept of medicines self-management to ensure that interventions target the most appropriate behaviours. In addition, investigation into how self-management can be measured is key for the evaluation of any intervention that aims to improve self-management.

Exploration of the concept of ‘patient activation’ in the context of medicines self-management may uncover new ways to encourage older patients to become more pro-active.

7.5 Key theme 5: Reframing the care transition

It is high time to re-think the care transition 'problem'. Despite the numerous policies and strategies that have been prioritised over the past decade, transitions still remain a significant healthcare challenge and therefore need to be considered from an alternative perspective.

We need to accept that the healthcare system is fallible, and investment is needed to prepare patients to compensate for the inherent weaknesses. There has been a drive to increase the information made available to the public about the quality and safety of healthcare, however the focus has been far wider than medicines (The Health Foundation 2013). Care transitions are indeed high-risk situations and the consequences of associated MRPs should be related to patients in order to develop a more open culture around medication safety.

Whilst we can try to reduce error and minimise harm, we need to also think differently and be open about the fact that things can and do, unfortunately, go wrong. Although we cannot rely solely on patients and carers to mitigate weakness in the system, they still need to be equipped with the knowledge that the system they are part of is complex and that they have an important role in protecting themselves from medicines-related harm. Though advisory documents highlighting how patients could and do avoid errors in their own care have been created by organisations, studies have demonstrated that these have caused more concern than benefit (Entwistle et al. 2005). For example, patients were offered very little practical support, making it challenging to engage with initiatives and some experts felt that this was an inappropriate shift of responsibility on to the patient (Entwistle et al. 2005). In addition, asking patients to challenge the system was met with conflict due to the patients' relationship and current expectations of HCPs and their own roles within healthcare. Therefore, to engage people in these types of behaviours and to ask patients and HCPs to re-think what they know about the system, necessitates further research. This also demonstrates that involvement of PPIE in the development of any interventions is required to ensure that due attention is paid to the patient perspective.

Care transitions also need to be seen as an opportunity to promote medicines reconciliation, optimisation and shared decision making, instead of resolving the acute complaint which is presented (Xiao et al. 2019). Rethinking Key Performance Indicators and shifting the focus from admission and discharge reconciliation to a more holistic medicines optimisation inpatient and/or post-discharge follow-up experience could be valuable. Work could be done to support other qualified staff (e.g. pharmacy technicians, Physician Associates) to take up some of these tasks, such as reviewing medicines management needs with the patient. However, significant training in the process of shared decision making would be required. Furthermore, the invisible work of patients to promote safety needs to be highlighted to HCPs so that they are aware of the downstream ramifications of their actions, and so that real life examples can be drawn upon to support other patients.

The vast majority of care transitions are unavoidable and elderly patients will continue to go into hospital. Rather than relying on patients and HCPs to 'fire-fight' (i.e. mitigate risks or deal with errors and medicines-related problems after hospital discharge), patients could become prepared for managing medicines at care transitions before they need to move settings. Taking lessons from the work of 'prehabilitation', patients and their carers could be prepared for post-discharge medicines management at an earlier stage in their journey. For some this prehabilitation program could even be before their regimens become too complex, resulting in them becoming disengaged with medicines management. Prehabilitation enhances a person's functional capacity to enable them to withstand a stressor, such as a hospital admission (Ditmyer et al. 2002). This work has predominantly been tested with patients prior to major surgery, and generic activities include strength training, nutritional support and reduction of negative emotions (Banugo and Amoako 2017). If older people could be equipped with and have ample time to practice the skills required to perform medicines management prior to hospital admission, they may also be more likely to engage in these behaviours after discharge.

In addition to this, to increase post-discharge support, risk prediction tools could be employed to pro-actively identify those older patients at most risk of

MRPs, so that efforts can then be focused on these individuals. Whilst some localities do prioritise primary care reviews for patient who live in a care home (through SMRs), and have a significant level of frailty or high risk medicines (through PINCER), some key factors as identified by this study are left out of risk prediction tools. Parekh et al. (2020) for example, have identified eight variables that can predict MRH after discharge: age, gender, antiplatelet drug, sodium level, antidiabetic drug, history of adverse drug reaction, number of medicines and living alone. This study, however, shows that concepts linked to the patient's level of engagement and relationship with their medicines were also important. Whether any safety strategies were employed, the level of medicines management capabilities and the presence of a family carer still impacted on patient's capabilities to safely manage their medicines. Therefore, further work needs to really identify these holistic risk factors for MRPs and models should take into account these factors so that risk can be reliably predicted in a more holistic, person-centred way.

7.5.1 Recommendations

For policy

Organisations must work with patients and family carers to identify methods of pro-actively working together to increase medicines safety at care transitions.

For practice

Develop and implement accurate risk prediction tools to identify patients at highest risk of MRH following hospital discharge.

For research

Further research is required to explore the concept of prehabilitation for medicines management and how an activity program might be designed to support the needs of older people living with frailty.

7.6 Key theme 6: System complexity

As shown in this present study, medicines management systems are increasingly complex, and artificial divides between secondary and primary care have acted as a barrier to successful COMM. This complexity stems from the involvement of multiple HCPs, patients with polypharmacy, multi-morbidity and multiple medicines changes, along with a lack of successfully co-ordinated working (Fylan et al. 2019b), which has implications not only for care quality, but also for intervention design.

The impact of this system complexity was shown in Phase 2, where participants often felt confused about their medicines after hospital discharge, or did not receive the level of follow-up care they expected within the community. Where they had had previous experience of post-discharge navigation, or had an advocate such as a family carer, patients became more competent at carrying out their medicines management behaviours. Whilst this study did not seek to understand how complexity can be reduced for these patients, the BCT components identified within Phase 3 are likely to improve the patient experience, overcoming some of the barriers that this system complexity introduces.

In an attempt to limit the impact of complexity and to develop highly functioning teams, further work should be conducted within and across organisations to understand each other's roles, responsibilities and limitations (Xiao et al. 2019; Baxter et al. 2020). Inter-professional learning, whilst logistically challenging in its delivery to such a wide range of professions, may help those new to practice to understand the different players involved within the patient journey, and the fuller extent of the remits of their role. By helping secondary care practitioners understand the challenges of primary care, and vice versa, teams may think differently about the actions that they take as well as work collaboratively to identify and solve risks to medication safety (Xiao et al. 2019). In addition, a unified reporting system for PSIs that spans the transition would be helpful, so that learning from incidents can be fed backwards and forwards (The Health Foundation 2013). The development of a robust and effective organisation-wide feedback loop is an important component of any

safety management system (The Health Foundation 2013). Equally, HCPs need to be made aware of the patient experience, not just when they are present within their setting e.g. a hospital ward, but also after the transition. Inter-professional learning should also, therefore, stimulate reflection about the downstream repercussions of actions for their patients. Finally, all efforts to reinforce that medication safety is everyone's responsibility should be doubled.

Often intervention design occurs in one setting (i.e. the hospital, or primary care) and rarely involves stakeholder engagement from all players across the affected sectors. This means that when researchers or quality improvement practitioners try to solve something, they have limited knowledge of the downstream ramifications of their actions (Berwick et al. 2003). It is often the case that HCPs cannot see the impacts of their immediate actions, as sometimes they do not manifest themselves until further down the pathway (such as the case with this study's potential PSIs).

7.6.1 Recommendations

For policy

Identify better ways to monitor and report incidents across transitions and share learning around the downstream impacts.

For practice

Create more opportunities for inter-professional learning that focuses on scenarios across transitions, and acts as an opportunity to share learning, identify others' roles, responsibilities and constraints.

For research

Intervention design across settings needs to incorporate the views of all individuals involved, especially patients, carers, HCPs and service commissioners. Co-design as a method to meaningfully integrate the patient and professional voice within intervention development should be employed.

7.7 Summary

Chapter 6 concluded with the systematic identification of eight BCTs for inclusion within a complex intervention. These have been deliberately considered and prioritised with the context of implementation within the current UK healthcare context (affordable, practical to deliver, cost-effective, acceptable and equitable) to ensure minimal barriers to uptake. Further recommendations could be made however without these boundaries, based on this study's findings and the key themes within **Chapter 7**. Firstly, in an ideal world, a review of older patients' medicines management would occur during admission and within the post-discharge phase, underpinned by the BCTs identified within Phase 3. Ideally this would take place in the home environment, where a careful medicines reconciliation with the patient and their family carers engaged as active partners could be conducted. A self-management plan would also be co-developed including the development of medicines management goals. Patients and their family carers should be pro-actively encouraged to report their medicines-related problems to their pharmacist (either community or primary care practice) at every contact.

The development of shared IT systems would prevent or limit medicines errors across transitions and reduce some of the current problems identified with communication across the secondary-primary care divide. A restructure of the way healthcare is delivered, for example by ensuring the Integrated Care Systems include local stakeholders from secondary and tertiary care, as well as primary care, may also overcome the challenges associated with silo working. In this way, teams will: learn about others' roles, responsibilities and remits, identify potential problems across the transition and, work to find solutions together reducing any negative downstream impacts. Furthermore, HCP training has traditionally often involved only one profession. Moving to a more cross-sector, as well as multi-disciplinary approach to education would also encourage this.

7.8 Study strengths and further considerations

The strengths and limitations of each phase of work have been presented in **Sections 4.8.4, 5.6.11 and 6.3.5**. This section aims to offer some critique of

the study as a whole, starting with an insight into the impact of maintaining the patient voice throughout. Reflexivity is also presented, with a particular focus on the research journey and researcher development.

Remaining true to the patient voice

Throughout the entire study, PPIE input has been sought to ensure that the research topic is underpinned by patient experience and that the work remained important to their needs. PPIE has had an incredibly positive impact on this study and has ensured that the resultant interventional components are grounded in stakeholder opinion, as well as the best available evidence from the literature.

The role of the PCLSG has been crucial in study design and conduct. They ensured that the data collection methods and tools were fit for purpose and offered various suggestions and advice when recruitment was slower than expected and even helped build my confidence in approaching patients on the ward as a researcher, by role playing different scenarios with me. I maintained frequent communication with the PCLSG and very much viewed them as critical friends and as an informal and vital support network, particularly in the latter stages of analysis and write up. As well as providing insight into their own unique experiences and offering support in research design, the PCLSG have been an incredible source of motivation and encouragement throughout my journey.

Overall, my positive experiences with PPIE have encouraged me to generate various outputs showcasing how important and beneficial the involvement of patients is within doctoral research. These outputs offer help and advice to others who want to increase their PPIE activity and have been widely viewed.

In addition, I strongly believe that I have maintained the integrity of my role as ‘faithful reporter’ and have employed specific methods to ensure that I remained unerringly true to the patient experience. Throughout all interviews, patients and their family carers were encouraged to offer an uninterrupted narrative of their journey. Inductive Framework analysis methods ensured that

all concepts were considered, not just those of importance to the researcher, and systematic coding accurately reflected the participants' own words.

To continue the strong ethos of PPIE within this study, the next steps would include using co-design methods to model the individual components into a complex intervention, including careful consideration of the content, when it would be delivered and identification of the personnel who could deliver it. Furthermore, patient representatives should offer suggestions of how the effectiveness of the intervention could be measured.

Further considerations

This study was designed to include dual centres to increase robustness of findings. Bradford was chosen due to its diverse population mix and high prevalence of T2DM. Leeds by comparison has a lower incidence of T2DM and a lower spend on medicines for diabetes, illustrating potentially poorer treatment of these patients. Therefore, these areas were considered to be different from each other enough to ensure a diverse population to draw the sample from.

By including Bradford participants in the sample, it was envisaged that a range of different perspectives could be gathered about how older people are looked after in the community. For example, due to Bradford's high number of multi-generational households we hoped to gather some insight into the specific challenges for these individuals. Due to the low ethnic diversity of those participants recruited, it is unclear whether the findings are representative of wider populations. Furthermore, those patients with severe cognitive impairment were excluded from this study and whilst some patients did have mild cognitive impairment, further work needs to explore the applicability of the suggested intervention components to this high-risk population.

This study has very much focused on the perspectives and experiences of older patients and their family carers, with little involvement of HCPs. Whilst I did not set out to gather their opinions, this study may lack insight into the knowledge around disease specific aspects of treatment, services and any

systematic differences in the quality of care between Leeds and Bradford health economies. Generalist input was sought during each phase of work to ensure that the analysis was directed by current practice and thinking. The patient experience was similar between both localities and no observable differences were identified in the analysis. Therefore, the findings of this study are likely to be true in other areas for similar patients. It is worth noting that HCP experiences may vary, especially around the themes of disease specific care and the pathway itself, and future work should be conducted to explore this.

This study has additionally focused on patients living with T2DM and frailty as examples of long-term conditions where MRPs frequently occur. Again, this has implications for the representativeness of the findings to other long-term conditions. The challenges that participants described were more generic, related to the complexity of care as a whole with little emphasis on T2DM-specific issues. Their admission to hospital in the first instance was not necessarily linked to their T2DM and consequently it can be cautiously concluded that the findings may somewhat resonate with other long-term condition management.

Finally, it is worth noting that the data were collected prior to the COVID-19 global pandemic, and the findings might not reflect the new world since general care pathways have been disrupted and changed. Whilst this could not have been predicted, the pandemic has magnified the challenges of COMM and the ability to manage medicines well at home has never been more important.

7.9 Reflexivity

Throughout this study I have tried to make clear my *a priori* assumptions and minimise the impact that I have had on the research. Whilst I am a pharmacist, I have worked hard to truly understand the patient experience, and this has often been challenging for me both personally and professionally. Really listening and hearing the participants describe the challenges that they face and sometimes observing the chaotic moments of their lives has made me reflect and think differently about how I can practice person-centred care.

Despite a ten-year professional career, this study has been the first time I have had authentic, intimate access to patients. I realise that I have underestimated the challenges that frailty has for individuals, not only with their medicines but also when taking part in research. I have been shocked at the medicalisation of their home environments, as medicines and care paraphernalia have overrun their living spaces. Mostly, I have been overwhelmed by the sheer amount of effort and work that patients and their family carers have to do to uphold medication safety and I worry for those who do not have the necessary skill, capacity or self-motivation to do so. This has, at times, made me feel very uncomfortable with current practice and I regularly feel tension between what I now know we should be doing and what we can do within system limitations when practicing clinically.

Conducting research on a ward where I was employed also had its benefits and challenges. Whilst it was of value to have a professional relationship with the staff and an understanding of the procedures, I feel disappointed and disheartened that these are the experiences of our patients. Here, the role of supportive leadership within the Trust to openly share and accept the findings and strive for improvement has been of real importance.

It was difficult to draw my researcher-participant relationships to a close at the end of the study, as I had built a depth of rapport with the families, I looked forward to my visits and truly felt invested in knowing what happened next for them in their journeys. Sadly, some of the participants did die, or their health deteriorated significantly during the study, and this was personally difficult for me. As a researcher, conducting serial interviews it is important to prepare your participants for the end of the project and ultimately the relationship, which I did by reiterating the duration of the study at each contact and sending thank you cards with a summary of the findings. However, what I failed to appreciate was that I also needed to significantly prepare myself. Completing the reflexive matrix iteratively whilst simultaneously undergoing regular debriefs with my supervisors and research group offered genuine comfort. Furthermore, being able to shine a greater spotlight on the under-reported experiences of these patients in both professional and academic forums has been greatly rewarding.

7.10 Conclusion

This thesis has resulted in the identification of eight evidence-based interventional components, which could be employed within the future to better support older people living with long-term conditions with their post-discharge medicines management. The methods employed followed the MRC guidance for complex intervention development and were underpinned by behaviour change theory. Firstly, a systematic literature review presented a synthesis of the evidence of effectiveness of trialled interventions through meta-analysis and theory-based analysis. Next, the experiences of older people and their family carers were explored using serial qualitative interviews. Data gathered from interviews was triangulated, where possible, with factual information from the participant's primary care record and their own diary entries. Framework analysis revealed key themes and sub-themes that impacted on their perception of medicines-related care and highlighted the behaviours that helped or hindered them to manage their medicines effectively after hospital discharge. A further analysis of potential PSIs revealed within these interviews was conducted, identifying the possible levels of physical and psychological harm for the participants. Finally, the behavioural determinants identified within the Framework analysis were mapped onto the TDF and potential candidate BCTs were identified using the BCTT. A consensus study, involving target population judges and experts in the field, helped model the intervention components, refining the list until eight were agreed upon.

Overall, this study has highlighted unique insights into the patient experience including the perceived gaps within current post-discharge medicines-related service provision, and has described the intervention components that could improve post-discharge medicines management. Recommendations for policy, practice and for future work have also been stated.

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Appendix 1 – Initial PhD Proposal

Schedule I

The Project

PhD1: Medicines safety for vulnerable older people after discharge from hospital

Aim: to investigate medicines-related care for older people after discharge from hospital, and to study the effects on patient safety of a new patient pathway.

Project Start Date (Effective Date) 3 October 2016

Background

Older people have acute hospital admissions for a variety of reasons and their hospital stays are often short. Moving across the interface of healthcare is known to result in errors which can cause patient harm and increase the risk of readmission and decreased quality of life (Ahmad et al 2014). Furthermore, sub-optimal medicines use results in patients not fully benefiting from their medicines. Errors might occur as a result of: communication issues between hospital and general practice staff; medicine reconciliation errors on admission, discharge and/or post-discharge; patients not understanding the treatment plan; intentional and non-intentional non-adherence with medicines (Mulhem et al 2013), and inconsistencies in follow-ups once the patient is back home e.g. not restarting medicines that were only intended to be stopped acutely.

The NHS England 5 year forward view and other policy and opinion pieces recognise the artificial divide created by NHS staff between primary and secondary care, and recommend that in the future, care needs to be provide by health care professionals where the patient needs it. So for example hospital staff might provide services in community settings or in the patient's own home. It is also recognised that greater integration and coordination of care is required between community-based and hospital-based staff. There is therefore an opportunity and a need to redesign NHS care to ensure the best use of staff and resources to maximise patient outcomes.

Gaps in the evidence

We currently do not have a clear picture of the pathway vulnerable older patients and their medicine take after discharge from hospital, the nature of medication errors and medicine related problems, and the touch points when these might occur.

We also do not know how pathways of care might be re-designed to reduce medication errors and medicine related problems and to ensure patients receive and take the medicines that they need.

Preliminary objectives

- to systematically review the literature pertaining to medicines errors and medicine related problems experienced by vulnerable older people following discharge from acute care.

