Optimising medication use for people living with dementia and their caregivers

Thesis submitted in accordance with the requirements of the University College London for the degree of Doctor of Philosophy by

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Plagiarism Statement

This thesis describes research conducted in the University College London (UCL) School of Pharmacy between 2013 and 2017 under the supervision of Professor Felicity Smith and Dr Mine Orlu. I, Dalal J M S Alsaeed, confirm that the work presented in this thesis is my own and that any parts of the work that have been conducted by collaboration are clearly indicated. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signature: ___________________________ Date: _____________________
Dedicated to my parents, Hana and Jamal, for their never-ending love, guidance and for teaching me there are no limits to what I can achieve
Abstract

**Background:** As people living with dementia (PLWD) gradually lose their ability to manage their medicines appropriately, family members or friends step in to assist them. A variety of medication and person-related factors affect the medication use process.

**Aim:** To identify and examine the factors contributing to the challenges to medication use from the perspective of PLWD and from their caregivers in the community and care home setting, in order to help maintain optimal therapy for this patient population, with a focus on the use of appropriate drug formulations, along dementia progression. In addition, to make recommendations for assistance for PLWD and caregivers to help alleviate caregiver burden and optimise the medication use process.

**Methods:** To enable a comprehensive examination of issues from perspectives of PLWD and their caregivers, in relation to care setting and dementia severity, participants were recruited from the community and care homes in London. Semi-structured interviews were conducted, and medicines administration was observed in 4 care homes providing different types of care (nursing, residential, and mixed). Interviews were audio-recorded and transcribed verbatim. A conceptual model was developed based on a review of the literature; the domains provided the framework for thematic analysis of the data to achieve the research aim. Analysis was an iterative process and constant comparison was employed across interview transcripts.

**Results:** Community results identified 6 areas that affect medication use; these are caregiver burden, the PLWD’s autonomy, scheduling and administering of medications, choice of formulations, interactions with formal care, and lack of medication information. Care home results also identified 6 areas; organisational aspects of the medication round, interactions between staff and residents, the residents’ autonomy, choice of formulation, staff knowledge, and interactions within the care home. Findings have also identified how key changes along dementia progression affect medication use. These include the development of swallowing difficulties, increase in the number and variety of medications, appropriateness of formulations, decline in cognition and communication, behaviour changes, caregiver expectations for the future, the PLWD’s autonomy, transition from self to caregiver-led care, and changes in support needs.
**Conclusion:** The study has identified challenges to medication use in PLWD and their caregivers along dementia progression and informed recommendations to optimise medication use and alleviate caregiver burden. Recommendations include a proposed medicines optimisation model for PLWD and their caregivers, suggestions for tailored consultations and medication use reviews, improvements for care home organisation, and specific recommendations for the pharmaceutical industry for the development of dementia-friendly formulations. Furthermore, suggestions are proposed to adapt the Family Caregiver Medication Administration Hassles Scale for caregivers of PLWD based on the findings.
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<table>
<thead>
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<th>Abbreviation</th>
<th>Definition</th>
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<tbody>
<tr>
<td>ADR</td>
<td>Adverse drug reaction</td>
</tr>
<tr>
<td>BAME</td>
<td>Black, Asian and minority ethnic</td>
</tr>
<tr>
<td>BPSD</td>
<td>Behavioural and psychological symptoms of dementia</td>
</tr>
<tr>
<td>CAQDAS</td>
<td>Computer-assisted qualitative data analysis software</td>
</tr>
<tr>
<td>CAS</td>
<td>Caregiver Activity Survey</td>
</tr>
<tr>
<td>COREQ</td>
<td>Consolidated Criteria for Reporting Qualitative Research</td>
</tr>
<tr>
<td>CQC</td>
<td>Care Quality Commission</td>
</tr>
<tr>
<td>CQUIN</td>
<td>Commissioning for Quality and Innovation</td>
</tr>
<tr>
<td>DBS</td>
<td>Disclosure and Barring Service</td>
</tr>
<tr>
<td>EMA</td>
<td>European Medicines Agency</td>
</tr>
<tr>
<td>FCMAHS</td>
<td>Family Caregiver Medication Administration Hassles Scale</td>
</tr>
<tr>
<td>GP</td>
<td>General practitioner</td>
</tr>
<tr>
<td>HCP</td>
<td>Health care professional</td>
</tr>
<tr>
<td>JRO</td>
<td>Joint Research Office</td>
</tr>
<tr>
<td>MAR</td>
<td>Medicines administration record</td>
</tr>
<tr>
<td>MCA</td>
<td>Multi-compartment compliance aid</td>
</tr>
<tr>
<td>MCI</td>
<td>Mild cognitive impairment</td>
</tr>
<tr>
<td>MDT</td>
<td>Multi-disciplinary team</td>
</tr>
<tr>
<td>MHRA</td>
<td>Medicines and Healthcare products Regulatory Agency</td>
</tr>
<tr>
<td>MMSE</td>
<td>Mini Mental State Examination</td>
</tr>
<tr>
<td>MUR</td>
<td>Medication Use Review</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
</tr>
<tr>
<td>NPSA</td>
<td>National Patient Safety Agency</td>
</tr>
<tr>
<td>NRES</td>
<td>National Research Ethics Service</td>
</tr>
<tr>
<td>ODF</td>
<td>Orally disintegrating film</td>
</tr>
<tr>
<td>ODT</td>
<td>Orally disintegrating tablet</td>
</tr>
<tr>
<td>OTC</td>
<td>Over the counter</td>
</tr>
<tr>
<td>OP</td>
<td>Original packaging</td>
</tr>
<tr>
<td>PEG</td>
<td>Percutaneous endoscopic gastrostomy</td>
</tr>
<tr>
<td>PLWD</td>
<td>Person/People Living With Dementia</td>
</tr>
<tr>
<td>PRN</td>
<td>Pro Re Nata (as needed)</td>
</tr>
<tr>
<td>SmPC</td>
<td>Summary of Product Characteristics</td>
</tr>
<tr>
<td>SODF</td>
<td>Solid Oral Dosage Forms</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
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First and foremost, I would like to thank God for providing me with this opportunity.