- to map and describe the current medicines–related systems and processes when vulnerable older people have transitions in care
- to describe and quantify errors and medicine related problems post discharge and to identify their causes
- to determine the barriers and facilitators to medicines optimisation in this context
- to propose, based on empirical findings, published research and health policy a re-designed pathway of care that improves patient safety
- to design a theoretically-framed, complex intervention to improve medicines optimisation for vulnerable older people

Research Plan

The PhD will be conducted in two phases and using mixed methods. In Phase 1 process mapping techniques will be used to investigate medicines-related care for older people after discharge from hospital. Phase 2 will comprise a study of a new patient pathway including hospital outreach into primary care for medicines reconciliation, and referral and handover to community pharmacy for Medicines Use Review or New Medicines Service. The pathway that vulnerable older people take after discharge from acute care will be studied by following the prescribing, dispensing and supply of their medicines. Against this background the points at which medication errors and medicine related problems occur will be identified and their nature and scale measured and quantified.

The PhD may look at 4 aspects of the pathway

1. **Prescribing** – including medicines reconciliation at the GP practice, prescribing post discharge and timing of prescribing in relation to time from discharge and need for next medicine supply. Clinical appropriateness of the medicines (e.g. presence/absence of dose titration, medicines continuing beyond the point of need, etc)
2. **Monitoring** – Were appropriate tests done or planned to be done
3. **Dispensing** – medicines the patient received on the first post- discharge prescription: reconciliation errors, dispensing errors and receipt of the new prescription or the old pre admission prescription.
4. **Administration** – in this context refers to adherence, both intentional and non-intentional non adherence?

The second phase of the PhD will propose alternative pathways of care for medicines optimisation between hospital and community settings. The process mapping will have identified:

1. Areas and types of risk
2. Poor practice that can lead to harm
3. Education and training issues etc

A multi-stakeholder group panel of GPs, community pharmacists, case managers, DNs, patients/representatives, practice managers, hospital Care of the Elderly doctors, practice and hospital pharmacists and commissioners) together with patients and carers will be convened to propose solutions to overcome these problems.

Evidence of alternative methods of service delivery would be sought from the literature and form observation of health care systems in other countries. The evidence from all sources would be used to propose alternative methods of care.

The third phase of the PhD would go ahead if time and resources permitted. This would be an intervention study testing an alternative pathway of care for medicines optimisation post discharge compared to normal practices.

The PhD will take a mixed-methods approach and may utilise medicines reconciliation and medication reviews to identify medicine related problems, root cause analysis, quantitative methods such as Error Producing Conditions Questionnaire, qualitative methods including one-to-one interviews, focus groups and experimental/quasi-experimental methods

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Appendix 2 – Completed reflexivity matrix (Rae and Green 2006)

	In the overall social space	Within the field of specialists	Within everything that is linked to membership of the scholastic universe
Pre-research	**How do the researcher's broader motivations affect the reason to conduct the research, the topic and research question and choice of methodology?** **What is the researcher's conceptualization of health?** My only experience of older age is my grandma (92) who has only been in hospital three times in my entire recollection. This work is certainly challenging my personal views of what it's like to get older. I want to improve services for patients and professionals – improve quality of life, make things easier for HCPs, and	**What is the relationship between the researcher and the field? How is the topic relevant to health care?** Community pharmacist for six years (looking after patients 'cradle to grave'). Hospital pharmacist for 2 years; practicing at the sharp end. I've felt the frustrations of the system and had to deal with problems arising from transitions of care including some very close calls/ near misses. In the past I have been more likely to look at medicines than the patient, especially home delivery patients who I never see in practice. Now my practice is	**Where do the researcher's interests lie within the relevant literature?** Working within the field means I could easily jump to conclusions based on only my own practice or about what we need to 'fix' – need to remain open minded and neutral, discuss holistically e.g. is this a pharmacy issue? Could also easily blame other sectors. I have no desire to paint 'pharmacy' in any particular light. I have focused on problems which may have influenced my interpretation of the literature (Safety I vs Safety II).

	these are preventable issues. Motivation has been massively driven by PPIE work which has demonstrated the scale and impact of the issue. Limited experience with quantitative research, but enjoying speaking with people, recognise the value of seeking patient opinion and experience – drive for qualitative methods.	changing to be more interested in the individual. I am quite risk averse by nature (conscious of litigious society) and believe that patients should always have a choice and should always be informed when medicines are changed. Historically focused on importance of compliance, but am moving towards patients being able to make informed adherence choices. What is my role here? Practitioner (problem solver) vs. researcher. Feel responsible for the patient's situation – as a pharmacist (feel let down by actions of others) and working within the Trust (knowing how systems should operate).	Have I given more weight to patient-centred outcomes?
Data collection	**What are the shared and divergent understandings between researcher**	**Do the researcher and participants share the same language? Are there any power differentials?**	**Are questions inadvertently shaped by popular scholarly opinion?**

	and participants? Are there any differences? Age difference, gender (more women in study; do I feel more comfortable approaching women?), not local to area. Culture – predominantly white British – have I been less willing to approach others after the first few failed attempts? Perceptions of housing situations – does it feel safe? Smells e.g. cigarettes? Cleanliness, clutter (described as memories by one participant), financial situation – considering why they have ended up like this e.g. downsizing. Get to see the impacts of 'our' actions (or lack of actions) on real patients. How do I actually 'see' them? – Chair bound, living in one room, all their	I see some of the patients as vulnerable and fragile – based on mobility, housing situation and support networks. Try to show that I am interested in them and their experiences; they can in effect tell me what they like. Actively downplay that I am a pharmacist and know how systems work – want them to explain to me their interpretation. Interviews in own homes, they are inviting me into their space, some houses full of equipment and boxes that the nurses used (untouched by patient) – who 'owns' the space? The power is with the patient (whether they know it or not), I don't want them to withdraw: does this affect how much I prompt and probe and maybe also what I ask?	Interview questions are underpinned by TDF by basing them on questions from Michie et al. (2014).

	clutter around them, sometimes appear lonely. How do I deal with the messiness of people's lives? – I am orderly and organised. Personally very challenging to be faced with chaos. Frustrations over slow rate of recruitment – why don't people want to take part, is it me/ the project/ their reservations about research? Consider it a learning journey - willing to make changes to practice e.g. improves communication to carers.		
Data analysis		**How does the researcher's experience shape the analysis? Are some data dismissed?** Limited experience of qualitative analysis – attended some training. I have a personal preference for systematic and	**How does the researcher moderate any drive for outcomes that might inadvertently lead to data omissions or fabrications?** PhD is time pressured, also NIHR milestones and targets. My personal drive is a bit of a rollercoaster (e.g.

		structured methods e.g. Framework matrices. The framework matrices are auditable and I am staying true to participant's words. All data managed comprehensively. PPIE involved with data analysis, interpretation of some findings – trying to balance analytical power. Co-created conversation.	why code rest of the interviews when they have the same themes arising). Currently overwhelming sense that problem is too big to fix and is more to do with loneliness/ lack of support networks, than medicines.

Appendix 3 – Phase 1 items

Sample search strategy (MEDLINE), reproduced from Tomlinson et al. (2020a) under the Creative Commons CC BY NC licence ©Oxford University Press

#	Search term
S1	(MH "Frail Elderly") OR (MH "Aged") OR "elderly or aged or older or elder or geriatric" OR (MH "Geriatrics")
S2	(MH "Patient Discharge") OR "hospital discharge"
S3	(MH "Patient Transfer") OR "transfer of care"
S4	(MH "Transitional Care")
S5	(MH "Continuity of Patient Care") OR "continuity of care"
S6	(MH "Patient Handoff")
S7	"hand off"
S8	"patient hand-off"
S9	"handover"
S10	(MH "Hospitalization")
S11	"post discharge"
S12	(MH "Aftercare") OR "follow up"
S13	S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12
S14	"medic*"
S15	(MH "Prescription Drugs") OR (MH "Prescriptions") OR "prescription"
S16	"treatment or intervention or therapy"

S17	(MH "Community Pharmacy Services") OR (MH "Pharmacy Service, Hospital") OR (MH "Pharmaceutical Services") OR (MH "Pharmaceutical Services, Online")
S18	S14 OR S15 OR S16 OR S17
S19	(MH "Medication Therapy Management") OR "medication management"
S20	(MH "Safety Management") OR (MH "Information Management") OR "medicines management"
S21	"continuity of medicine"
S22	"continuity of medication"
S23	"continuity of medicine management"
S24	(MH "Delivery of Health Care, Integrated") OR "integrated care" OR (MH "Systems Integration")
S25	(MH "Progressive Patient Care") OR (MH "Patient-Centered Care")
S26	(MH "Medication Systems")
S27	(MH "Patient Safety")
S28	"Medic* safety"
S29	S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28
S30	"Medic* history"
S31	(MH "Medical History Taking")
S32	(MH "Medication Reconciliation") OR (MH "Medication Adherence") OR (MH "Self Medication") OR "*medic reconciliation"
S33	(MH "Self Administration")
S34	"medic* administration"

S35	(MH "Medication Errors") OR "medicine errors"
S36	(MH "Patient Participation") OR "patient activation"
S37	(MH "Patient Education as Topic")
S38	(MH "Communication")
S39	(MH "Patient Care Planning") OR (MH "Managed Care Programs")
S40	(MH "Patient Discharge Summaries")
S41	(MH "Patient Care Management")
S42	S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41
S43	S1 AND S13 AND S18 AND S29 AND S42

Appendix 4 – Phase 2 data collection tools

Patient information sheet

Participant Information Booklet

Research Study Title: Improving medicines-related care for older people after hospital discharge.

My name is Justine Tomlinson. I am a pharmacist and research student at the University of Bradford.

I invite you to take part in my research study about the medicines older people take after they leave hospital. I designed this study along with four patients and carers.

Before you decide if you want to take part, please take time to read this leaflet carefully. It explains why I am doing this research and what I am asking you to do. Talk to others about it, if that would help you decide.

Please contact me if there is anything that is not clear or if you would like any more information.

Mrs Justine Tomlinson
j.e.c.tomlinson@bradford.ac.uk
01274 232381
07519003797

Part 1 of this booklet tells you the purpose of this study and what will happen if you take part.
Part 2 gives you more detailed information about the conduct of the study.

Protocol Reference: 240564 Version: 0.4
Ethical Approval: Granted by Yorkshire & The Humber - Bradford Leeds Research Ethics Committee on 3rd July 2018

Part 1

1. What is the purpose of this study?

Changes are often made to older people's medicines when they have a stay in hospital. For example, medicines might be started, stopped or doses may be changed. Changes can leave people feeling confused, anxious or unsure about what medicines to take when they return home.
This study will look in to the medicines-related care given to older people after a hospital stay. I would like people living with diabetes to take part. Your opinions and experience will be used to help improve care for others.

2. Why have I been invited?

You have been invited because you are in hospital and changes have been made to your usual medicines. You are aged over 75 and live with type 2 diabetes.
36 people will take part in this study.

I will also ask you if you have a relative or friend who helps you with your medicines at home. If you do, I would like to extend this invitation to your relative or friend with your permission. Your relative or friend will be able to take part in this study alongside you if they want to.

3. Do I have to take part?

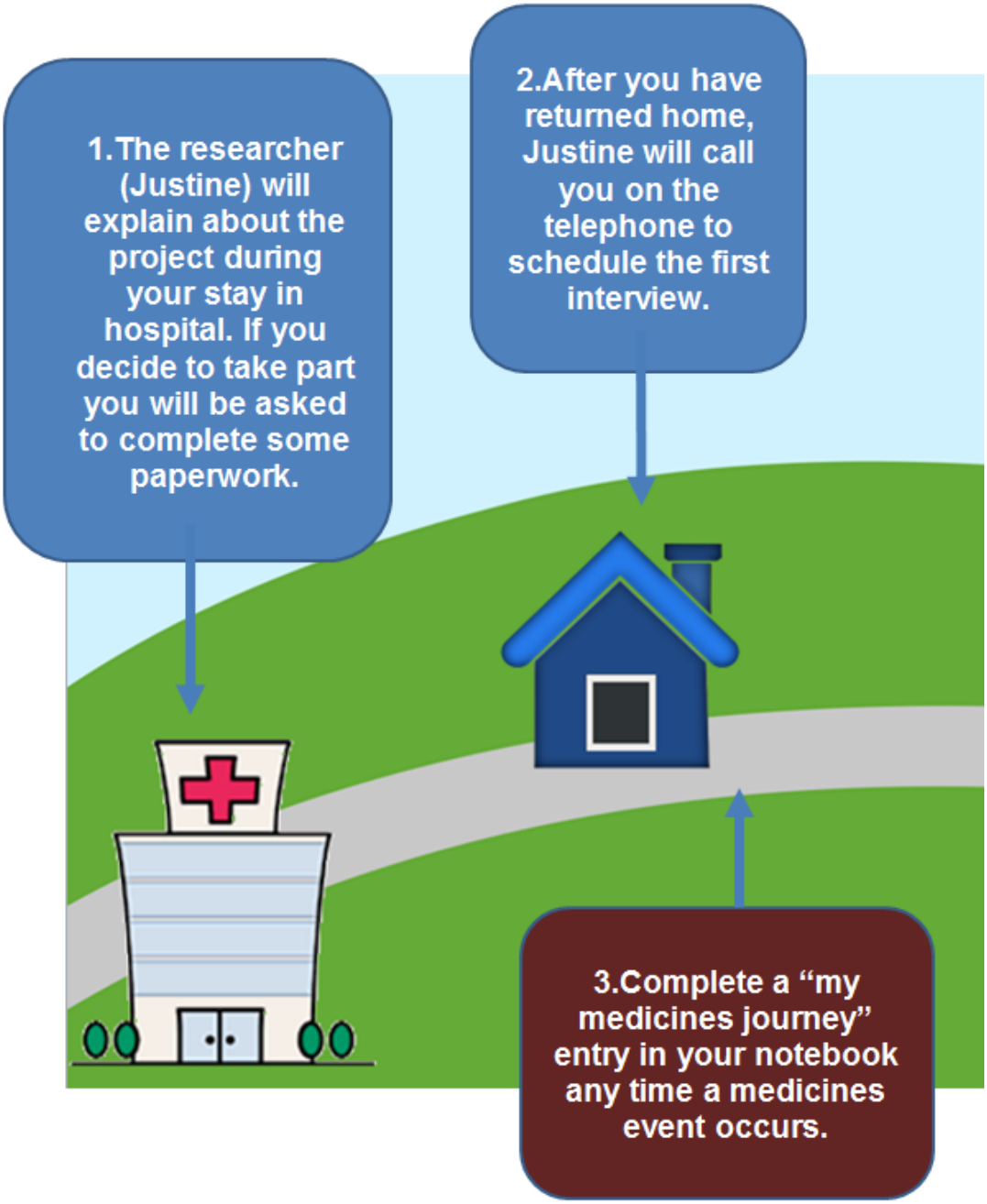
No. Taking part is your free choice. You do not have to do so; however your help is extremely valuable to us. If you decide to take part, but then change your mind, then that isn't a problem. You don't have to give me a reason. This will not affect the standard of care that you receive or any future treatment.

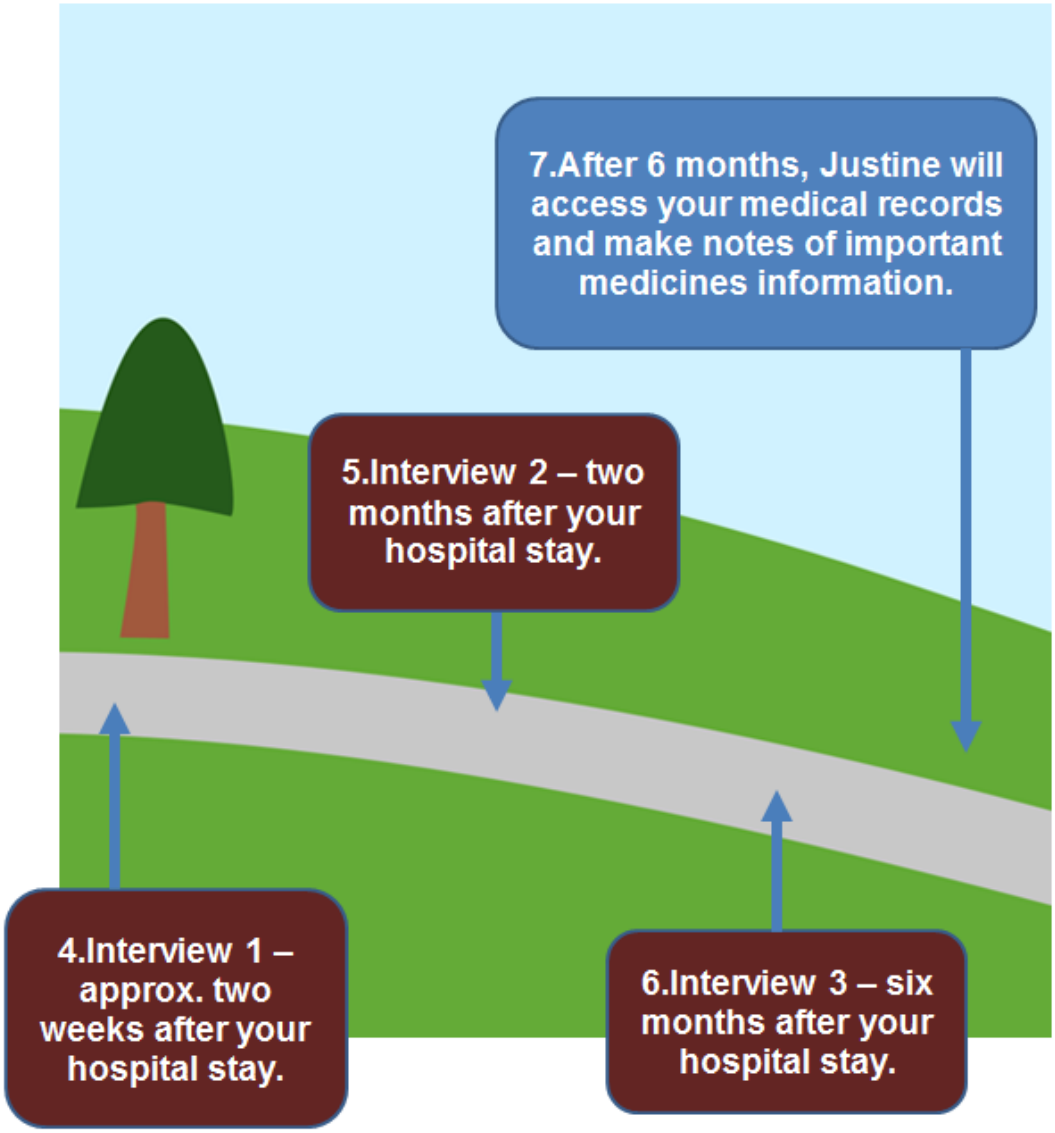
4. What will I have to do?