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Impact Statement

Dementia is fast becoming a global challenge due to the shift in demographics towards an older population. Governments worldwide are endeavouring to develop and implement strategies to deal with this global challenge, from early diagnosis to better provision of healthcare. One area requiring improvement is medication use in this patient population. This is further complicated as people living with dementia (PLWD) rely on family caregivers for assistance with medication use, thus both should be involved in any effort in optimising medication use. Supporting family caregivers is deemed a priority by the UK government, and the present study has gained their perspectives to inform recommendations that meet their and the PLWDs’ needs.

The implications of the study findings on practice and policy are wide-ranging. System-level recommendations include improvements to care home organisation, which includes flexible medication rounds, medication-specific training and education for staff. Furthermore, the findings advocate the inclusion of the pharmacist in the care home setting to optimise medication use by reviewing residents’ medications.

The findings have also informed recommendations for GP consultations and pharmacy services (MURs) to tailor them for PLWD and their caregivers. A guideline for GPs to use in consultations is proposed, and improvements regarding the operational aspects of the consultation are suggested. Changes to medication use identified in the findings are also included in the guideline to ensure consultations are adapted along the dementia trajectory. Suggestions for the content and operation of tailored MURs are also proposed to meet PLWD and their caregivers’ needs. The informational needs of caregivers and PLWD are also identified and are advised to be included in consultations with HCPs.

The findings have also assisted in identifying areas not available in the Family Caregiver Medication Administration Hassles Scale and have proposed refinement of the tool for use in caregivers of PLWD. Furthermore, suggestions for how it should be piloted and evaluated are also detailed. This adapted tool can assist in identifying medication-related burden in caregivers of PLWD and measure the effectiveness of interventions. Information regarding changes to medication use along dementia progression are also identified and can be used to design and develop leaflets for
future caregivers and PLWD to prepare them and bring to their attention areas of concern they might wish to discuss with their HCP.

The findings also identified formulation issues at both care settings and along dementia progression, and emphasised the importance of reflecting this in prescribing decisions. Previous research has focused on older people in general. The study findings also provide input for the European Medicines Agency and the pharmaceutical industry on recommendations for the design and development of formulations that are age-appropriate and dementia-friendly to tackle challenges associated with cognitive and physical impairment and swallowing difficulties. Stakeholders from academia, the pharmaceutical industry, regulatory bodies and the public (PLWD and their caregivers) should endeavour to focus on developing dementia-friendly formulations, support and services that meet the PLWD and their caregivers’ needs. The findings also propose ideas for future research to move the work forward and develop and test interventions to optimise medication use and alleviate caregiver burden.
Chapter 1: Introduction

1.1. Dementia and older people

Population demographics in both developed and developing countries are shifting towards a population with a higher proportion of people aged 65 years of age and above (Stegemann et al., 2010; Stegemann, 2016). It is predicted that by 2050, people aged 60 onwards will reach 1.25 billion globally (Prince et al., 2013). In the United Kingdom (UK), it is predicted that 23% of the population will be 65 years of age or over in the year 2035 (ONS, 2012). This shift is due to a variety of factors, such as improved healthcare to advances in therapy, resulting in an increase in life expectancy. The elderly are a heterogeneous patient group; there is the ‘early old’ from 65 to 74 years, the ‘middle old’ ranging from 75 to 84 years, and the ‘late old’ ranging from 85 years onwards (Swanlund, 2010). Unfortunately, it is not always simple to provide care based on age group alone. Therapy and care needs to be tailored to elderly patients and they should be considered as individuals due to the difficulty in classifying them in a specific group because of many factors such as medical history, functional and cognitive status, severity of illness, and co-morbidities. A rise in the elderly population means that more attention needs to be placed on their long term care and on age-specific diseases, such as dementia.

As people age, it becomes more likely they will suffer from a variety of chronic diseases, and they may be more prone to developing cognitive impairment and dementia. Dementia is a syndrome characterised by a progressive deterioration in cognition, ranging from mild to severe, affecting daily function. It may also cause disturbances in behaviour. Dementia is an umbrella term that encompasses a number of syndromes that include Alzheimer’s disease, vascular dementia, and Lewy body dementia (Ray and Davidson, 2014). Mild cognitive impairment (MCI) is a precursor condition to dementia, where individuals present with mild changes to cognition without it affecting daily activities (Alzheimer’s Association, 2017). Table 1.1 displays a table with the common types of dementia.
Table 1.1: Common dementia subtypes (adapted from (Prince et al., 2014))

<table>
<thead>
<tr>
<th>Dementia subtype</th>
<th>Early symptoms</th>
<th>Tissue damage</th>
<th>% of dementia cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alzheimer’s Diseases</td>
<td>Impaired memory, apathy and depression, gradual onset</td>
<td>Cortical amyloid plaques and neurofibrillary tangles</td>
<td>50-70%</td>
</tr>
<tr>
<td>Vascular Dementia</td>
<td>Similar to AD but memory less affected, mood fluctuations more prominent, physical frailty, stepwise onset</td>
<td>Blood supply to critical regions of brain, or more diffusely</td>
<td>20-30%</td>
</tr>
<tr>
<td>Lewy Body Dementia</td>
<td>Marked fluctuation in cognitive ability, visual hallucinations, Parkinsonism</td>
<td>Cortical Lewy bodies</td>
<td>&lt;5%</td>
</tr>
<tr>
<td>Fronto-temporal Dementia</td>
<td>Personality changes, mood changes, disinhibition, language difficulties</td>
<td>No single pathology – damage limited to frontal and temporal lobes</td>
<td>5-10%</td>
</tr>
</tbody>
</table>

Currently, there are four licensed medications that may assist in slowing down the progress of dementia and alleviating its symptoms, and consist of three acetylcholinesterase inhibitors (rivastigmine, galantamine, and donepezil) and one N-methyl-D-aspartic acid receptor antagonist (memantine) (Abetz et al., 2009; Brady and Weinman, 2013; López-Pousa and Arranz, 2013). However, these medications do not treat the underlying causes of dementia, such as beta-amyloid accumulations, neurodegeneration, and tau protein aggregation (Popp and Arlt, 2011).

The increase in life expectancy and the elderly population also means that the number of people living from dementia is on the rise. There were 46.8 million people living with dementia globally in 2015, and this number is estimated to reach 131.5 million in 2050 (Prince et al., 2015). These projections take into account increases in high, middle and low income countries, with the latter indicating sharper increases from 19.5 million in 2015 to an estimated 89 million in 2050 (Prince et al., 2015). An
estimated 42% of the population in the UK have a close friend or family member who is living with dementia (Department of Health, 2013).