If you agree to help me, I will ask you to have 3 interviews with me and write in a notebook. This picture on the next page shows the different things that will happen.

I will visit you to fully explain the study before you make your decision. You will have the opportunity to ask me any questions you like.

I will ask you to sign and date a consent form and will note down your contact details. You will be able to keep a copy of these and I will store copies securely at the University of Bradford.

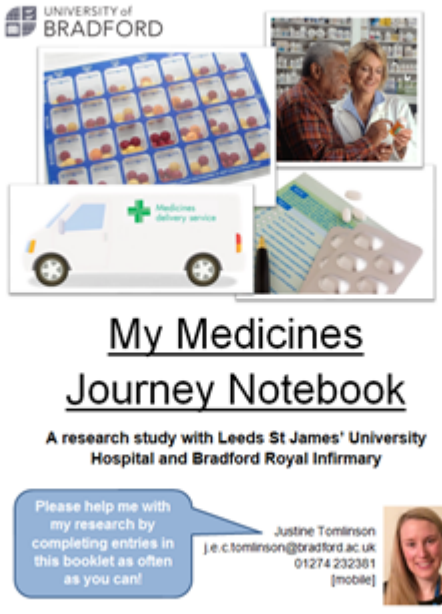

1.The researcher (Justine) will explain about the project during your stay in hospital. If you decide to take part you will be asked to complete some paperwork.
2.After you have returned home, Justine will call you on the telephone to schedule the first interview.
3.Complete a "my medicines journey" entry in your notebook any time a medicines event occurs.


7.After 6 months, Justine will access your medical records and make notes of important medicines information.
5.Interview 2 – two months after your hospital stay.
4.Interview 1 – approx. two weeks after your hospital stay.
6.Interview 3 – six months after your hospital stay.

Notebook: I will give you a 'my medicines journey' notebook. You will make brief notes in this about anything significant that happens with your medicines whilst taking part in this study. Your carer, relatives or friends could also make notes in this notebook.

You can write about:

- Problems you have with your medicines, such as issues getting your repeat supply
- Changes that are made to your medicines and how you feel about them
- Anything you find that helps you with your medicines
- Discussions with healthcare professionals, care workers, family and friends about your medicines.



Interviews: When you go home I will telephone you to arrange a suitable time for our first interview. This can take place at a location of your choice, with your friend/ relative.

I will ask questions about your medicines and any problems you have had. I will look at your 'my medicines journey' notebook and ask you about any notes you have made.

The interview will take about 40 minutes and we can stop at any time for a break.

I will audio record all interviews. This helps me to remember all of our discussion.

If you allow it, I will also video record the interview. Video clips from everyone's interviews will be edited into a short film.

This film will be shown to NHS staff and other patients to encourage them to think about different ways of working. The video can be recorded from behind you, if you wish for your face to be hidden. If you prefer not to be video recorded then that is fine.

I will arrange for us to have another two interviews; six weeks and six months later.

After our three interviews, with your written permission, I will access your medical record at your GP practice and community pharmacy. I will note information about when you have contacted the GP, how many times you have been to hospital and any information about your medicines that has been recorded in the last six months.

5. What are the possible disadvantages and risks of taking part?

There is no risk of harm to you through taking part in this study.

During interviews, you may be asked questions which upset you. If you do become uncomfortable you can stop the interview at any time. There will be no effect on the care you receive from healthcare professionals either in hospital or at home.

6. What are the benefits of taking part?

You will be providing valuable real life experiences of medicines-related care. This information will be used to improve future patient's medicines care following a hospital stay. This could include improving quality of life for patients and reducing unnecessary hospital stays. As a thank you for taking part in this study I will send you £50 in Love to Shop vouchers. I will send one £25 voucher after 3 months and one after 6 months.

7. **What happens when the research study stops?**

I will keep you up to date with the study results. Any information that I collect from or about you will be stored securely at the University of Bradford for five years before it is destroyed.

If the short film helps other people, I may ask your permission to show this to other patients or healthcare providers. The film may also be used for training purposes. This will not happen unless you opt in.

8. **Who can I contact for further information on the study?**

If you have any questions about the study please ask a member of the ward staff to contact Justine Tomlinson (researcher) on 01274 232381 or 07519 003797.

9. **Will my taking part in the study be kept confidential?**

Yes. Strict ethical and legal procedures will be followed and all information about you will be held confidentially. These details are included in Part 2.

This concludes Part 1 of the information booklet. If Part 1 has interested you and you are considering participating in the study, please continue to read the additional details in Part 2.

Part 2

10. What happens to the information gathered during the study?

Your participation will be completely confidential and known only to me and my supervisor (Dr Jon Silcock). We will keep all your personal information safely.

All data will be held in accordance with the Data Protection Act and the General Data Protection Regulation, which means that it is kept safely and cannot be revealed to other people, without your permission.

Audio recordings will be copied onto paper and any personal information (e.g. your name) removed so you cannot be identified. Once this copy has been completed by a specialist company (Language Insight) and checked by me for accuracy, the recording will be deleted.

If you have allowed me to video record our conversations, these will be made into a short film by a specialist editing company based at the University of Bradford.

Any information collected from your medical records or 'my medicines journey' notebook will also have your personal details removed so that you cannot be identified.

Paper notes will be stored in a locked filing cabinet at the University of Bradford. Electronic data will be stored securely on password-protected University of Bradford computers.

All information will be destroyed five years after the end of the study, unless you give separate permission for the edited film to be reused after the study has ended.

11. Involvement of your GP and community pharmacy

Your GP and community pharmacy will be informed about your taking part in this study. I will send them a copy of your signed consent form that gives me permission to access your medical records.

12. What will happen to the results of the study?

I will compare the information gathered to identify where and why common medicines-related problems occur. I will also explore how you cope with these problems and what things you do to help with medicines.

I will use these results to work with patients, carers and NHS staff to develop different ways of better supporting patients with their medicines after a hospital stay.

I will write a paper in an academic journal so that others can learn from our findings. You will not be identified in any report, publication or presentation. I would like to share some interview quotes and notes from your 'my medicines journey' notebook, however these will be anonymised.

The short film will be shown at local events in Bradford and Leeds. If you have given permission to be involved in the film your name will not be included. I will show you the final edit of the film so that you can confirm you are happy for me to use it.

We will send you newsletters to keep you informed of the results.

13. What will happen if I don't want to carry on with the study?

You can withdraw from taking part in the study at any time, without giving a reason. This will not affect your future treatment or the standard of care that you receive. If you withdraw within the first 6 months, then all your data will be deleted.

14. What if there is a problem?

I am a qualified, registered pharmacist regulated by the General Pharmaceutical Council. If I identify any risk of harm in your current care, I have a duty of care to discuss this with you and your healthcare provider. I will always explain this to you first.

If you are unhappy with any aspect of the study, please contact me first. Alternatively if you wish to complain formally you may contact the study supervisor, Dr Jon Silcock, on 01274 234698.

15. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. They ensure that your safety, rights, well-being and dignity are protected.

This study has been reviewed and given permission to go ahead by the Yorkshire & The Humber - Bradford Leeds Research Ethics Committee.

16. Further information and contact details.

Who to contact for information about this study:
Mrs Justine Tomlinson
Doctoral Training Fellow
j.e.c.tomlinson@bradford.ac.uk
01274 232381 or 07519 003797

Who to contact if you are unhappy with the study:
Dr Jon Silcock
j.silcock@bradford.ac.uk
01274 234698

If you want to complain at any point during the study to an independent body, you can contact your local Patient Advice and Liaison service (PALS):
0113 2066261

Or the Information Commissioner's Office:
0303 123 1113

Interview topic guide

Topic Guide – Interview 1: 2 weeks post-discharge

Participant identifier: Date:

Introduction:

My research is interested in what happens to patient's medicines when they move from hospital to home. I am really keen to hear how you have been getting on with your medicines since your stay in hospital.

I'd like to ask you some questions about your experiences with your medicines. This will take approximately 40 minutes. If you would like a break or want to stop for any reason at all, then please do let me know.

[Check audio and video recorder]

Story-telling narrative:

Q Would you like to start by telling me a little bit about your hospital stay and how you got on with your medicines on returning home?

Prompt: What happened next?
Prompt: What did you think/ feel about that?
Prompt: How has this affected you?

Q Can you please tell me a bit about the different medicines you take?

Prompt: Were there any changes made whilst you were in hospital?
Prompt: Were these changes explained to you?

Q What was explained to you about what would happen with your medicines when you returned home?

Prompt: What were you told about your further medicines supply for when you returned home?
Prompt: How did you find out?

Prompt: If you hadn’t have been told any information, what would you have done?

Q Is there anything else you would have liked to have been told about your medicines when leaving the hospital?

Prompt: What did you find helpful?

Q Have you experienced any problems with your medicines since returning home?

Prompt: How you manage the ordering of your medicines?
Prompt: And how do you get on taking them?
Prompt: Who helps you with your medicines?

Diary:

Q Can you tell me more about this entry in your notebook?

Prompt: What happened then?
Prompt: What did you think/ feel about that?
Prompt: Who did you talk to about it?
Prompt: What options did you have? Why did you decide to do that?
Prompt: If the issue hadn’t of been resolved, what would you have done?

Duration of interview:

Audio number:

Video number:

Topic Guide – Interview 2: 2 months post-discharge

Participant identifier: Date:

Introduction:

I am really keen to hear how you have been getting on with your medicines since the last time we spoke.

I'd like to ask you some questions about your experiences with your medicines. This will take approximately 40 minutes. If you would like a break or want to stop for any reason at all, then please do let me know.

[Check audio and video recorder]

Story-telling narrative:

Q How have you been getting on with your medicines?

Prompt: What happened next?
Prompt: What did you think/ feel about that?
Prompt: How has this affected you?

Q Have you experienced any problems with your medicines since our last chat?

Q Have you spoken to anyone about your medicine changes since you have been in hospital for example your GP or pharmacist?

Prompt: Do you intend to?
Prompt: Why?

Q How do you make sure you continue to get the right medicines since the changes have been made?

Prompt: How easy or difficult is it to manage your medicines after you have been in hospital?
Prompt: Do you think there are there any special skills required to do this?

Q How do you feel about your medicines since returning home after your stay in hospital?

Prompt: Are you worried about anything?

Prompt: How do these emotions affect your ability to look after your medicines?

Q How confident are you that you will not experience any problems with obtaining the correct medicines from the GP/ community pharmacy?

Prompt: Why?

Diary:

Q Can you tell me more about this entry in your notebook?

Prompt: What happened then?

Prompt: What did you think/ feel about that?

Prompt: Who did you talk to about it?

Prompt: What options did you have? Why did you decide to do that?

Prompt: If the issue hadn't of been resolved, what would you have done?

Duration of interview:

Audio number:

Video number:

Topic Guide – Interview 3: 6 months post-discharge

Participant identifier: Date:

Introduction:

I am really keen to hear how you have been getting on with your medicines since the last time we spoke.

I'd like to ask you some questions about your experiences with your medicines. This will take approximately 40 minutes. If you would like a break or want to stop for any reason at all, then please do let me know.

[Check audio and video recorder]

Story-telling narrative:

Q How have you been getting on with your medicines?

Prompt: Have any further changes been made?
Prompt: What happened next?
Prompt: What did you think/ feel about that?
Prompt: How has this affected you?

Q Have you experienced any problems with your medicines since our last chat?

Q Have you spoken to anyone about your medicine changes since you have been in hospital for example your GP or pharmacist?

Q Now that you have left hospital, what are your priorities for keeping well?

Prompt: How important is it to you that you look after your medicines?
Prompt: How important do you feel it is to take your medicines as prescribed?
Prompt: What do you believe are the benefits of managing/ taking your medicines?
Prompt: Can you think of any downsides?

Q In what way is your ability to manage your medicines affected by your home or local environment? E.G. being housebound?

Q How do you make sure that your medicines are looked after?

Prompt: Is there anything that you do routinely that helps you to manage your medicines?

Prompt: What prevents you from doing this?

Prompt: Are there any strategies that could help you to overcome this?

Prompt: Is there any reward or incentive that would encourage you to manage and take your medicines?

Diary:

Q Can you tell me more about this entry in your notebook?

Prompt: What happened then?

Prompt: What did you think/ feel about that?

Prompt: Who did you talk to about it?

Prompt: What options did you have? Why did you decide to do that?

Prompt: If the issue hadn't of been resolved, what would you have done?

Duration of interview:

Audio number:

Video number:

My Medicines Journey notebook

My Medicines Journey Notebook

A research study with Leeds St James' University Hospital and Bradford Royal Infirmary

Please help me with my research by completing entries in this booklet as often as you can!

Justine Tomlinson
j.e.c.tomlinson@bradford.ac.uk
01274 232381
07519 003797

The purpose of this 'My Medicines Journey' booklet is to allow me a way to see and understand the challenges patients and their friends and family face with medicines following a hospital stay.

Instructions

I would like you to tell me about your medicines – in particular any problems you have with ordering, obtaining or taking them, especially after changes are made in hospital.

Try to write something every week. I will ask to see this when I come to have a chat with you.

Who can fill it out?

It can be you or family member or a friend who fills out the entry on your behalf. Please make sure the person filling out the entry makes it clear who they are at the top of their entry.

What information should I include?

You can write about:

- Problems you have with your medicines e.g. if you are struggling to obtain them
- Changes that are made to your medicines and how you feel about that
- Things that help you to receive and take your medicines
- Discussions with healthcare professionals, care workers, family and friends about your medicines
- Anything that you feel is important for us to know.

Top Tips for using this 'My Medicines Journey' booklet

- Keep this booklet handy so you can easily make an entry – perhaps you could keep it with your medicines to help you remember to fill it out, or put a reminder in your diary.

- Make your entries as soon as possible after any medicines-related event you want to tell us about. This will help you record facts, thoughts and feelings accurately.

- Never think that details about your medicines are insignificant – I want to know as much as you can tell me; **no matter how trivial you think it is.**

- The next two pages contain helpful examples of things you can write about and how to fill out an entry.

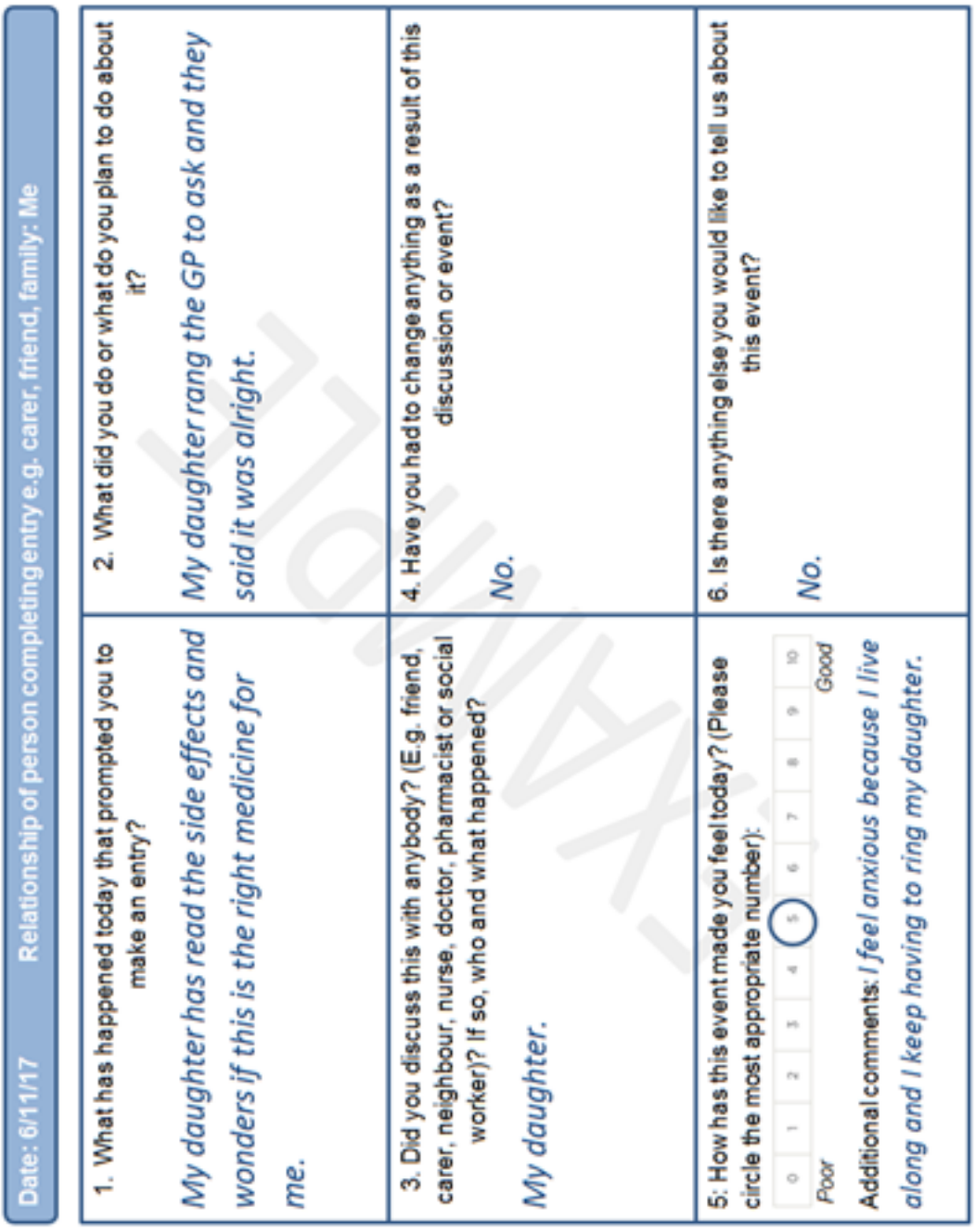
- If you run out of space and want to keep writing, please continue on a blank sheet, provided at the back of the booklet – just make sure to add the date to the top of the page to help me.

- If you are struggling to make entries into this booklet or would like to speak to someone about it, then please telephone me (Justine) on 01274 232381 or 07519 003797 to discuss this. I will call you back if you like.

Thank you for participating in this research project. By taking part, you are making a real difference to the future medicines-related care that patients like yourself will receive.