Governments worldwide, as well as in the UK, have developed strategies to deal with this global challenge. In the UK, the National Dementia Strategy was issued in 2009. It is a five year plan that aims to raise awareness about dementia, as well as to implement early and better diagnosis, improve quality of care at all stages of the disease and at all settings, and reduce antipsychotic prescribing (Department of Health, 2009). The UK government has also agreed to provide funding of £130 million to this cause by 2025 (Alzheimer’s Society, 2013). In 2012, the then Prime Minister issued his challenge on dementia, which is a national programme aimed at improving dementia care and research (Department of Health, 2012a).

There are approximately 850,000 People Living with Dementia (PLWD) in the UK, and these numbers are predicted to increase to 1.7 million by 2051 (Department of Health, 2009; Alzheimer’s Society, 2014). It is estimated that two-thirds of these PLWD live in their own home, while the other third reside in care homes (Alzheimer’s Society, 2007; ONS, 2012). As the number of PLWD increases, so does the strain on healthcare services to meet their needs. The people with dementia attending memory clinics increased by 682% from 2008/2009 to 2014 (Hodge and Hailey, 2015). Dementia is costing the UK around £26.3 billion, with £11.6 billion attributed to family caregiver costs (Alzheimer’s Society, 2014), although indirect costs may be underestimated (Deb et al., 2017). The Department of Health has also issued the national dementia Commissioning for Quality and Innovation (CQUIN) in 2012 to highlight the importance of early diagnosis of dementia, as well as prompt and appropriate referral of patients (Department of Health, 2012b). The Department of Health and social care services are endeavouring to maintain PLWD in their homes for longer by providing better services and support that meet the needs of caregivers and PLWD (National Collaborating Centre for Mental Health, 2007). As PLWD gradually lose their independence, the cost to the government and society increases. Examples of such costs are caregiver burden and placement into residential or nursing homes for better care (Schmidt and Lieto, 2005).
1.2. Dementia in London

The proportion of people aged 65 and over in London varies by Clinical Commissioning Group, with the highest in Havering (16.4%) and the lowest in the Tower Hamlets (8.0%) and Central London at the average point (11.5%) (Healthcare for London, 2009). London has approximately 72,009 PLWD (Alzheimer’s Society, 2014). An estimated 34% of PLWD in London need constant supervision or care (Healthcare for London, 2009). There are around 17,300 new cases of late-onset dementia in London annually (Healthcare for London, 2009). In 2007, 54.8% of PLWD in London were at the mild stage, 32.3% at the moderate stage and 12.9% at the severe stage (Healthcare for London, 2009). There are approximately 40,000 PLWD in London residing in the community, while 23,000 PLWD are living in care homes (Healthcare for London, 2009).

Dementia services in London may not be fulfilling PLWD and their caregivers’ needs as they have expressed frustration with access to support. A compromise in the quality and provision of these services and support was reported, as they were not able to meet PLWD and their caregivers’ expectations which included timely diagnosis, treatment and information (Healthcare for London, 2009).

1.3. The role of the caregiver

As PLWD gradually lose their ability to manage their medicines appropriately, family members or friends step in to assist them. A family caregiver is defined as a relative or friend who has a personal relationship with the PLWD and provides assistance with a range of activities (Blum and Sherman, 2010). Some of the medication-related activities include administering medicines, managing side effects, and maintaining the medicinal supply (Goldstein and Rivers, 1996; Francis et al., 2002; Smith et al., 2003, 2015). PLWDs’ ability to make decisions may also be impaired (Hirschman et al., 2005, 2004). This requires PLWD to rely heavily on their family caregivers to manage their medicines and make decisions regarding their treatment, thus creating a burden for their caregivers, which may negatively impact the caregiver’s quality of life (Francis et al., 2002; Smith et al., 2003; Slattum and Johnson, 2004; Croog et al., 2006; Cotrell et al., 2006; Sörensen et al., 2006; Arlt et al., 2008; Schoenmakers et al., 2010; Brodaty et al., 2014).
The role of a caregiver of a PLWD may be difficult to handle, with some describing their average day as a ‘36-hour day’ (Brodaty and Green, 2002). Caregiver burden not only affects the caregiver, but can also lower the quality of life of the PLWD and is one of the reasons PLWD are placed in nursing homes (Bruce and Paterson, 2000; Gaugler et al., 2005; Buhr et al., 2006). Caregivers of PLWD are in most cases elderly and thus may already have conditions affecting their health, may be on a number of medications, and may have visual and physical problems; these all affect how they manage and administer medications for PLWD (Small and Dubois, 2007). In a survey conducted by the Alzheimer’s Society in the UK, 30% of family caregivers (n=61) stated that they found managing and administering medications a challenge (Alzheimer’s Society, 2012). They may also take on these duties with little to no formal support, adding to their burden (Crawford et al., 2015).