Helpful examples for completing entries in your 'My Medicines Journey' booklet

Example 1:



Date: 6/11/17 **Relationship of person completing entry e.g. carer, friend, family: Me**

1. What has happened today that prompted you to make an entry?

My daughter has read the side effects and wonders if this is the right medicine for me.

2. What did you do or what do you plan to do about it?

My daughter rang the GP to ask and they said it was alright.

3. Did you discuss this with anybody? (E.g. friend, carer, neighbour, nurse, doctor, pharmacist or social worker)? If so, who and what happened?

My daughter.

4. Have you had to change anything as a result of this discussion or event?

No.

5: How has this event made you feel today? (Please circle the most appropriate number):

0 1 2 3 4 5 6 7 8 9 10

Poor *Good*

Additional comments: *I feel anxious because I live along and I keep having to ring my daughter.*

6. Is there anything else you would like to tell us about this event?

No.

Helpful examples for completing entries in your 'My Medicines Journey' booklet

Example 2:

Date: 10/10/17 **Relationship of person completing entry e.g. carer, friend, family: patient**

1. What has happened today that prompted you to make an entry? *I felt a bit dizzy after the medicine and wondered if this should happen.*	2. What did you do or what do you plan to do about it? *I was wondering if I had the right dose. The tablets are a different colour to what the hospital gave me.*
3. Did you discuss this with anybody? (E.g. friend, carer, neighbour, nurse, doctor, pharmacist or social worker)? If so, who and what happened? *I rang the pharmacist and had a word. She told me that it was OK. She has checked it for me. Do I have to take all of these tablets?*	4. Have you had to change anything as a result of this discussion or event? *No, but I needed to check that it is the right dose. I don't understand why it is a different colour.*
5: How has this event made you feel today? (Please circle the most appropriate number): 0 1 2 3 4 5 6 **7** 8 9 10 *Poor* *Good* Additional comments: *I get confused which colour I should take and when.*	6. Is there anything else you would like to tell us about this event? *I still don't know whether I will need to take these tablets for the rest of my life.*

Date:	Relationship of person completing entry e.g. carer, friend, family:

1. What has happened today that prompted you to make an entry?	2. What did you do or what do you plan to do about it?
3. Did you discuss this with anybody? (E.g. friend, carer, neighbour, nurse, doctor, pharmacist or social worker)? If so, who and what happened?	4. Have you had to change anything as a result of this discussion or event?
5. How has this event made you feel today? (Please circle the most appropriate number): 0 1 2 3 4 5 6 7 8 9 10 *Poor* *Good* Additional comments:	6. Is there anything else you would like to tell us about this event?

Participant consent form

UNIVERSITY of BRADFORD
School of Pharmacy & Medical Sciences

Improving medicines-related care for older people after hospital discharge

Do you consent to take part in the study?

Please read each of the following points and ask if there is anything you don't understand or you are unsure about. Please write your initials in each box if you agree.

1. I confirm that I have had the opportunity to ask questions about the study and, if I asked, my questions were answered fully. ☐
2. I have read and understand the information sheet [version 0.7 dated 2nd July 2018]. ☐
3. I understand that my participation is voluntary and I am free to withdraw at any time during the next 6 months, without giving any reason, and without my medical care being affected. ☐
(Please initial one box):

If I withdraw from the study, I give permission for the use of information already collected about me as outlined in the participant information booklet.	
If I withdraw from the study, all information already collected about me must be destroyed and not used by the researcher.	

4. I understand that my interviews will be **audio** recorded and securely transferred to Language Insight for transcription. Excerpts may be made into a film about patients' experiences with their medicines by the University of Bradford. ☐
5. I give permission for my interviews to be **video** recorded. I understand that video clips may also be used in the above film and that I will have an opportunity to watch the final film before the researcher will seek my permission for it to be used. ☐
6. I understand that the research team will inform my GP and my community pharmacy that I am taking part. ☐
7. I give permission for records held by my hospital, my GP and my community pharmacy to be shared with the researcher and used to obtain information about my health conditions, the pharmacy services that I use and prescribed medicines. ☐

8. I understand that all information collected about me will be kept confidentially and securely. ☐

9. I agree to allow any information or results arising from this study to be used for healthcare and/or further medical research upon the understanding that my identity will remain anonymous. ☐

10. I give permission for the researcher to remind me of our interview appointments. ☐

I prefer to be reminded via: (Please initial one box)

Telephone	
Post	
SMS text message	

11. I understand that during the course of this study I may become temporarily unable to consent for myself. In order to assist with this, I wish it to be noted that should I become unable to consent for myself I would prefer: (Please initial one box)

To remain in the study, with research activity such as interviews suspended, until I can consent for myself again.	
Not to continue in the study but allow the continued use of all information already collected as outlined in the participant information booklet.	
Not to continue in the study and for all my information already collected be destroyed.	

12. I agree to take part in this study ☐

Your name (print).....

Your signature ..... **Date**.....

Researcher's signature ..... **Date**.....

Office use: Patient ID number for study: _____
One copy to researcher and one copy to the patient

About you

Name: _____

Date of Birth: _____

NHS number: _____

Gender: ☐ Male ☐ Female

Your contact details:

Home address:

_____

_____

Postcode: _____

Contact email address (if you have one): _____

Home phone number: _____

Mobile number (if you have one): _____

GP name: _____

GP surgery: _____

Which community pharmacy do you usually use for you prescriptions?

_____

Thank you!

Protocol for assessing capacity

UNIVERSITY of BRADFORD
School of Pharmacy & Medical Sciences

Protocol for Assessing General Understanding and Capacity

- This should be done prior to signing the consent form.
- The person must be able to hear the statements and questions.
- Check that the person has read the information booklet.
- Identify that they can ask questions at any time.
- Tick the correct box to record the participant's answer.

Participant name: _____

"I know that you have read the information leaflet, but one of the things we need to check is that people understand the study and what it will involve for them if they choose to take part. So if I can read you a small section of the information leaflet and then check your understanding of it. Is that all right?"

Q1 "I am asking you to take part in a research study on investigate older people's experiences of their medicines after a hospital stay. If you take part, I would conduct 3 interviews with you over 6 months. I would also like you or anyone who helps you with your medicines to try to fill out entries in this notebook [show notebook]."

"Are you happy to do this?"

Yes……go to Q2 ☐

No……."Is there anything I can explain that might make you willing to take part, or any questions I can answer?" If refusal is adamant: end interview. ☐
If explanations can be given (without compulsion) and the person agrees to take part, proceed to Q2.

Q2 "So, in a few words, can you tell me what the study is about?"

If answer implies or includes: Investigate older people's experiences of their medicines after a hospital stay, go to Q3.

If answer is muddled or confused on first 'pass', return to Q1.
If answer is muddled or confused on second 'pass', return to Q1.
If answer is muddled or confused on third 'pass' then it is unlikely that this person meets the inclusion criteria for the study. Ensure that details are documented below. ☐

Q3 "From what I said earlier, can you tell me what would happen to you if you agreed to take part in this study?"

If answer implies or includes: Three interviews and notebook then proceed to completing the consent form using the checklist for research staff. ☐

If answer is incorrect go to Q4.

Q4 "Just to remind you, I said I would conduct 3 interviews with you over 6 months. I would also like you or anyone who helps you with your medicines to try to fill out entries in this notebook [show notebook]. Are you still happy to take part in the study?"

Yes……go to Q5. ☐

No……."Is there anything I can explain that might make you willing to take part, or any questions I can answer?" If refusal is adamant: end interview. ☐
If explanations can be given (without compulsion) and the person agrees to take part, proceed to Q5.

Q5 "So, can you tell me what would happen to you if you agreed to take part in this study?"

If answer implies or includes: Three interviews and notebook then proceed to completing the consent form using the checklist for research staff. ☐

If answer is muddled or confused on first 'pass', return to Q4.
If answer is muddled or confused on second 'pass', return to Q4.
If answer is muddled or confused on third 'pass' then it is unlikely that this person meets the inclusion criteria for the study. Ensure that details are documented below. ☐

Comments:

_____
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Research staff member name: Role:

Signature: Date:

Appendix 5 - Design process of ‘My medicines journey’ notebook with PCLSG

The co-design of the participant diary is documented here as an in-depth example of how PPIE were meaningfully involved in this project.

Background

Research studies that use diaries report varying uptake and success of the method. One study required participants to keep a daily diary documenting healthcare concerns and problems following hospital discharge (Waring et al. 2014). Only two participants maintained this for the eight week study duration. Informal discussions with the MAXimising Involvement in MUltiMorbidity in Primary Care (MAXIMUM) project team illustrated that when their participants were given a choice of format (paper based, voice recorded or telephone), uptake was still very low (Daker-White et al. 2014).

Aim

To develop a diary for the documentation of medicines-related problems, by careful planning, iterative design and piloting by the PCLSG.

Methods

Step one: Before attempting any prototypes, the PCLSG were asked to generate fundamental design points from their perspectives of a patient or carer being asked to complete diary research. This exercise aimed to identify the barriers and facilitators to using this method. Key considerations identified by Bytheway (2012) (see box below) were used to facilitate their discussion.

Step two: The PCLSG were given different examples of diaries that had been utilised in other research projects:

- Chronic health management (Jacelon and Imperio 2005) – participants were asked to keep a journal for 15 minutes each day with a focus on

their daily activities. Three topic examples with reflective questions are given to guide the entries: health, dignity and independence.

- The MAXIMUM study (Daker-White et al. 2014) – participants were asked to complete four written healthcare diary entries over three months with each entry on one A4 page consisting of four open questions to guide reflection.
- Self-care (Freer 1980) – health diary sheet comprised of 11 structured questions and sliding scales which participants completed every evening for four weeks.
- Study of medication (Johnson and Bytheway 2001) – highly structured diary where participants must tick the relevant times of the 24 hour-chart to indicate when they had taken their medication, they felt symptoms, they ate and so on over the course of 14 days.

Two key considerations in diary design (Bytheway 2012):

1. What information is the participant required to record?
2. What will the diary page look like?

Other points to consider include:

- Difficulties in completion – can the participant read/ write/ feel that they have something worthwhile to contribute?
- Quality of the data – how accurate is the record that they keep in the diary?
- Influences on behaviour – will the keeping of the diary influence the participant to do anything differently that they would normally if they hadn't been keeping the diary?
- Ethical considerations – will it cause any distress/ anxiety/ inconvenience?

The PCLSG were tasked to reflect on the design and format of these example diaries whilst noting any positive or negative thoughts they had.

Step three: A prototype diary was created based on the outcomes of step one and two. The PCLSG offered in-depth feedback before redesign and further

development. This iterative process continued until final consensus was received.

Step four: Once finalised, a PCLSG member asked their luncheon group peers (average age 83 years) to review the design, layout and language used to ensure that it was appropriate. The other PCLSG members were asked to pilot the diary page and to offer a completed example.

Results

Step one: Numerous considerations were highlighted from the initial exercise (see table below). Two individuals had been involved in diary research and their past experiences generated lots of discussion within the group.

Topic	**Considerations voiced by the PCLSG**
Content	• Give the participant examples of things to put in the diary and when to fill it in – e.g. changes to medicines such as dose increase or decrease, are medicines in suitable and accessible containers, changes in day to day routine that affects the medicines (for example day out or holiday), emotions since leaving hospital, incidents (highs and lows), non-delivery of medicines, changes of circumstance (for example if the formal carers change). • Event based rather than every day. • Ask participants to record unanticipated events and any changes that they have had since discharge e.g. side effects. • Note any new illnesses that may cause the GP to alter medicines or to start a new one. • Diet – are they keeping to any special instructions related to their medicines/ T2DM? Are medicines clashing with diet? • Record contact details of the GP and community pharmacy within the diary.

Recruitment	• Offer participants a choice of diary and ask them during recruitment what would be easiest for them to complete – e.g. different variations such as one that uses stickers and tick boxes or another that has free text boxes or one with a combination. • Provide a financial incentive for filling in the diary e.g. £20 gift voucher. • Need to consider mental capacity, language barriers. • Make sure to highlight the beneficial effects of filling in the diary – e.g. the diary will not only help them but will help other patients in the future and ensure fewer mistakes happen.
Format	• Needs to be in an easy to complete format. • Appeal to participants' willingness to participate (e.g. by using stickers). • Font size, minimum 12 or 14. • Hard back? A5 size? • Different colours of paper available for those with any difficulty reading black on white. • Keep it simple – do not make it complicated. • The front cover could include: • Pictures or cartoons of medicines, tablets, prescriptions, a pharmacist. • Research project name and researcher contact details. • A title (debate of the use of the words diary, journal, pathway, record…) such as MY MEDICINE JOURNEY. ➢ Need to maintain privacy/ confidentiality – keep front cover details to minimum.
Page design	• Simple wording and plain English. • Tick boxes or smiley face system (or emoji's).

	• Option to give an idea of how they're feeling e.g. on a sliding scale plus opportunity for own comments. • Boxes on a page with different questions, not just a blank page. • Using pictures, comics, rating scales 1-10. • Scales that use 'strongly agree' to 'strongly disagree' can sometimes be confusing.
How to use	• Highlight that both patients and carers can fill in the diary – consider whether the carer would fill in as themselves or the patient. ➢ The person writing will need to add their initials and relationship to the participant. The date recorded and the date of the 'incident' could be included too. • Reminders – telephone call monthly or SMS reminder or postcard – ask the participant which they would prefer to receive. • Ensure that the procedure and method for collection of the diary are explained explicitly by the researcher. • Follow-up check on how the participant is finding the diary. • How important or practical is timing of the day to patients for when diary is filled in? • Do they send them back every month? The diary could include tear out pages and postal envelopes. • Could recommend the participant keeps it with their medicines to remind them to fill it in.
Burden	• Apathy in completing the diary – need to reduce the burden to participants in remembering to fill in.

Step two: The PCLSG members were able to discuss positive and negative comments relating to all diary examples from previous research projects (see table below).

Diary example	**Positive comments**	**Negative comments**
Chronic health management (Jacelon and Imperio 2005) – totally unstructured, daily entry	+ There is the option to tape record the diary if the person is unable to write + Provides list of example topics that the researcher wants to focus on	-Requires high level of literacy - 15 minutes per day could be onerous for older person - Some questions need further clarification e.g. "Why did you feel dignified?"
MAXIMUM (Daker-White et al. 2014) – guided reflection, event driven entry	+ Less structured format allows person to write about what they want to	- Guidance needs to be clearer e.g. how does the person choose which day/ entry to write about? - Some questions are less focused and may cause anxiety or confusion e.g. "how do you feel about it?"
Self-care (Freer 1980) – structured sheet of 11 questions and scales, daily entry	+ Visual analogue questions well received + Each box is a question, good layout, clear	-Some questions do not provide enough information to be able to answer them -The boxes need to be numbered to help flow or if audio recording

Study of medication (Johnson and Bytheway 2001) – highly structured, charting of activity hour by hour, daily entry	+ The researchers offer to collect the diary + Boxes to tick are helpful for people that struggle to write	- Appears very tedious to fill in hour by hour - Instructions ask for the person to complete the diary twice a day which may be too much effort - Examples of things that 'upset your routine' would be useful

Step three: The prototype underwent four rounds of iterative design until the final version was agreed. Feedback from the group on draft versions included:

- Make the front cover 'less busy',
- Change the wording to be more personable, for example changing 'the researcher will…' to 'I will...'
- Simplify the language
- Make the diary sheet questions more specific, such as from 'how has this made you feel?' to 'how has this made you feel today?'

Step four: Piloting the diary provoked changes in the overall size of the document from A5 to A4 with a minimum font of size 14, as peers struggled to read smaller texts (the PCLSG had originally requested A5 size and size 12 font). Feedback also led to the inclusion of a watermark over the example entries to make it very clear that these are for information.

Discussion

The proposed research involves a diary that will be used by participants and their informal carers to document medicines-related events during the six months post-discharge period. The PCLSG were heavily involved in generating ideas for the diary's design and format, which were then synthesised into a prototype. All members offered constructive feedback that was incorporated into subsequent versions and the process repeated. Whilst

most comments were useful, some were off-topic or of less relevance or methodological value. This led to a slight tension caused by differences in the researcher's and PCLSG member's expectations of the diary. Setting out clearer objectives and expectations at the start may have helped reduce this (INVOLVE 2012). Explaining and justifying the research design and being open to compromise are also recommended strategies (Brett et al. 2014).

Reflections

Whilst the design process was greatly lengthened by involving and collaborating with the PCLSG, the overall process was beneficial. The resulting co-designed diary is participant-friendly and easy to use. The PCLSG members felt that their ideas had been listened to and that their input had been valued by the researcher.

Even though the diary was designed by the PCLSG (who are reflective of the participants that will be included in this study), it was valuable to pilot it with different people who had not been involved in its design. Whilst the PCLSG had championed an A5 format with size 12 font, this was later amended to A4 format with size 14 font based on pilot feedback. It has been highlighted in other work that as PPIE members develop expertise in research, they feel further from 'ordinary older people' (Cornes et al. 2008). This is a difficult dilemma, whereby the more PPIE are involved in the research, the less objective and representative of 'lay' audiences they become.

Appendix 6 – Study Approval

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Mrs Justine Tomlinson
Univeristy of Bradford, Faculty of Life Sciences/ School of Pharmacy
Richmond Building, Room M24
Richmond Road, Bradford
BD7 1DP

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

09 July 2018

Dear Mrs Tomlinson

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Optimising post-discharge medicines-related care for older people living with long term conditions**
IRAS project ID:	**240564**
REC reference:	**18/YH/0233**
Sponsor	**Leeds Teaching Hospitals NHS Trust**

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a 'green light' email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

NHS
Health Research Authority
Yorkshire & The Humber - Bradford Leeds Research Ethics Committee
NHSBT Newcastle Blood Donor Centre
Holland Drive
Newcastle upon Tyne
NE2 4NQ

Telephone: 0207 104 8081

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

02 July 2018

Mrs Justine Tomlinson
University of Bradford, Faculty of Life Sciences/ School of Pharmacy
Richmond Building, Room M24
Richmond Road, Bradford
BD7 1DP

Dear Mrs Tomlinson

Study title:	**Optimising post-discharge medicines-related care for older people living with long term conditions**
REC reference:	**18/YH/0233**
IRAS project ID:	**240564**

The Research Ethics Committee reviewed the above application at the meeting held on 19 June 2018. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Appendix 7 – Phase 3 survey

Introductory email

Dear XXX,

I hope this email finds you well. I am contacting you to ask for your help in taking part in a quick survey.

As you may know, my research aims to improve the hospital to home transition for older patients through better medicines management. The current phase of work is looking to identify possible components of an intervention targeting **older patients and their family carers** that would promote post-discharge medicines management behaviours. The behaviours we are seeking to encourage include:

- Medicines concordance and adherence
- Medicines supply management e.g. ordering or maintaining stock within the home
- Checking medicines supplies and actioning error resolution
- Seeking support from healthcare professionals about medicines
- Monitoring effects and side effects of medicines

By completing this survey, you will be helping me to identify which behaviour change techniques should be included as active ingredients within our intervention.

More information about how to complete the survey is given here: INSERT LINK

It should take you **no longer than 30 minutes** to complete. Please make sure you finish the survey by **xxx 2020**.

Please do feel free to forward the survey link to any of your colleagues who you think would be able to complete it.

Many thanks for your time, I really do appreciate your help.

Justine (NIHR Logo and disclaimer)

Survey (introduction, two example questions, closing statement)

Introduction:

Our analysis has identified all possible techniques designed to change behaviour (also known as Behaviour Change Techniques, or BCTs) from within the literature. With your help, we aim to identify which BCTs should be included as active ingredients within our intervention to support post-discharge medicines management.

Please review each of the following 35 BCTs and their definitions. Examples are given to stimulate thinking but are not definitive. Please rate yes or no for the following questions about each BCT, in the context of medicines management behaviours and older patients:

Could it be effective in promoting medicines management in older people?

Could it be an acceptable method to older patients?

Could it lead to any unintended adverse effects for patients (such as unintentional non-adherence, confusion, poor quality of life)?

Please note that this is a preliminary exploration of the types of BCTs that could be included in an intervention. Later, a more thorough investigation will take place addressing further factors, such as, cost-effectiveness, practical issues related to delivering the BCTs and equitability. At this stage, we simply want you to consider whether the following BCTs may be effective and acceptable.

Thank you.

Two example questions:

Technique 1: Information regarding behaviour, outcome

Example: Provide the patient with written or verbal information e.g. about their medicines management responsibilities after hospital discharge or when/ how to get help if a problem is identified

Could this technique be effective in promoting medicines management in older people?

Yes

No

Would it be an acceptable method to older patients?

Yes

No

Could it lead to any unintended adverse effects for patients (such as unintentional non-adherence, confusion, poor quality of life)?

Yes

No

Technique 2: Self-monitoring

Example: Establish a method for the patient to monitor and record medicines management behaviour(s) E.g. recording when supplies are due to be ordered or received, recording adherence, keeping a symptom diary

Could this technique be effective in promoting medicines management in older people?

Yes

No

Would it be an acceptable method to older patients?

Yes

No

Could it lead to any unintended adverse effects for patients (such as unintentional non-adherence, confusion, poor quality of life)?

Yes

No

Closing statement:

My heartfelt thanks for taking the time to complete this survey. If you would like to be informed about the findings of this work, please contact me via email j.e.c.tomlinson@bradford.ac.uk

If you would like to know more about the BCTs described in this survey, or indeed about the methods, please visit https://www.ucl.ac.uk/health-psychology/BCTtaxonomy/index.php

Appendix 8 - Phase 1 data

Full description of included studies, reproduced from Tomlinson et al. (2020a) under the Creative Commons CC BY NC licence ©Oxford University Press

Interventions offered during hospital admission

Study details	Participants and setting	Intervention	Delivered by/ frequency	Control	Duration of whole intervention/ follow-up duration	Outcome measures
Basger et al. (2015)	216 elderly patients (>65 years) admitted to a small 50-bed private hospital for treatment of chronic medical condition or rehabilitation after joint surgery, taking ≥ 5 medicines, Australia Mean age = 81	• Medication counselling • In depth interview to Medicines reconciliation • Medication review to detect drug related problems • Opportunities for self-management discussed • Information transferred to PCP within 3 days of discharge	Specially trained clinical pharmacist/ once at discharge	Usual care involving discharge counselling performed by a nurse	Provided once during admission/ 3 months	No statistically significant increase in medicines related problem detection in either arm between follow-up and discharge ($0.09 \leq p \leq 0.97$). Resolution rate of identified problems within intervention arm was 42.4% (318/750). No change in QoL scores except within vitality domain (I:19.2 vs C:12.5; p=0.04).

Bolas et al. (2004)	162 patients (>55 years) admitted for unplanned causes to the medical admissions unit, taking ≥ 3 long term medicines, Northern Ireland Mean age = 74	• Preparation of full medication history and medicines reconciliation • Education about medication changes • Pharmaceutical discharge letter faxed to PCP and community pharmacy • Personalised medicines record sheet • Discharge counselling • Medicines helpline for patients requiring further information after discharge	Hospital based community liaison pharmacist/ Education provided daily – all other activities once only during admission	Usual care	Helpline active for 3 months, all other activities provided during admission/ 3 months	No statistically significant difference in readmission rates (Figures NR; p>0.05). Intervention arm had fewer errors between discharge prescription and home medication at 14 days (drug name (I:1.5% vs C:7%; p<0.005), dose (I:10% vs C:17%; p<0.07) and frequency of dosing (I:11% vs C:18%; p<0.004).
Graabæk et al. (2019)	400 patients (>65 years) admitted to the medical acute unit, Denmark Mean age = 75	• Structured medication review on admission • Medicines reconciliation • Recommendations for change reported to physician • Medication report created to aid physician preparing discharge	Clinical pharmacist/ review and reconciliation once during admission, counselling once at discharge	Usual care – medication history, reconciliation and review conducted by physician	Provided once during admission/ 6 months	No statistically significant difference in readmission rates at 1 month (I:30 (15%) vs C:36 (18%); p=0.72) or 6 month (Figures NR; p=0.245). No significant difference in mortality at 3 months (I:13 (6.5%) vs C:16 (8%); p=0.601)

		• Patient counselling on medication changes				
Hockly et al. (2018)	33 patients (>18 years), taking ≥ 4 medicines prior to admission, with medicines changes, who used the same pharmacy for their repeat prescriptions, UK Mean age = 66	• Transfer of discharge information to community pharmacy	Hospital staff/ once at discharge	Usual care – standard discharge practice (letter sent to GP only)	Provided once during admission/ 3 weeks	Lower number of discrepancies in the intervention arm (GP data; I:25 (14%) vs C:50 (26%); p=0.00034; RRR 29%; NNT 4) (patient reported data; I:10 (8%) vs C:31 (23%); p=0.000043; RRR 47%; NNT 2).
Lalonde et al. (2008)	83 patients (>18 years) being discharged from geriatric, family medicine or psychiatric wards with ≥ 2 medicines changes whilst inpatient , Canada Mean age = 71	• Medication Discharge Plan created and given to patient at discharge • Transfer of information to PCP and community pharmacist by fax	Hospital pharmacist/ once at discharge	Usual care - routine hospital discharge where the patient or PCP did not receive a medication plan.	Provided once during admission/ 1 week	No significant difference in medication discrepancies (I:13.2% vs C:15.3%; p=0.6).
Legrain et al. (2011)	665 patients (>70 years) admitted to the acute geriatric unit with stays longer than 5 days, France	• Comprehensive chronic medication review including medicines reconciliation	Intervention-dedicated geriatricians/ education provided over 4 sessions – all	Usual care	Provided during admission/ 6 months	Lower readmission rate in intervention arm (I:64 (20.2%) vs C:99 (28.4%), p=0.01) at 3 months and at 6 months (I:103 (32.5%) vs C:133 (38%), p=0.12).

	Mean age = 85	• Education on medications and self-management • Transition of care communication with outpatient healthcare professionals; brief report detailing 3 key messages	other activities once during admission			Event-free survival higher at 3 months for intervention arm (Hazard Ration =0.72, p=0.03). No significant difference in mortality (I:56 (17.7%) vs C:65 (18.7%); p=0.74).
Scullin et al. (2007)	762 elderly patients (>65 years) admitted to medical ward at one of three general hospitals and take ≥ 4 long term medicines OR one high risk medicines OR previous admission within last 6 months OR given an IV antibiotic on day one of admission, Northern Ireland Mean age = 70	• Medicines reconciliation • Medication review • Counselling tailored to patient focusing on medication changes • Medicines record sheet prepared for patient outlining dosage instruction • Medicines record sheet faxed to PCP and community pharmacy	Specially trained project pharmacists and pharmacy technicians/ daily medication review and counselling provided as required - all other activities once during admission	Usual care	Provided during admission/ 12 months	Intervention arm had reduced length of index admission (2 days less; p=0.003), a reduced number of readmissions (I:141 (38%) vs C:172 (44%); p=0.027) and reduced length of stay if readmitted (I:9.7 vs C:13.1, p=0.068) and longer time to first readmission (p=0.0356).
Tamblyn et al. (2019)	4656 patients covered by provincial drug insurance, discharged from internal medicine,	• Electronic medicines reconciliation using community drug list and hospital drug information system.	Electronic intervention/ during admission, transfer between	Usual care – manual reconciliation by pharmacist	Provided throughout admission/ 2 months	Medication discrepancies were significantly reduced in the intervention arm (I:437 (26.4%) vs C:1029 (56%); OR 0.24 CIs 0.12-

	cardiac or thoracic surgery units, Canada Mean age = 70	• Discharge prescription and information about changes transferred to PCP and community pharmacy	units and at discharge			0.57). Adverse drug events (I:76 (4.6%) vs C:73 (4%); OR 0.24 CIs 0.33-1.48) and readmission rates at 1 month (I:170 (10.3%) vs C:261 (14.2); OR 0.22 CIs 0.06-1.14) or 3 months (I:292 (17.6%) vs C:433 (23.6%); OR 0.37 CIs 0.11-1.40) were not statistically different between arms.
Tong et al. (2017)	832 patients admitted to general medical unit at an adult major referral hospital, Australia Mean age = 73	• Patient receives personalised medication management plan	Pharmacist/ once at discharge	Usual care involving a standard discharge summary prepared by junior doctor and electronic transfer to PCP	Provided once during admission/ At discharge	Intervention arm had less medication errors in the discharge paperwork (I:15% v C:61.5%; p<0.01; Absolute Risk Reduction 46.5%; CIs 40.7-52.3%).

Interventions commenced during hospital admission that include continuing support post-discharge

Study details	Participants and setting	Intervention	Delivered by/ frequency	Control	Duration of whole intervention/ follow-up duration	Outcome
Buurman et al. (2016)	674 elderly patients (>65 years) at high risk of functional decline, admitted to the internal medicine ward of one of three large teaching hospitals for a minimum of 48 hours, Netherlands Mean age = 80	• Medicines reconciliation • Discussion with PCP and additional support enabled (e.g. pharmacist support) • Home visit for patient education	Community care nurses acting as 'transition coaches'/ Inpatient visit, 2 days post discharge, then at 2, 6, 12 and 24 weeks	Usual care	6 months/ 12 months	No significant difference in readmission rate (I:106 (33.5%) vs C:88 (29%); p= NR) or time to first readmission (Hazard ratio 1.21; CIs 0.91-1.60; p=0.76). Intervention arm demonstrates significant protective effects with regards to mortality at 1 (HR 0.63; CIs 0.39-0.99; p=0.047) and 6 months (HR 0.75; CIs 0.56-0.99; p=0.045).
Casas et al. (2006)	155 patients with exacerbation of COPD and minimum admission length of 48 hours in two tertiary hospitals, Belgium and Spain	• Educational programme (2 hours) on self-management • Individually tailored care plan shared with PCP	Specialised nurses/ education provided just before discharge, telephone calls	Usual care	Helpline active for 12 months, all other activities provided within 1	Intervention group had lower rate of readmission (I:29 (45%) vs C:60 (67%); p=0.028). No significant difference in mortality (I:12

	Mean age = 71	• Post-discharge telephone calls • Web-based call centre for help	weekly for first month		month/ 12 months	(19%) vs C:14 (16%) p=0.67).
Chan et al. (2015)	699 patients (>55 years) admitted to internal medicines, family medicines, cardiology or neurology wards at a general safety net hospital and trauma centre, USA Mean age = 66	• Disease specific patient education • Self-management coaching • Medicines reconciliation • Written medicines information • Post-discharge telephone calls • Medicines helpline for patients requiring further information after discharge	Registered nurse who spoke patient's native language/ education and self-management coaching provided once during admission and within 24 hours of discharge, two telephone calls; 1-3 days and 6-10 days	Usual care	Helpline active for one month, all other activities provided within 10 days of discharge/ 30 days	No significant difference in overall Care Transitions Measure-3 score (I:80.5% vs C:78.5%; p=0.18) or patient satisfaction with communication about medicines (p=0.13). More patients in intervention arm reported receiving medication counselling (92.1%) than control arm (86%) (p=0.02).
Coleman et al. (2006)	750 elderly patients (>65 years) with a long term condition, with admission to large hospital/ service delivery system, USA Mean age = 76	• Personalised patient-held record • Home visit for education, self-management coaching and medicines reconciliation • Post-discharge telephone calls	Advanced practice nurses acting as 'transition coaches'/ Initial contact during admission, home visit once within 72 hours of discharge, three	Usual care	One month/ 6 months	Intervention arm less readmissions at 30 days (I:31 (8.3%) vs C:44 (11.9%); p=0.048) and at 90 days (I:63 (16.7%) vs C:83 (22.5%); p=0.04). No difference for 6 month readmissions (I:97

			telephone calls within 1 month			(25.6%) vs C:114 (30.7%); p= 0.28). Intervention patients were less likely to be readmitted at 90 days (I:20 (5.3%) vs C:36 (9.8%); p=0.04) and 180 days (I:33 (8.6%) vs C:52 (13.9%); p=0.046) for same condition as index admission. No difference at 30 days (p=0.18).
Gillespie et al. (2009)	400 elderly patients (>80 years) admitted to two internal medicines wards at a University Hospital, Sweden Mean age = 86	• Medicines reconciliation • Medication review • Patient education • Comprehensive account of medicines changes faxed to PCP • Post-discharge telephone call	Clinical pharmacist/ one telephone call 2 months after discharge, all other activities provided during admission with extra education at discharge	Usual care which does not involve pharmacists and focuses solely on cause of admission	2 months/ 12 months	Intervention arm had a 16% lower rate of readmission and ED visits combined (I:266 vs C:316; OR 0.84; CI 0.72-0.99) and less drug related readmissions (I:9 (4.9%) vs C:45 (24%); OR 0.20; CIs 0.10-0.41). No difference in just hospital readmissions (I:106 (58.2%) vs C:110 (59.1%); OR 0.96; CIs 0.64-1.46).

Huang and Liang (2005)	126 elderly patients (>65 years) admitted to large medical hospital with hip fracture due to falling, Taiwan Mean age = 77	• Individualised discharge plan • Information brochure regarding medication safety • Patient education • Home visit • Post-discharge telephone calls • Medicines helpline for patients requiring further information after discharge • Collaboration with PCP for medication modification	Specialist nurse/ one home visit within 7 days of discharge, weekly telephone calls for 3 months, all other activities provided once at discharge	Usual care of routine hospital discharge	3 months/ 3 months	Intervention arm had a shorter length of index admission (I:8.17 days vs C:10.06 days; p=0.002), fewer readmissions (I:4 (6.35%) vs C:13 (20.6%); p=0.02) and longer time to readmission (I:2.91 vs C:2.67 months; p=0.02). QoL scores improved by greater amount in intervention arm (18.6 v 15.3 point improvement).
Koehler et al. (2009)	41 elderly patients (≥70 years) taking ≥ 5 long term medicines and with ≥ 3 chronic conditions, admitted to a University Hospital, USA Mean age = 79	• Pharmacist-led medicines reconciliation • Medication review • Intensive patient education programme including self-management • Post-discharge telephone call • Personal health record and supplemental	Care co-ordinators (experienced nurses) and study clinical pharmacist/ education and review provided daily during admission, reconciliation at admission and discharge, one	Usual care including nurse-led medicines reconciliation and patient education	7 days/ 60 days	Intervention arm had lower rate of 30 day readmission (I:2 (10%) vs C:8 (38%); p=0.03). No significant difference at 60 days (I:4 (20%) vs C:1 (5%); p=0.18). Time to readmission was longer in intervention arm (I:36.2 vs C:15.7 days; p=0.05).

		discharge form given to patient • Discharge form faxed to PCP	telephone call within 7 days of discharge			
Lee et al. (2015)	840 patients (>21 years) admitted to medical ward of tertiary hospital and at high risk of readmission, Singapore Mean age = 69	• Patient education • Medicines reconciliation and review • Discharge information in format of care plan • Post-discharge telephone calls • Home visit	Multi-disciplinary team, mainly pharmacist and nurse case manager/ one home visit within two weeks of discharge, telephone calls within 72 hours of discharge and once weekly thereafter. All other activities provided during admission.	Usual care of standard hospital discharge	3 months/ 6 months	No significant difference in readmission rates at 1 month (I:117 vs C:139; p= 0.124), 2 month (I:183 vs C:186; p= 0.957) or 3 month (I:214 vs C:225; p= 0.561) There was a 28% reduction in mortality at 180 days (Hazard Ratio 0.72; CIs 0.61-0.86; p<0.001). Intervention arm also had reduced length of subsequent stay (3.6 fewer bed days; p=0.004).
Ravn-Nielsen et al. (2018)	974 patients (>18 years) taking ≥ 5 medicines, admitted to the acute admission wards, Denmark	• Structured medication review • Communication with physician • Medicines reconciliation	Trained clinical pharmacist/ all provided once during admission, a telephone call to patient within 1 week of	Usual care	6 months/ 6 months	Intervention arm had lower rate of readmissions at 1 month (I:68 (14.3%) vs C:111 (22.3%); HR 0.62 CIs 0.46-0.84) and 6 months (I:189

	Mean age = NR; Median age = 72	• 30-minute motivational interview with patient at discharge for education and self-management • Transfer of information to PCP via fax or telephone call • Post-discharge telephone calls with patient	discharge and at 6 months after discharge.			(39.7%) vs C:243 (48.8%); HR 0.75 CIs 0.62-0.9). ED visits (I:15 (3.2%) vs C:21 (4.2%); HR 0.74 CIs 0.38-1.44) and mortality at 6 months (I:54 (11.3%) vs C:50 (10%); HR 1.05 CIs 0.68-1.63) showed no difference between arms.