Receiving the diagnosis of dementia may be the start of the caregivers’ transition into their role (Ducharme et al., 2011). Transitions have been defined as occurring due to disruptive change, which the diagnosis of dementia can fall under (Schumacher and Meleis, 1994; Blum and Sherman, 2010). Some PLWD often overestimate their abilities in managing their medicines as they would like to stay independent and retain their autonomy for as long as possible (Cotrell et al., 2006; Arlt et al., 2008). This can create challenges when a transition is needed from self-led management to caregiver-led management. Autonomy is defined as ‘a person’s ability and opportunity to make decisions relating to his/her own wishes’ (Rosin and van Dijk, 2005). A stable partnership between the PLWD and their caregiver is favourable to build trust and ease the medication management process.

As PLWD’s cognitive abilities decline, their capacity to make decisions may also be compromised, which may give rise to ethical dilemmas regarding medication use. The Mental Capacity Act provides a legal framework for caregivers and HCPs to make decisions on behalf of PLWD when they lack the capacity (“Mental Capacity Act 2005: Code of Practice,” 2007). The act protects the PLWD’s right to autonomy until proven they are incapable of making decisions by themselves. However, it also encourages PLWD to be involved in the decision-making process with appropriate support for as long as possible. The PLWD’s capacity to make their own decisions regarding medication use is of importance to their autonomy in that context. They may in some instances lack the capacity to make decisions regarding when and how medications should be taken, but they can still be supported to respect their autonomy.
Respect for a person’s autonomy is important in health and social care, and in PLWD there are tensions in trying to maintain the PLWD’s autonomy due to decline in cognitive ability (National Collaborating Centre for Mental Health, 2007).

Caregiver duties may be reluctantly adopted by family and friends as the population is ageing (Martin et al., 2012). Recent survey results from England stated that 5 million adults took on caring duties; this accounted for 3 million households (The NHS Information Centre, 2010). From those adults surveyed, 10% stated they cared for someone living with dementia. It is estimated that 1 in every 3 people will take care of a PLWD in their lifetime (Department of Health, 2013). As the number of people diagnosed with dementia increases, there will be a reciprocal rapid demand for care, which is expected to rise by over 50% between 2007 and 2032 (Carers UK, 2014). Caregivers of PLWD often feel left out due to transitioning from being a spouse to a caregiver without support, lack of respite care, and lack of education and coping strategies as dementia progresses (Ray and Davidson, 2014). Providing support for family caregivers is deemed a priority, which has been highlighted by UK government reports (HM Government, 2010, 2008). One of the key messages from those reports was for healthcare professionals (HCPs) to involve caregivers in the patient’s care. Another key point was the timely delivery of relevant information and advice; this is especially vital during times when the patient and caregivers’ circumstances change (HM Government, 2010). Every caregiver’s circumstances are different, as are those of the person they are taking care of. That is why the support provided should be personalised, so as to be assured of its effectiveness.

Access to health and social care services in the UK were described as a ‘huge maze’ by family caregivers of PLWD (Peel and Harding, 2014). This highlights the issue that important information is not being provided to the PLWD and their caregivers, and effective and accessible sources of information and support are needed to overcome this. To be able to deliver better support services, family caregivers have to be recognised as experts and involved in designing and delivering these services.