Interventions commenced post-discharge

Study details	Participants and setting	Intervention	Delivered by/ frequency	Control	Duration of whole intervention/ follow-up duration	Outcome
Ahmad et al. (2012)	340 elderly patients (>60 years) taking ≥ 5 long term medicines, discharged from general or academic hospitals, Netherlands	• Medication review • Medication counselling using cognitive behaviour techniques • Home visit • Medicines reconciliation	Specially trained community pharmacists and pharmacy technicians/ Review only once, all other activities occur at	Usual care according to Dutch pharmacy standards	12 months/ 12 months	Reduction in drug related problems (Mean number of problems I:1.51 baseline to 1.37 follow-up vs C: 1.58 to 1.62).

	Mean age = 70	• Collaboration with PCP • Removal of redundant medications from home	1, 3, 6, 9 and 12 months after discharge.			
Char et al. (2017)	200 patients (>21 years) taking ≥ 5 long term medicines, attending first outpatient clinic appointment following recent stay in hospital (Singapore) Mean age = 74	• Medicines reconciliation • Collaboration with PCP • Best possible medication history created for patient	Pharmacist/ once following discharge, before seeing PCP in outpatient clinic.	Usual care with no medicines reconciliation by pharmacist	Provided once at post-discharge PCP appointment/ 30 days	Intervention arm experienced fewer medication discrepancies than control (I:15 (15.8%) vs C:54 (57.4%); p<0.001). No significant difference in 30 day hospital readmission rates (I:6 (6%) vs C:4 (4%); p= NR).
Gurwitz et al. (2014)	3661 elderly patients (>65 years) discharged from hospital for any admission, USA No mean documented	• Discharge information populated with medicines alerts provided to PCP • System prompt to schedule an appointment within one week	Automated electronic health records based intervention/ once within 3 days of discharge	Usual care	Provided once post-discharge/ 30 days	No significant difference in rate of 30 day readmission (I:351 (18.8%) vs C:356 (19.9%); Hazard Ratio 0.94; CIs 0.81-1.1) or attendance for 30 day follow-up (Hazard ratio 0.99; CIs 0.91, 1.1).

Haag et al. (2016)	25 elderly patients (≥60 years) discharged from tertiary care academic medical centre for any type of admission, USA Mean age = 84	• Post-discharge telephone call • Medication review • Medicines reconciliation • Recommendations communicated electronically to Outpatient Care team	Specially trained clinical pharmacist/ once within 7 days of discharge	Usual care	Provided once post-discharge/ 5 weeks	No significant difference in rate of 30 day readmission (I:2 (18%) vs C:1 (9%); p=0.53) or ED visits (p > 0.99). Medication appropriateness between arms was not significant (I:8 (73%) vs C:10 (91%); p=0.31) and 43.6% of problems identified in intervention arm persisted at 30 days.
Holland et al. (2005)	872 elderly patients (≥80 years), from 10 hospitals following an emergency admission and taking ≥2 medicines, UK Mean age = 85	• Home visit • Medication review • Patient education • Collaboration with PCP • Removal of redundant medications from home	Specially trained pharmacists/ all activities provided twice; 2-8 weeks post-discharge and 6-8weeks after first visit	Usual care	Maximum 4 months post-discharge/ 6 months	Readmission rate was 30% higher in intervention arm (234 vs 178; p=0.009). QoL scores decreased for both arms with no significant difference (I: -0.131 vs C: -0.137; difference of +0.006 in favour of intervention arm; p=0.84). Visual analogue scale scores also decreased but with a difference of 4.1 units in favour of control arm (I: -7.36 vs C: -3.24; p=0.042).

Tuttle et al. (2018)	159 patients (>21 years) discharged from large tertiary-referral hospital following acute illness and detection of chronic kidney disease stage 3-5, (USA) Mean age = 69	• Home visit • Medicines reconciliation • Medication review • Provision of advice and self-management strategies • Provision of information to PCP	Pharmacists/ once within 7 days of discharge	Usual care at discharge, with no follow-up	Provided once post-discharge, lasting 1-2 hours/ 90 days	No significant difference in 90 day readmission rate (I:19 (26%) vs C:18 (26%); p= 0.95) or composite analysis of emergency care utilisation and readmission (I:32 (44%) vs C:28 (41%); p=0.72).

ED = Emergency department; NNT = Numbers needed to treat; PCP = Primary care provider; QoL = Quality of Life; RRR = Relative risk ratio

Intervention components coded using an adapted taxonomy of discharge interventions, reproduced from Tomlinson et al. (2020a) under the Creative Commons CC BY NC licence ©Oxford University Press

Interventions offered during hospital admission (A= at admission; I = whilst inpatient; D = at discharge. GP = General Practitioner; CP = Community Pharmacy)											
	Follow-up										
Study	Telephone	Home visit	Patient Education **A/ I/ D**	Self-Management (education / coaching)	Medication intervention: reconciliation **A/ I/ D/**	Medication intervention: clinical review **A/ I/ D/**	Patient – centred discharge document	Collaboration within care team	Timely cross sector communication	Patient hotline	Total number of components
Basger et al. (2015)			✓ D	✓	✓ D	✓ D			✓ GP		5
Bolas et al. (2004)			✓ I/D		✓ I		✓		✓ CP/GP	✓	5
Graabæk et al. (2019)			✓ D		✓ A	✓ A/I		✓			4
Hockly et al. (2018)									✓ CP		1
Lalonde et al. (2008)							✓	✓	✓ CP/GP		3

Legrain et al. (2011)			✓ I	✓	✓ I	✓ I		✓	✓ OUTPATIENT CLINIC		6
Scullin et al. (2007)			✓ I/D		✓ A	✓ I	✓		✓ CP/GP		5
Tamblyn et al. (2019)					✓ A/I/D				✓ CP/GP		2
Tong et al. (2017)							✓				1
Interventions commenced during hospital admission and include continuing support post-discharge (A= at admission; I = whilst inpatient; D = at discharge; P= post-discharge. GP = General Practitioner; CP = Community Pharmacy)											
	Follow-up (first time point when occurs after discharge)										
Study	Telephone	Home visit	Patient Education **A/ I/ D/ P**	Self-Management (education / coaching)	Medication intervention: reconciliation **A/ I/ D/ P**	Medication intervention: clinical review **A/ I/ D/ P**	Patient – centred discharge document	Collaboration within care team	Timely cross sector communication	Patient hotline	Total number of components
Buurman et al. (2016)		✓ 2 days	✓ P		✓ P			✓	✓ CP/GP as needed		5
Casas et al. (2006)			✓ D	✓					✓ Primary care team		4

	✓ 1 week										
Chan et al. (2015)	✓ within 1 to 3 day		✓ I/D/P	✓	✓ I/D		✓			✓	6
Coleman et al. (2006)	✓ unknown	✓ 48 to 72hrs	✓ P	✓	✓ P		✓				6
Gillespie et al. (2009)	✓ 2 months		✓ I/D		✓ A	✓ I		✓	✓ GP		6
Huang and Liang (2005)	✓ 1 week	✓ 3 to 7 days	✓ D				✓	✓	✓ GP	✓	7
Koehler et al. (2009)	✓ 5 to 7 days		✓ I/D	✓	✓ A/D	✓ I/P	✓		✓ GP		7
Lee et al. (2015)	✓ within 72hrs	✓ within 2 weeks	✓ I/D		✓ I/D	✓ I	✓	✓	✓ Nurse to nurse		8
Ravn-Nielsen et al. (2018)	✓ 1 week		✓ D	✓	✓ D	✓ A		✓	✓ GP/CP		7
Interventions commenced post-discharge											

	Follow-up (first time point when occurs after discharge)										
Study	Telephone	Home visit	Patient education	Self-Management (education / coaching)	Medication intervention: reconciliation	Medication intervention: clinical review	Patient – centred discharge document	Collaboration within care team	Timely cross sector communication	Patient hotline	Total number of components
Ahmad et al. (2012)		✓ one week	✓		✓	✓		✓			5
Char et al. (2017)					✓			✓			2
Gurwitz et al. (2014)									✓ GP		1
Haag et al. (2016)	✓ 3 to 7 days				✓	✓		✓			4
Holland et al. (2005)		✓ 2 to 8 weeks	✓			✓		✓	✓ Discharge letter sent to pharmacist conducting review		5
Tuttle et al. (2018)		✓ within	✓	✓	✓	✓		✓			6

		7 days									

Abbreviations: CP= community pharmacist; GP= general practitioner/ family doctor

Appendix 9 - Phase 2 data

Example of Ruth's diary entries; adapted to maintain anonymity

Date: Feb 2019	Relationship of person completing entry e.g. carer, friend, family: Ruth
1. What has happened today that prompted you to make an entry?	2. What did you do or what do you plan to do about it?
3. Did you discuss this with anybody? (E.g. friend, carer, neighbour, nurse, doctor, pharmacist or social worker)? If so, who and what happened? *"I still have not [had] my dose altered yet, my blood sugar is still up and down. My son is not very pleased because the district nurse who has been coming said he thinks I am alright in doing it myself. He has only been coming for two days. I feel alright myself but my son thinks it is not long enough"*	4. Have you had to change anything as a result of this discussion or event?
5. How has this event made you feel today? (Please circle the most appropriate number): 0 1 2 3 4 5 6 7 8 9 10 *Poor* *Good* Additional comments:	6. Is there anything else you would like to tell us about this event?

Example of Betty's diary entries; adapted to maintain anonymity

Date: Sept 2018	Relationship of person completing entry e.g. carer, friend, family: Betty
1. What has happened today that prompted you to make an entry? *"Dr's appointment, for sodium results from blood tests 7 days ago"*	2. What did you do or what do you plan to do about it? *"My daughter came with me"*
3. Did you discuss this with anybody? (E.g. friend, carer, neighbour, nurse, doctor, pharmacist or social worker)? If so, who and what happened?	4. Have you had to change anything as a result of this discussion or event? *"Sodium – normal* *Blood pressure – high* *Dr stopped bendroflumethiazide* *Added propranolol"*
5. How has this event made you feel today? (Please circle the most appropriate number): 0 1 2 3 4 5 6 **7** 8 9 10 *Poor* *Good* Additional comments:	6. Is there anything else you would like to tell us about this event? *"Next appointment Oct, check BP and have more blood tests"*

PSI ratings

Participant	Age	PSI	MRP classification (Nicosia et al. 2020)	Severity rating: 0=no risk of harm; 10=death							Adjudication	Severity ratin	
				HCP 1	HCP 2	HCP 3	HCP 4	Mean	Median	Harm: <3 minor, 3-7 moderate, and >7 severe		PCLSG 1	PCLSG 2
Elaine	96	The discharge note says "U&Es to be checked in a couple of weeks" but the GP practice haven't been in touch about that. She recently received a letter saying the GP wants to do blood tests in a month's time, but that would be approximately 6 weeks since discharge	Problem with communication, care co-ordination and medication information	5	6	4	2	4.25	4.5	Moderate		10	5
Patricia	85	She was admitted to hospital with a pulmonary embolism, having been taking tranexamic acid for vaginal bleeding. On discharge, she was given her new supply of meds but whilst in the discharge lounge, someone from the ward brought her old medicines from home and sent those with her too (including items that had been ceased such as the tranexamic acid, ramipril, aspirin and amlodipine)	Problems with obtaining medications [expired/ disposal issues]	7	9	8	8	8	8	Severe		10	8
Harry	90	On discharge, the hospital nurse rang the daughter and asked her to remove his tamsulosin from the dosette box. The virtual ward then visited to do this and cling-filmed it over. The district nurse came to visit and were concerned that all the tablets had fallen out – they told the daughter this was a silly thing to do	Problems with taking medications [problems with organising meds]	1	6	4	3	4.25	3.5	Moderate		10	5
James	79	He usually takes 8.5mg of warfarin but was being dosed at 1.5mg whilst in hospital for a couple of days. He queried this and the hospital adjusted the dose back	Problems with medication effects	5	6	5	2	4.5	5	Moderate		10	6
		The phlebotomist isn't going to see him for three weeks and they haven't said when the next appointment is. He needs to ring up but he can't be bothered; he'll just keep taking his usual dose. He doesn't have enough tablets for three weeks though	Problem with communication, care co-ordination and medication information	6	9	7	2	6	6.5	Moderate		10	6

		On discharge he was given medication that he hadn't taken for over two years e.g. carbocisteine	Problems with obtaining medications [expired/ disposal issues]	2	8	1	2	3.25	2	Moderate		10	6
Shirley	81	She was discharged over the Christmas period and the hospital refused to supply her with any medication. She didn't have much left at home	Problems with obtaining medications	6	8	6	5	6.25	6	Moderate		10	6
Dorothy	82	Her INR was monitored regularly whilst in hospital but they never wrote the figures in her yellow book for her. On discharge she was given an additional yellow book – she now has 2 books running in her purse and she doesn't know which one is being used	Problem with communication, care co-ordination and medication information	3	7	7	1	4.5	5	Moderate		10	4
		She was due her INR test last week but was away. She was supposed to them this Wednesday, but had forgotten	Problems with medication effects	4	7	5	Not PSI	5.3	5	Moderate		6	4
		The GP has requested for the heart failure nurse to visit her three times now. They haven't been yet – this could be because they are too busy or maybe she wasn't in	Problem with communication, care co-ordination and medication information	4	7	Not PSI	Not PSI	5.5	Not PSI	Not PSI	Not PSI - we don't know what the GP has said or whether the nurse has turned up	10	4
Ruth	90	Her son has to phone up the pharmacy nearly every week because they haven't sent her medication on time and she has none left	Problems with obtaining medications	6	7	5	3	5.25	5.5	Moderate		10	3

Robert	80	During admission, his metformin was ceased due to high lactate. This was not communicated to Robert, who was told the HCPs were trailing him on some new medication. He did not like this being done behind his back so after discharge he resumed his old regimen, including continuing metformin, lansoprazole and furosemide which had all been stopped on the discharge paperwork. The diabetes nurse who came to visit him at his house the next day said this was ok. The GP continued to supply them until Robert went to the surgery approx. two months later to query the discharge note. The diabetes nurses looked into this but never got back to him. Three weeks later he asked the GP who looked into his records and said that the metformin should have been stopped a long time ago. They explained they were stopping it because they had given him too many. He does not feel like he has got to the bottom of this, but has accepted that he no longer takes metformin	Problem with communication, care co-ordination and medication information	8	8	7	3	6.5	7.5	Moderate		10	4
Elsie	84	Following discharge, Elsie was very immobile due to painful foot surgery and relies on her carers more for medicines administration. Whilst her carers were supposed to attend four times per day, their visits have become more sporadic and sometimes they only come twice a day. This has an impact on the number of times she can take her painkillers as she only has them when they are brought to her	Problems with taking medications [problems with administration]	5	5	Not PSI as only pain medicines missed	4	4.67	5	Moderate		10	10
Marie	81	Her medicines are changing all the time and she's getting confused with what to take. She's overdosed by accident twice, so her daughter looks after the medicines immediately post-discharge	Problems with taking medications [forgetting]	7	9	Not PSI	5	7	7	Severe		10	9
		Her daughter has had to ring the chemist to tell them not to bring any more medication until Marie rings them – she has carrier bags full and is getting confused	Problems with obtaining medications	4	7	Not PSI	1	4	5.5	Moderate		10	9

		She went four days without a special tablet for her blood because the chemist messed up with her tablets – they should have been in her MCA but they weren't. The chemist blamed it on their new staff. This happened again two weeks later with her water tablets for her heart failure. The dosette boxes were corrected when she alerted the chemist	Problems with obtaining medications	6	7	6	4	5.75	6	Moderate		10	9
Hazel	91	The hospital stopped lots of her medicines. She mentioned this to her GP at an appointment and the GP expressed her confusion. Hazel only has one kidney and the GP said she had to take certain medicines which had been stopped in hospital (furosemide and ramipril). The GP explained that some of the tablets she couldn't do without, and restarted them	Problem with communication, care co-ordination and medication information	5	8	7	Not PSI	6.67	7	Moderate		10	9
		Her daughter was looking at her MCA and felt like something was missing. They went to the chemist and they explained that they didn't think she needed the item any more, and had knocked it off	Problems with obtaining medications	5	7	7	3	5.5	6	Moderate		10	9
		Clopidogrel had been temporarily stopped for two weeks on discharge. This was not restarted in primary care. She was later admitted with acute coronary syndrome and the hospital contacted the GP to find out why it had been stopped. It was restarted, lifelong, during this later admission	Problem with communication, care co-ordination and medication information	8	8	9	9	8.5	8.5	Severe		10	9
		The chemist keeps sending her Gaviscon every month even though she doesn't want it. She has eight bottles currently. The chemist won't accept them back as they have left the shop	Problems with obtaining medications	1	4	Not PSI	Not PSI	2	1	Minor	1	10	9

Betty	85	She was commenced on pregabalin for pain associated with severe stenosis after a hospital stay. Her dose started at 50mg then rapidly increased. She had another hospital admission and her dose was increased to 200mg, then a week later up to 300mg. She started to have side effects such as falls and double vision. This went on until a paramedic that attended a fall recognised the symptoms as a side effect of the pregabalin. She was subsequently admitted as she had fallen on her left side and had just had a pacemaker fitted. Other HCPs had mentioned to the patient and her daughter that her symptoms might be medication side effects in the past (e.g. whilst in a community bed for two weeks the doctor had said this) but because she didn't see these doctors again, nothing was done. She has now been reduced back to 50mg	Problems with medication effects/ Problem with communication, care co-ordination and medication information	8	9	7	3	6.75	7.5	Moderate		10	9
Joan	78	The chemist is supplying items that she doesn't need, she doesn't know what to do with it	Problems with obtaining medications	1	5	Not PSI	Not PSI	3.33	4	Minor	4	10	8
		The hospital only supplied her with 7 oxycodone immediate release capsules. She tried to reorder these from her chemist (she was describing them as tiny yellow, like an antibiotic) but ended up with a supply of antibiotics instead. She didn't get any immediate release oxycodone and now manages just with her modified release ones	Problems with obtaining medications	4	8	2	6	5	5	Moderate		10	8
		She rang the GP to find out why she hadn't been prescribed citalopram for 2 months. It was on the discharge letter as 'GP to continue' but none had come with her delivery from the chemist. She hadn't rung because she thought the GP had cancelled it (which they hadn't), but she started getting panic attacks again, prompting her to query it. The GP restarted it and added it to her repeat prescription	Problems with obtaining medications	6	6	4	4	5	5	Moderate		8	8
		No one has reviewed her since discharge (2 months) when her blood pressure medication was stopped. Her blood pressure has always been high, now it's suddenly gone low – she can't understand why no one has checked it	Problems with medication effects	5	5	4	Not PSI	4.67	5	Moderate		8	8

Appendix 10 – Phase 3 data

Behavioural determinants mapped to the TDF and BCTT

TDF domain (V1)	Behavioural determinants of post-discharge medicines management	Supportive quotes	BCTs identified to target key domain – Michie et al. (2008)* & Cane et al. (2015)^
Knowledge	Extent of knowledge about which medications have been changed and why (barrier & facilitator)	"I think more or less the medicine, take out the chew tablet, I don't know." (Eleanora) "they never said why they'd taken those off and those new ones back on" (Joan) "…because I'm more or less taking what I was taking before, there's not much change I don't think." (Doris) "I think some of them have changed but I'm not sure which." (Nancy)	1. Information regarding behaviour, outcome* 2. Goal/ target specified: behaviour or outcome* 3. Persuasive communication* 4. Antecedents^ (Provide information

	Confusion about indications and dosages (barrier)	"So of course when they found out she's got an embolism and they had to give her blood they had to stop giving her the blood thickener and put her on a blood thinner." (Patricia's daughter) "No, he did change one of my tablets, did the heart specialist. I don't know what he changed. I'm on that much medication I don't know what amount I have to take." (Marie) "…but you still don't know why they took her in twice and why, you know, she's had the stopping of the cholesterol and the acid tablet, you used to take two and now they've changed that just to one." (Betty) "Not really, no, not really, she didn't say xxxxx you've got cellulitis, you get that from the nurses and no, she never explained anything to me." (James)	about antecedents (*e.g. social and environmental situations and events, emotions, cognitions)* that reliably predict performance) 5. Information about health Consequences^ 6. Feedback on Behaviour^ 7. Biofeedback^ (Provide feedback about the body (e.g. physiological or biochemical state)

		“We thought she were on a water tablet already but apparently that had stopped last year when she had this other episode…” (Elaine’s daughter)	using an external monitoring device
	Unanswered questions about side effects and monitoring (barrier)	“Because, I mean if she’s been on these tablets for 18 months and it’s that that caused the problem, should somebody have checked owt before it got to the stage where that’s happened? Then they could have seen levels have dropped that far…” (Elaine’s daughter) “So why I had it and then I didn’t have it I don’t understand. They’ve never explained.” (Elsie)	
	Support from others to fill	“I just wondered if there’s any more that’s like that, you know, because I were having trouble for a while with my stomach…” (William)	

	knowledge gaps (facilitator)	"…when it comes to checking anything, if anybody queries it then my daughter does it." (Hazel) "Well one of the nurses what used to come, she wrote it down for me what everything did…" (Barbara) "Well to be honest I couldn't understand it so my son read it, you know, he's up on everything…" (William)	
Skills	Level of mobility limits access to medicines (barrier) Skills to interpret discharge	"No, they're supposed to be given to me at the correct time every day by one of the carers but that's all gone to pot as well. Nobody's given me any today." (Elsie) "Anything I want I've got to ask for it and I don't like that side of it, but I can see that it's not possible for me to do everything myself because I can't even get up never mind walk…" (Nancy) "…because when I read it I couldn't understand it at all…" (Betty)	1. Goal/ target specified: behaviour or outcome* 2. Monitoring* 3. Self-monitoring* 4. Rewards, incentives* 5. Graded tasks, start with easy*^

	paperwork (barrier & facilitator) Work done to ensure correct medicines administration (e.g. stock control, medicines	"I was discharged and I don't know if there's anything at all on it that tells me what I've had, I don't think there is." (Hazel) "It said something in the hospital notes about too much lactate so I assume that means lactic acid in the blood stream, something like that." (Robert's wife) "I thought it was, you know, that pink slip that they send with it, that pink booklet that came with it, it was on there and it said 'doctor to continue' or something that, and I think that's what made me ring" (Jean) "…because on the lid it says what you're taking doesn't it, and when you're taking them? So, we did read that to make sure that they were the ones that I should be taking" (Elizabeth) "Because I'd ordered some and I hadn't got it all. So, I took that up and showed them what they'd prescribed for me while I was in hospital." (Charles)	6. Increasing skills; problem solving, decision making* 7. Rehearsal*^ 8. Demonstration by others* 9. Perform behaviour in different settings* 10. Body changes^ 11. Habit reversal^ 12. Habit formation^

	reconciliation) (facilitator)	“My daughter’s done all the calendar for me, because I'm getting confused, I'm on that much medication” (Marie) “The other stuff that’s being discontinued… So I took that back, put that out straight away” (Patricia’s daughter)	
	Willingness to ask questions (barrier & facilitator)	“I suppose I should have asked but I don’t I’m afraid.” (Margaret) “Oh I could ask the doctors about that and quite often the nurses didn’t know” (Marilyn) “Well, I used to think sometime, ‘well, what’s it for?’ you know? And I… I didn’t get told you know. I felt like saying, ‘well, what’s this for? What’s this for?’ you know? No, I didn’t know.” [Alice]	

		“I asked questions three or four times “What is this medication doing for me? How long am I going to be on it? And what’s happening within?”” (John) “I didn’t really think about it to be honest you know I just let them do what they had to do you know what I mean. I mean they were doing their job and that was it you know” (Doris) “I’m not just one that’ll take anything; I need to know what I’m taking and why.” (Nancy) “Well, I’ve always been like that anyway. If I don’t like something and I don’t see… I want to know why not. Like I say, it’s the only way you find out stuff is to ask. If you don’t ask, you don’t know.” (Marie) “you’ve got to ask, you know, all the time what they’re doing and why they’re doing it, you know?” [William]	

Social /professional role and identity	Belief that medics will relay any important information (barrier) Unwillingness to 'bother' medics (barrier)	"Yeah, well I suppose I could ask them couldn't I like, you know, but… I think if they wanted me to know they'd tell me wouldn't they?" (Barbara) "…well they just go by what district nurses tell them about this. And I suppose they know and the home care as well, everything is written down in that book…" (Joan) "And I told him [nurse] about it but I thought that he'd have reported it, you know, but he didn't seem to bother." (William) "…but they were just run off their feet especially… There were about three nurses to look after 27 beds." (Charles) "I mean they've so many patients haven't they to look after, and they're writing things down on computers all the time and I suppose it's just time and they do everything… cut things to get quicker I suppose…" (William)	1. Social processes of encouragement, pressure, support*

	Previous career (e.g. retired nurse) (barrier & facilitator)	“Because they are shorthanded, I do know that, but I mean I didn't bother them, I just let them get on with it. I didn't bother them.” (Ruth) “I’ve never seen a ward like this. I know they make mistakes in hospital these days.” (Winifred) “Yes, I suppose it’s being with, with being a nurse I think that hits you like that.” (Joan) “They don’t have the same rapport that we used to have when we were training and I think it’s lacking in some way in their education really because they’re more or less wandering around the ward not quite knowing what’s the matter with everybody.” (Marilyn) “I know how to give medications out and you don’t… say ‘can we have more?’ ‘You can’t have more, no’. I’ve never done	

	Paternalistic culture (e.g. the doctor says I have to take them so I do) (barrier & facilitator)	that. I just take what I'm supposed to take and that's it." (Shirley) "Anyway, was there on Tuesday and he's [GP] very pleased with it. I've done everything he told us to do and it's all working." (Betty) "I just do as I'm told, stop them if they [GP] tell me to stop them and start them if they tell me to start them, so." (Mary) "…so I have to be careful and do what they tell me…" (Enid) "The District Nurse told me take it out and clingfilm the pack. But then when they (community care team) came and said you know, 'it's not acceptable'… 'where's he's tablets?'. 'All the tablets fell out'." (Harry's daughter) "I haven't a clue what the yellow one does or the red one does. I haven't a clue what they're doing to me, but faithful, I'll take them." (John)	

	View of own responsibility for medicines management (barrier & facilitator)	“I take what is given me by the doctor. I don't know.” (Eleanora) “I’m in the charge of the carers and the carers do their best.” (Elsie) “Well in hospital they just brought it to me, usually every meal time, yeah so no I didn’t have anything to do with that, they just gave it to me, you know, whatever.” (Elizabeth) “No I leave it [medicines] for the carers…[…]… It’s something I won’t be doing.” (Margaret) “…every time I go in hospital some doctor or other changes some tablets. I think because they change every time you go, just take them, so that’s all I do.” (Hazel) “I mean I have to do it [meds management] all myself you see? And it’s not right at my age.” (Alice)	

	Perceptions of relationships with healthcare professionals (barrier & facilitator)	“I don’t need anyone to help me with my medications, if they’re there I know when to take them, I don’t take them when I shouldn’t take them.” (James) “I haven’t been allowed to manage them. The carers do it. All my medicines are in the centre table in the kitchen, they’re altogether and they dealt them out either first thing in the morning or they do it again at lunchtime.” (Elsie) “I think it’s the doctors, they can’t do anything. I mean the pharmacy has been brilliant, I can’t knock them..” (Elaine’s daughter) “…it all went smoothly but that’s because I deal with the chemist a lot” (Patricia’s daughter) “the ones that go on night duty as a night in charge and they’re quite unaware of most of the diagnoses of the patients, so they don’t know what’s been gone on in the day or the day before	

		and so their lack of knowledge really leaves you in a spot if you had drugs changed or, you know, that sort of thing." [Marilyn] "I couldn't tell you what my doctor's like; I don't even know his name." (Alice) "Not much, they tend not to come rather than they're here all the time, you know, they're not… I don't see the GP very much at all." (Nancy) "People that are doing their job and in most cases are doing the best they can. And if they look after you you mustn't complain." (John) "The pharmacist just came and give me my medication, didn't say, you know." (Charles) "That was three or four weeks ago, about four weeks ago now. And I still haven't got my tablets through from the doctors. Well it will be my doctors, who won't have prescribed it." (William)	

	View of self as 'expert' (barrier & facilitator)	"No, my doctors don't seem to bother. Even when I went to XXXXX last time, the never phoned me or anything like that" (Ruth) "I know that if they stopped some tablets and I wanted to know why, it would be pointless asking them (GP)." (Robert) "Right now I consider myself an expert on what medications I take and you become like, sort of selfish; I know what I want, I know what I need to take and anybody who comes in and disrupts that, well then they're creating an issue." (James) "Oh I know what they're for, it's all to do with just take one puff in a morning and it goes down into your airways and one thing and another, so there's really nothing to explain about that, it's just the colour of the thing that's changed, that's all." (Marie)	
Beliefs about capabilities	Perceptions of fluctuating health	"I were thinking to myself I think they've let me out too early; I'm not ready, you know, because I didn't feel… I didn't feel as if I	1. Self-monitoring*

	and prolonged recovery (barrier) Confidence to resolve problems (barrier & facilitator)	could cope, you know, with everything and I was forgetting my tablets" (William) "The thing was, when I came out, I couldn't read them for it to stay in, you know. And I could have been doing the wrong tablets…" (Elizabeth) "Since she's been in hospital she doesn't go out of bed…[…]… I don't know whether it's...why she's doing that or if she's just more tired, so it's just different." (Elaine's daughter) "I wasn't getting any Warfarin at all to begin with and until I turned round and said 'I want to see somebody'. I said 'somebody's told me that if I mess about with Warfarin it's dangerous'." (Robert) "Like I asked about the leg; this is my leg not yours, so I don't care what you think about that, if I'm not happy about it I will tell you and I will ask you to see your superior." (James)	2. Graded tasks, start with easy* 3. Increasing skills; problem solving, decision making* 4. Coping skills* 5. Rehearsal* 6. Social processes of encouragement, pressure, support* 7. Feedback* 8. Self-talk* 9. Motivational interviewing* 10. Verbal persuasion^

		"…but inside the bag of medication there was no explanatory items, I just had to work it out for myself…. Just by looking at it, yeah." (James)	11. Focus on past success^
Beliefs about consequences	Anticipating gaps in care (facilitator)	"Well yeah, 'cause it's belt and braces, I needed to make sure that they'd got the right you know…[…]… That's why I rang them 'cause I thought if there's going to be any delay I'll just go and pick it up myself." (Patricia's daughter) "I once took tablets with me and they all went missing. So I swore blind I'd never take tablets again." (Robert) "so when I'd been in the doctors I went straight to the chemist as well and I give them a copy of the new tablets because I thought if I don't do it, nobody's going to do it." (Elaine's daughter) "Because when I first went up I said to her, "have you had a prescription from the hospital?" They weren't sure because, as I say, it could have gone to [de-identified] Surgery but they haven't received it." (Charles)	1. Self-monitoring* 2. Persuasive communication* 3. Information regarding behaviour/ outcome* 4. Feedback* 5. Emotional consequences^ 6. Salience of consequences^ 7. Covert sensitization^ 8. Anticipated regret^

	Beliefs about missed/ incorrect doses (facilitator)	“a lot of things can happen in hospital and you always have to be careful what you’re taking because sometimes they give you a prescription and the chemist sends you the wrong thing, you know.” (Winifred) “If I don’t take the diabetic, I can go into a coma, faint, to me it’s not happened yet, I say be careful for taking the medicine.” (Eleanora) “Well I don’t know what would happen if I didn’t. Would I collapse and die? I don’t know. You don’t know, do you?” (Mary) “I have to stick to it because with all them what I take, I would be lost if I missed any and anything, you know, and you’re not supposed to double up.” (Enid) “I think well if they’re not delivering my tablets, if I miss one a day, it throws me all out. And I can’t miss one a day; I’ve got to take every tablet so.” (Enid)	9. Social and environmental consequences^ 10. Comparative imagining of future outcomes^ 11. Vicarious reinforcement^ 12. Threat^ 13. Pros and cons^ 14. Covert conditioning^

	Trust and faith in the system (barrier & facilitator)	"…my mum was discharged on Thursday so Wednesday was her last day of supply so for me it was imperative that it came on that day 'cause she needed to start it the Thursday morning you see. That's why I rang them…" (Patricia's daughter) "Yeah, but they said 'you can take them', was it… Paracetamol, you know, 'three or four times a day', I said 'I don't want to'. I take two in a morning and two at night, that does me. .. But I don't take them… I try and not take them, I don't want to get really, really hooked on them." (Shirley) "My mind, because many a time I've read up where people have been given the wrong medication, so to be safe, for my peace of mind, nobody else's, I like to question each tablet." (Marie) "I thought that really I had faith in the fact that I knew they'd changed some things round and I thought well surely they're	

	Perceptions about quality of post-discharge care (barrier & facilitator)	giving the right things 'cause that's how you feel isn't it?" (Patricia's daughter) "I've got another box of them and then I just hope that they'll send me some more. They say they've got my new prescription now so I'm just hoping that the next lot will be everything that's on there, hopefully." (Joan) "He'll explain it you know, I just trust him [pharmacist] as well." (Mary) "Well you, you feel like you can't trust people don't you, to do their job and communicate" [Elaine's daughter] "Which is unusual really, you'd think they'd check it [blood pressure] because surely it's always been high, now suddenly it's gone low, so I think really they should really check it." (Joan)	

	Perceptions about lack of easy access to the GP (barrier)	"Well I think they're good because they [chemist] messed about a lot with hospital, you know when they're changing them, I mean they've got to change all these dosette boxes and get them back to me and they don't complain" (William) "Someone from the hospital rang me up and keeps asking me questions, yeah about my diabetes and then I've got the xxxxx ringing me up about my diabetes, I said, "I wish you would get your act together and sing off the same hymn sheet, I'm being bombarded."" (James) "There's no communication. It's like a different factory set up, 'oh we're not speaking to them, we're not speaking to them because we get work off them so keep quiet.' That's the way I feel and that…" (Betty's husband) "…when I phone them I never get no b****y answers because she's like my b****y a**e her in reception" (Barbara)	

	Previous experience in context of post-discharge meds management (facilitator)	“It’s terrible to get an appointment. All they say is, “The doctor will ring you back.”” (Marie) “No, because trying to get to see my GP it could take you two or three weeks to book an appointment.” (Charles) “Yeah, it’s impossible, they just don’t… nobody answers. They just… they keep you on there like, like I say it were 35 minutes one day” (William) “They always say the doctor’s coming but when the doctor comes it’s always a nurse and they don’t say anything.” (Elsie) “If your tablets have been changed you’ve got to let them know.” (Dorothy) “I’d had, I had a lot of this with my dad didn’t I, he was in hospital an awful lot so I just over the years think oh well that’s okay ‘cause when he comes out I’ll look in the dosette box, I’ll see what he’s on, I know what the list is and I’ll find out and	

		make sure he gets the right thing at the right time and that's what we've always done isn't it?" (Patricia's daughter) "I had to go through all that again, you know? Cause I… I phoned them up. I said, 'well, I've been in hospital'. 'Oh, have you?'. 'Yes', I said, 'I've been in there a month altogether'." (Alice)	
Motivation and goals	Lack of curiosity in medication: "I just take what's in the box" attitude (barrier)	"I just take it." (Dorothy) "Don't ask me love, I just take what's in the box…" (Marie) "I just take them. I suppose if you've been an old soldier and it's… I just take them." (Charles) "I didn't take… I thought 'well, I like take what you give me and that and that's the end of it'."[Harry] "Now, probably somebody will say, "Well, read the delivery note, the prescription, it tells you all about your tablets," but how many people read that information? I don't. I don't read it all." (John)	1. Goal/ target specified: behaviour or outcome* 2. Contract* 3. Rewards, incentives* 4. Graded tasks, start with easy* 5. Increasing skills* 6. Social processes of encouragement*

	Intrinsic motivation driven by beliefs about the system (barrier & facilitator) Prioritisation of certain medicines	"You see when I go in hospital, everything changes. That gets changed and they don't know I'm in hospital, so when I come out, I've got to phone them and say, 'I haven't got my medicine'." (Alice) "We are expecting to attend a follow-up… I know our GP will have received a copy of this and that's it isn't it. Just have to wait and see now." (Mary) "When I first come out because them's things you do forget don't you? And every time they [Reablement] tell you, then it goes in book that they're prompting you, so that goes against you." (William) "No only when they change the tablet, hospital ring straight to my chemist and it carry on that way." (Eleanora) "But Penicillin, I mean you only get them for about eight days, so one box probably a week, and I know how to cope with	7. Persuasive communication* 8. Information regarding behaviour/ outcome* 9. Motivational interviewing* 10. Goal setting^ 11. Review of outcome goals^ 12. Review behaviour goals^ 13. Action planning^