### 1.4 Barriers to medicines use in PLWD

A variety of problems exist with regards to medicines for older people; one such problem is polypharmacy, which is the use of 5 or more medications (Stegemann et al., 2016). A study focusing on medication errors in 55 care homes in the UK identified that elderly patients were taking an average of 8 medicines (Barber et al.,
The increase in the likelihood of acquiring chronic diseases with age and consequently the issue of polypharmacy leads to the risk of non-adherence and medication interactions (Murray et al., 2004), which then leads to unwanted clinical and economic consequences. Polypharmacy is a risk in dementia, with this risk increasing as the disease progresses (Edirisinghe et al., 2015). It is imperative that patients adhere and comply with their treatment regimen to reach the expected therapeutic goals. Adherence rates in the elderly are variable but as the amount of medicines taken and the complexity of the regimen increases, the adherence rate potentially decreases (Miller, 2008; Brady and Weinman, 2013). Medications for the elderly, especially those with cognitive impairment, need to be simplified to make it easier for this patient population to adhere to their therapy and manage their medicines correctly and safely. Reviews should endeavour to distinguish between polypharmacy which means ‘on many medications’ and its negative connotation of ‘too many medications’ to ensure patients are taking the right medications tailored to their needs (Steinman and Hanlon, 2010; Wahllich et al., 2013). Other factors associated with unintentional non-adherence in PLWD include difficulty swallowing medications, lack of ease of medication administration, caregiver burden, caregiver preferences for drug delivery method, and quality of relationship between the dyad and HCPs (Brady and Weinman, 2013). The term dyad represents the caregiver-PLWD unit.

Potentially inappropriate medication use that may lead to adverse drug reactions (ADRs) is also prevalent in this patient population, with rates varying between 15% to 46.8% (Patel et al., 2017). Potentially inappropriate prescribing in a study population of 6826 PLWD found prevalence of 64.4% (Barry et al., 2016).

Changes in cognitive function that occur with age do not have a uniform presentation and these changes vary from one individual to the next (Stegemann et al., 2010). Cognitive impairment is one of the risk factors for non-adherence and inability to manage medicines (Cooper et al., 2005; Ahn et al., 2009; Allaire et al., 2009; Hayes et al., 2009; Campbell et al., 2012; Hudani and Rojas-Fernandez, 2016; El-Saifi et al., 2017). The prevalence of non-adherence in PLWD was shown to be between 2%-59% (Hudani and Rojas-Fernandez, 2016). It has been shown that decreases in patients’ Mini Mental State Examination (MMSE) scores are associated with a greater need for caregiver assistance and medicines management (Gray et al., 2001; Hutchison et al., 2006; Alagiakrishnan et al., 2013).
Another problem hindering adherence in this patient group is dysphagia (Perrie et al., 2012; Brady and Weinman, 2013). Dysphagia is the clinical term for swallowing disorders (Miller and Patterson, 2014); the process of swallowing is complex and involves two actions which are bolus formation and airway protection (Liu et al., 2014). As people age, their ability to swallow declines gradually; this is further compounded with certain diseases, such as dementia, as well as polypharmacy (Easterling and Robbins, 2008; Stegemann et al., 2010). In addition, certain medications, such as antipsychotics, may contribute to dysphagia (Stegemann et al., 2012; Fusco et al., 2016). Dysphagia has become a great healthcare issue; it is more common in nursing home residents and it is estimated that up to 53% suffer from it (Chouinard et al., 1998; Langmore et al., 2002). It is estimated that 11% of people in the community setting in England may have dysphagia (Holland et al., 2011; Liu et al., 2016). Sufferers of dysphagia not only have difficulties swallowing food, but also oral medicines which can lodge in their throats or cause aspiration (Carnaby-Mann and Crary, 2005; Stegemann et al., 2012; Fusco et al., 2016). It is often difficult to recognise and therefore patients may be automatically labelled as being challenging. Furthermore, many dysphagia sufferers believe their condition to be untreatable, indicating that they would not discuss this issue with HCPs (Ekberg et al., 2002; Schiele et al., 2013; Lau et al., 2015). Studies on different forms of dementia have found the prevalence of dysphagia to be between 13-57% (Bine et al., 1995; Horner et al., 1994; Kyle, 2011; Langmore et al., 2007; Logemann et al., 2008; Suh et al., 2009; Yamamoto et al., 2010). Another study examining dysphagia in Finnish care homes found that 62% of the 173 people with dysphagia also had dementia (Lindroos et al., 2014). Each type of dementia has different mechanisms by which the swallowing difficulties develop. For instance in Alzheimer’s disease there is a delayed oral transit time (Ikeda et al., 2002; Alagiakrishnan et al., 2013). At a certain point during their disease progression, all PLWD will develop dysphagia (Suh et al., 2009). A study using videofluoroscopy to observe the swallowing mechanism in 25 Alzheimer patients found that only 4 patients could swallow without difficulty (Horner et al., 1994). Furthermore, the same study found the severity of dysphagia correlates with the severity of dementia.