	(barrier & facilitator) Perception of importance of medicines (barrier & facilitator)	them; it's the main ones that are for the heart and the blood that I have to watch, you know what I mean?" (Enid) "Some medications I cannot miss. Some of them it's fine but some of them I just cannot miss them." (Winifred) "I can't just ignore them love, that's why I'm so keen on them, I have to think and time when I take them, you know what I mean?" (Enid) "No, doesn't, no because I'm nearly at the end of my time aren't I? (Laugh) I am, I am, I am, yeah, so it doesn't bother me, no, no it doesn't bother me at all." (Barbara)	
Memory, attention and decision processes	Changes to routine disrupt pre-admission established daily patterns (barrier)	"I mean we've managed like we always do, but it's been hard work, like I say because her routines gone now…" (Elaine's daughter) "I've started to take my medication different now, different times. She wrote it all down what I've got to do. So I get up	4. Self-monitoring* 5. Planning, implementation* 6. Prompts, triggers, cues*

	Memory lapses affect knowledge and capability (barrier)	about half past six in a morning and take a cup of coffee, make myself a cup of coffee, and then just wait a bit and take another couple of tablets and then I take another one that leaves me two after I've had my breakfast." (Betty) "Well I get upset love but I think I can't double up, I can't take double, and then I've got to get back into it gradually by saying 'oh I won't take that at four today, I'll take it at five' or below, whichever is nearest time and I have to bring it back down back myself because nobody helps you…" (Enid) "Now that my memory's going and I'm not as sharp as I was." (Elsie) "Remembering to keep my supply in; I'd start to panic." (Mary) "Well yes because it tells me what to take you know because I'm losing my memory a bit I think you know so it just keeps me concentrating." (Doris)	

	Forgotten medicines related questions by the times medics were present or appointments occurred (barrier) Drawing assumptions after discharge (barrier)	"…she didn't know so she said 'oh you'll have to ask doctor' but by the time you get to see him, I forgot about it." (William) "It's just guesswork on our part but if it says that then you've got to guess haven't you that that's what they're meaning." (Robert's wife) "And so, I said to my daughter, "Did I have that sort of thing last time?" So anyway, she read it and she said, "Yeah, you probably did." But she said, "I don't really know what they did, you know.""(Elizabeth)	

	Medicine regimens are complex (barrier)	“Because she was telling me the name of medicine, I don’t remember, is too many tablet, you know, nearly 20 tablets a day.” (Eleanora) “I’m on that much medication I don’t know what amount I have to take.” (Marie) “Well, you know, I just… with everybody telling me things I just think oh I can’t do with this every time, do you know what I mean? Doctor telling me… I mean you’ve to take notice of your doctors, that’s what you go for, but then I just think oh I’m going to just sit back and forget them, you know? And then I think oh I can’t because I’m just doing harm to myself” (Enid)	
Environmental context and resources	Multiple different medicines within the home causes confusion (barrier)	“I'm getting confused, I'm on that much medication and then I get used to that and then it’s getting changed again, then the chemist, I'm not kidding you, I'm up to here with medication, to me, I’ve told them, I said it’s all a waste of resources, because I'm sending them back carrier bags full.” (Marie)	7. Environmental changes* 8. Restructuring physical environment^ 9. Discriminative cue^ 10. Prompts/ cues^

	Delayed or over-supplies within community (barrier)	"I should really sort them out because I've got that many medicines I don't take." (Joan) "I'd only just made it up so there's 50-odd Metformin tablets there, the only thing I do is put them in a plastic box, what am I going to do with them then?" (Robert) "…every week I have to ring them up; you haven't given me this and you haven't...and this is short, I've got this one I don't want…" (James) "I rang the doctor up and he said 'I'll get some sent out' but they only sent a couple of week's out instead of a month." (Shirley) "Well it's been a case of the chemist sending me things and getting carried away, I've got sharps boxes, I had about six of them and then that thing for your bowels, I've had loads of that and you know, yeah is it Amitriptyline, I've got a lot of that." (Joan)	11. Restructuring social environment^ 12. Avoidance/ changing exposure to cues for behaviour^

	Haphazard attendance of formal carers or community health care professionals (barrier)	"…homecare, she [social worker] stopped the first team, they wanted to give me the second team, now this the second team for two weeks since hospital nobody is coming." (Eleanora) "Well I haven't any now; I can't take anything for pain or anything because they've (formal carers) not given me these that I always have." (Elsie) "Well the doctor has put it down, three times he's put it down for her (Heart Failure nurse) to come but they haven't been yet, so whether they're busy or whether it's because I haven't been in I don't know." (Dorothy)	
	Adaptation of physical layout of medicines at home (facilitator)	"I keep them in the magazine rack, they're in a sandwich box in magazine rack, so they're in order, go round sort of thing…" (Joan) "My daughter, she sorts out my medication for me until I get used to it myself, you know I've two little cups or little glasses	

	Use of practical physical resources (e.g. handwritten checklists, MCAs)	and she'll do my morning ones in one and do the night ones in the other." (Marie) "I've put what I'm taking in the lid, in that lid and do it that way and just take them." (Doris) "I'll put them where they belong and I've got a drawer I put them in." (Shirley) "I just go round, it isn't a clock on it, but I do top as… you see my morning heart tablets I take first thing so they don't go on there. And then I do my Warfarin because they're important and then I work round with all my day tablets till it comes to my Warfarin, you know, because I work then quarter of an hour, if you know what I mean, in between which is on that tray" (Enid) "…when the next prescription comes from there, well they're going to have it put into these containers for me so I'll be able to get my own then." (Elizabeth)	

	(barrier & facilitator) Clarity of written information (barrier & facilitator)	"On the paperwork [PILS], and then they send that for you. Like this one came here this morning and they send it like this and you can check it to make sure." (Winifred) "no it (discharge note) was very specific yeah, yeah it's fine." (Patricia's daughter) "I know when I was in hospital they never put it down (INR reading), I don't know which book they're using, they gave me a book in hospital. Now where have they put it? And they haven't put it down, oh they have on that." (Dorothy) "Well yes because it (discharge letter) tells me what to take you know…" (Doris) "Oh yes. It said how many times a day but like I say , there's one lot of tablets I had to take once a week for three weeks	

		when I came home, this one tablet weekly for three weeks." (Charles) "Well it lets me know what they're for. [laughter]. If there's any change I just read, you know because it explains how to take them and explains all the side-effects they can have on you." (Charles) "No, nobody, I mean they're all wrote down here but that's just… I don't know what it means, you know, and I don't know what they're for." (William) "He said, "All the tablets are down here what you're taking," and that, you know and that, so…" (Ruth)	
Social influences	Practical input from informal carers (facilitator)	"…when it comes to checking anything, if anybody queries it then my daughter does it." (Hazel) "They ring it on my mobile and I don't see them half the time, our xxxxx looks at my phone, she says, "Mum, you've got an	1. Social processes of encouragement*^ 2. Demonstration by others*^ 3. Social comparison^

	Support from healthcare professionals (barrier & facilitator)	appointment, you've another appointment, you've another here."" (Dorothy) "He only has tablets in the morning. So, we've got people coming in in the morning to give him his tablets and then err at night time to put… to do the connection for the night bag." (Harry's daughter) "My tablets, my daughter in law has to phone them. It's a repeat prescription but my daughter in law has to phone them and make sure they've put it in because they don't always put it in." (William) "No, you see the doctors before for warfarin, take six, are ringing me to say "No, you take it," ringing me "No more taking six, take five."" (Eleanora) "They put a letter, it's still there, it's sellotaped down. It comes in your bag of tablets. It's sellotaped to my bag that I need a	4. Information about other's approval^ 5. Social support (emotional)^ 6. Social support (practical)^ 7. Vicarious reinforcement^ 8. Restructuring social environment^ 9. Identification of self as role model^ 10. Social reward^

		review for my six months, I think it's six months my review or something. So, I just have to ring up and get that." (Joan) "…first time it's ever happened, we're not sure if it'll ever happen again, the diabetic nurse actually made a house call." (Robert's wife)	
Emotion	Frustrations over reduced ability to self-manage medicines (barrier)	"I said 'Where's all my tablets gone?' and they said 'Oh we have to keep them and to give them you, you know' so but the fact that they were taken without saying anything to me made me extremely cross at the time." (Mary) "…but when it's the same I can't understand why they don't use my own dosette box which makes life easier for me and easier for them but they won't do it." (William) "…like when I were in hospital and, like I said they wasn't using my dosette box, they said I wasn't allowed, well I said, "Why did you ask me to bring them all in?"" (Marie)	1. Stress management* 2. Coping skills* 3. Reduce negative emotions^ 4. Emotional consequences^ 5. Self-assessment of affective consequences^ 6. Social support^

	Frustrations over perceived lack of continuity/ follow-up (barrier) Concern when unexpected	“Yes I want to be in charge of my own medicine, I don’t want somebody coming in and saying “Take this, take that.” I want to know what it is and how it works.” (Elsie) “I mean it is just that annoying when you have to keep ringing and thinking why but it’s not the first time I’ve had to go over the medication in doctor’s surgery.” (Elaine’s daughter) “I said, “They told me it was sent late, say mid-afternoon. Now they're saying they haven't received it.” …[…]…So why? Who is telling stories? It took two days to get a prescription.” (Betty’s husband) “I said, “Yes, but in ten minutes you still haven't told me why you stopped Metformin.” I said, “I've asked many times and I'm not going to leave now until I know.” “We were giving you too many.” I thought that's the most feeble excuse.” (Robert)	

	medicines were supplied (barrier)	"…but one of the things that absolutely stunned me I have to say, she was given that carrier bag which is down there with her new medication in because they had made some alterations but alongside that they shoved in all the other stuff that she took in with her." (Patricia's daughter) "I said it's all a waste of resources, because I'm sending them back carrier bags full and it's just getting dumped, so to me it's just a waste of medication." (Marie) "I wanted to say do you think you're a doctor that you're prescribing these? I don't need these, when I need them I'll let you know." (James)	
	Worries/ anxiety about onward medicines management (barrier and facilitator)	"I went down to the doctors with the discharge note on the Wednesday because I were worried about the dosette box that comes." [Elaine's daughter]	

Behavioural regulation	Flexible action plans developed by patients and carers (facilitator) Reminder strategies for new medicines (e.g. checklists, dosette boxes) (facilitator)	"…if there had have been a problem I'd just get in the car and go and collect it." (Patricia's daughter) "Yeah, because it's nearly a certain time you see and if they haven't come at a certain time I phone them" (Ruth) "I understand it a bit better now but I still keep that [checklist] beside us to check it, you know, to see I'm doing it right." (Betty) "What times we have to do them …[…]… We tick it off when we've done it." (Mary – homemade checkbox list) "No, I do, I cut them. I cut them off of strip and then I know I've finished them then." (Ruth)	Self-monitoring of behaviour^

	Adapting personalised routines (facilitator)	"Well this board one is a brilliant idea…. I forget everything you see, so I put that board there and just write what you're having and you'll remember which a good idea is." (Winifred) "I've got three tablets I take at the bedside. The one I take as I get out the bed and two I take after I've got showered and that and then I used to come in the kitchen and there were three there I had to take and I used to take them and then I had some I had to take you know when I got sat down but now I just get that out and go through that list." (Doris) "Yeah, like an eggcup and I put them all in there for me to take, when I have to take them, you know, but you see on a morning when I'm having my breakfast and that, well I have them here and I take the biggest ones first, that's four of them, and then the little ones" (Ruth)	

BCT descriptions developed specifically for this study

Potential BCTs	**Elaboration on how the BCT could be used to encourage post-discharge medicines management, based on the definition of that BCT (Michie et al. 2014)**
Information regarding behaviour, outcome*	Provide the patient with written or verbal information E.g about their medicines management responsibilities after hospital discharge or when/ how to get help if a problem is identified
Goal/ target specified: behaviour or outcome*	Set or agree on a goal defined in terms of medication management practices to be achieved E.g. agreeing new medicines-taking routines, to ask for a medicines discussion with the community pharmacist
Persuasive communication*	Credible source presents arguments in favour of medicines management. Note, there must be evidence of presentation of arguments; general pro-behaviour communication does not count. E.g. Doctor tells the patient that they can successfully perform medicines management, despite their recent hospital stay
Antecedents^	Provide information about antecedents (e.g. social and environmental situations and events, emotions, cognitions) that reliably predict medicines management performance.
Information about health Consequences^	Provide the patient with examples of consequences of managing medicines E.g. medication error, risk of harm, feeling in control, symptom reduction

Feedback on Behaviour^	Monitor and provide informative or evaluative feedback to the patient about their medicines management performance
Biofeedback^	Provide feedback about the body (e.g. physiological or biochemical state) using an external monitoring device E.g. blood pressure
Monitoring*	Observe or record medication management activities/ outcomes of medication management with the patient's knowledge as part of a behaviour change strategy
Self-monitoring*	Establish a method for the patient to monitor and record medicines management behaviour(s) E.g. recording when supplies are due to be ordered or received/ outcomes of medicines management
Rewards, incentives*	Arrange for patient to receive an award (E.g. money, certificate, valued object) if there has been effort and/or progress in achieving medicines management
Graded tasks, start with easy*^	Set the patient easy to perform tasks, making them increasingly difficult, but achievable until medicines management is performed E.g. adherence tasks followed later by error detection tasks
Increasing skills; problem solving, decision making*	Analyse, or prompt the patient to analyse, factors influencing their medicines management behaviour and generate or select strategies that include overcoming barriers and/or increasing facilitators
Rehearsal*^	Prompt practice or rehearsal of medicines management behaviour one or more times in a context or at a time when the performance may not be

	necessary, in order to increase habit and skill E.g. checking of medicines prior to administration during hospital admission
Demonstration by others*	Provide an observable example of the performance of the medicines management behaviour, directly in person or indirectly e.g. via film, pictures, for the patient to aspire to or imitate
Perform behaviour in different settings*	E.g. in hospital, at home
Body changes^	Alter body structure, functioning or support directly to facilitate the performance of medicines management tasks
Habit reversal^	Prompt rehearsal and repetition of an alternative behaviour to replace an unwanted habitual behaviour e.g. to prompt regular use of pain reliever rather than when in pain for chronic pain conditions, or to prompt the use of steroid inhalers regularly rather than only when short of breath
Habit formation^	Prompt rehearsal and repetition of the behaviour in the same context repeatedly so that the context elicits the behaviour E.g. ask the patient to review an administration checklist before taking each dose, suggest to the patient to take their medicines at meal times/ put medicines next to the tea-bags to help them remember to take their medicines and build medicines into daily routines

Homework	Set homework tasks e.g. via buddy or peer support who could check with the patient to see how they have got on with medicines management tasks
Social processes of encouragement, pressure, support*	Social support (emotional): others listen, provide empathy and give generalised positive feedback.
Self-talk*	Prompt positive self-talk (aloud or silently) before and during the medicines management behaviour
Motivational interviewing*	Elicit self-motivating statements and evaluation of own behaviour to reduce resistance to change
Verbal persuasion^	Tell the person that they can successfully perform the wanted behaviour, arguing against self-doubts and asserting that they can and will succeed
Focus on past success^	Advise to think about or list previous successes in performing medicines management (or parts of it)
Emotional consequences^	Provide information (e.g. written, verbal, visual) about emotional consequences of performing medicines management E.g. can increase satisfaction and reduce frustration
Salience of consequences^	Use methods specifically designed to emphasise the consequences of performing the behaviour with the aim of making them more memorable (goes beyond informing about consequences) E.g. provide images of a well organised medicines cupboard alongside quotes from other patients describing the benefits of doing this

Covert sensitization^	Advise to imagine performing the unwanted behaviour in a real-life situation followed by imagining an unpleasant consequence E.g. Imagine not checking medicines before taking them, then experiencing side effects because the medicine was incorrectly dispensed
Anticipated regret^	Induce or raise awareness of expectations of future regret about performance of the unwanted behaviour
Social and environmental consequences^	Provide information (e.g. written, verbal, visual) about social and environmental consequences of performing the behaviour E.g. reduces burden for family
Comparative imagining of future outcomes^	Prompt or advise the imagining and comparing of future outcomes of changed (performing medicines management tasks) versus unchanged (non-performance) behaviour E.g. better quality of life, less hospital readmissions, less confusion about medicines
Vicarious reinforcement^	Prompt observation of the consequences (including rewards and punishments) for others when they perform the behaviour
Threat^	Inform that future punishment or removal of reward will be a consequence of performance of an unwanted behaviour
Pros and cons^	Advise the person to identify and compare reasons for wanting (pros) and not wanting to (cons) change the behaviour

Covert conditioning^	Advise to imagine performing the wanted behaviour in a real-life situation followed by imagining a pleasant consequence
Contract*	Create a written specification of the behaviour to be performed, agreed on by the patient, and witnessed by another
Goal setting^	Set or agree on a goal defined in terms of the medicines management behaviour or outcome to be achieved
Review behaviour/ outcome goals^	Review goal(s) jointly with the person and consider modifying goal(s) or strategy in light of achievement. This may lead to re-setting the same goal, a small change in that goal or setting a new goal instead of (or in addition to) the first, or no change
Action planning^	Prompt detailed planning of performance of the behaviour (must include at least one of context, frequency, duration and intensity). Context may be environmental (physical or social) or internal (physical, emotional or cognitive)
Prompts, triggers, cues*	Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance e.g. prompt patient to keep their inhalers next to their toothbrush as a trigger to administer twice a day
Environmental changes*	Change, or advise to change the physical environment in order to facilitate performance of the wanted

	behaviour or create barriers to the unwanted behaviour (other than prompts/cues, rewards and punishments)
Discriminative cue^	Identify an environmental stimulus that reliably predicts that reward will follow the behaviour
Restructuring social environment^	Change, or advise to change the social environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour (other than prompts/cues, rewards and punishments)
Avoidance/ changing exposure to cues for behaviour^	Advise on how to avoid exposure to specific social and contextual/physical cues for the behaviour, including changing daily or weekly routines
Social comparison^	Draw attention to others' performance to allow comparison with the person's own performance
Information about other's approval^	Provide information about what other people think about medicines management. The information clarifies whether others will like, approve or disapprove of what the person is doing or will do e.g. other people do ask their community pharmacist for advice and the pharmacist welcomes this
Social support (emotional)^	Advise on, arrange, or provide emotional social support (e.g. from friends, relatives, 'buddies' or staff) for performance of medicines management
Social support (practical)^	Advise on, arrange, or provide practical help (e.g. from friends, relatives, colleagues, 'buddies' or staff) for performance of the behaviour

Identification of self as role model^	Inform the patient that one's own behaviour may be an example to others
Social reward^	Arrange verbal or non-verbal reward if and only if there has been effort and/or progress in performing medicines management
Reduce negative emotions^	Advise on ways of reducing negative emotions to facilitate performance of medicines management e.g. remind person that slips and lapses in behaviour are inevitable and are not to be worried about as long as the intention is good