Behavioural and psychological symptoms of dementia (BPSD) may also pose challenges to caregivers in both the community and care home settings and may distress the caregiver (Feast et al., 2016). This challenging behaviour affects 70% of
care home residents and they are likely to be prescribed antipsychotics to treat these symptoms (Maidment et al., 2016). Behaviour can also affect the administration of medications (Gruber-Baldini et al., 2004). Pain experienced by PLWD may be difficult to recognise and is thus under treated (Barry et al., 2015; Lautenbacher et al., 2016). This may affect their wellbeing and behaviour, and care home staff need to find ways to identify pain without verbalisation from the PLWD (Sampson et al., 2015; Van Den Steen et al., 2015; Lautenbacher et al., 2016; Oosterman et al., 2016). Research has demonstrated how challenging behaviour may stem from pain that PLWD are not able to verbalise, and using pain killers may alleviate behavioural symptoms associated with pain (Husebo et al., 2014; Sampson et al., 2015; Lichtner et al., 2016).

Progression of dementia and increase in dependence will often lead to a transition to a care home (Crawford et al., 2015). The British Geriatrics Society estimated that 78% of care home residents have at least one form of cognitive impairment (British Geriatrics Society, 2011). In the UK, at least three quarters of care home residents have dementia (Matthews et al., 2013; Gordon et al., 2014). The care home setting also includes barriers to optimal medication use in PLWD which include polypharmacy, inappropriate prescribing patterns and care home processes (Blass et al., 2008; Barber et al., 2009; Somers et al., 2010; Tjia et al., 2010; Vetrano et al., 2013).

1.5. Formulations

With regards to medications, the oral route is the easiest and most preferred by patients (Stegemann et al., 2010, 2012). Around 70% of medications are in solid oral dosage form (SODF) (Schiele et al., 2013). This can be problematic for older people due to dysphagia and polypharmacy, thus swallowing a range of oral formulations can be difficult. Furthermore, some of the drugs they are taking can negatively affect their swallowing mechanism, such as anticholinergics and antipsychotics (Robbins et al., 2008; Stegemann et al., 2012). One study found that 61% of the dysphagic patients they studied (n=36) found swallowing tablets challenging and 39% also found difficulty when they were given oral dispersible dosage forms to swallow (Carnaby-Mann and Crary, 2005). Some patients and their caregivers or HCPs modify the medicine by crushing tablets or opening capsules that were not meant for this modification (Paradiso et al., 2002; Morris, 2005; Kelly et al., 2010). Some of the
implications of this are negative changes to the pharmacodynamic and pharmacokinetic profiles of the medicine, compromised dosing accuracy, reduced efficacy, and possible ADRs as well as powdering and fragmentation of the split tablet (van Santen et al., 2002; Stubbs et al., 2008; Wahlich et al., 2013). An appropriate formulation should be used instead of modifying the existing medication. One study in the Netherlands found that in 46% (n=275) of cases studied where the patient modified their medication, a more appropriate dosage form was available but not prescribed (Rodenhuis et al., 2004). A survey conducted in England on patients and caregivers found that 60% (n=792) experienced difficulties swallowing, and 68% (n=477) of those who answered said they modified the formulation, while 64% omitted the medicine altogether (Strachan and Greener, 2005). This highlights the issue that patients and caregivers might not realise that swallowing difficulties should be brought up to the doctor’s attention and it can be inferred that practitioners may not be enquiring about the patient’s ability to swallow. Furthermore, this also indicates that inappropriate formulations are being prescribed to patients with dysphagia. This not only affects the patient whose disease state will only get worse because they are not receiving the appropriate therapy, but also affects the health service by incurring avoidable costs.

One study of nursing homes in the UK used questionnaires aimed towards 540 nursing staff to evaluate the type of problems encountered by them when administering oral medicines to residents with swallowing difficulties and how they managed these problems (Wright, 2002). The results showed that 15% of patients had difficulties swallowing and 5% refused their medications. Furthermore, 56.5% (n=305) of nurses admitted that they covertly administered medications to those who refused, 26.9% (n=145) omitted the dose, and 61.3% (n=331) modified medications by crushing tablets or opening capsules before administration. These numbers raise two significant issues which are the legal and ethical implications of modifying medications (thus rendering it as unlicensed) and covertly administering them to patients respectively (Treloar et al., 2001; Haw and Stubbs, 2010; Kelly et al., 2011; Stegemann et al., 2012). Some of the reasons behind these decisions include the need to ensure that the patient receives their medication on time, being busy, and having no agreed set of guidelines or policies (Barnes et al., 2006).

Incentives for pharmaceutical companies are needed to develop appropriate formulations for the elderly population. The European Medicines Agency (EMA) has
published papers highlighting this need (European Medicines Agency, 2011, 2013). There is a legal requirement for the development of medicines for paediatrics, but this is not the case for geriatrics. The agency has recently published (August 2017) a draft of a reflection paper on the aspects of medicines for older people that require development to fulfil their medicinal needs (European Medicines Agency, 2017). This will be open for public consultation until January 2018 to stimulate a discussion. There is a need for regulatory bodies to have a better understanding of the quality of medicines for older people, especially those with cognitive impairment, to ensure medication use is optimised and patient clinical outcomes are achieved.

1.6. Optimising medicines use

Safe and effective medication use is a priority for all patients, especially elderly patients due to their heterogeneity, their need for tailored medicines and formulations (such as accessible doses, flexible regimens, and easy to use dosage forms), and the difficulties they face with medication management and administration (Orwig et al., 2006; Stegemann et al., 2010). This is even more vital in PLWD due to their decline in cognitive abilities and risk of medication mismanagement (While et al., 2012; Elliott et al., 2015). Furthermore, when compared with other diseases, PLWD have an increased risk of developing ADRs and suffering treatment failures due to factors such as polypharmacy and non-adherence (Maidment et al., 2012). The National Patient Safety Agency (NPSA) in 2009 published a report on how to improve medicines use in the NHS which highlighted the problem of formulations and swallowing difficulties in the elderly population, as well as polypharmacy and complex medicine regimes for elderly patients with memory problems (National Patient Safety Agency, 2009). In addition, there should be more regular medication reviews for this patient population. A study conducted in the Netherlands illustrated the inconsistency of medication reviews done for elderly patients by care home physicians and general practitioners (GP), with them not meeting the minimum requirement (Hurkens et al., 2013). The British Geriatrics Society highlighted the importance of medication reviews in care homes to improve medication management, with a minimum frequency of 6 months (British Geriatrics Society, 2013). Medication reviews will not only assist in enhancing medication management, but also provide the patient with tailored and understandable information about their medicines. Poor medication knowledge has been shown to negatively affect adherence and cause medication wastage, with the latter costing the NHS £300 million in 2009 (Chan et al.,...
Medication reviews should also address both the patient and their caregiver as it has been demonstrated that they both share similar medication use patterns (Thorpe et al., 2012).

One way to optimise medication use is to adopt a patient-focused approach as seen in Figure 1.1. Medicines optimisation is ‘about ensuring that the right patients get the right choice of medicine, at the right time. By focusing on patients and their experiences, the goal is to help patients to: improve their outcomes; take their medicines correctly; avoid taking unnecessary medicines; reduce wastage of medicines; and improve medicines safety’ (Royal Pharmaceutical Society, 2013). This collaboration between patients and their HCPs can help empower patients. Implementing these principles to improve knowledge, attitudes and behaviour in the context of medications throughout the medication process, from prescribing to dispensing to administration can assist in improved patient outcomes by ensuring they get the most out of their medications. Unfortunately, this model is not tailored for dyads, and may be unsuitable for caregivers and PLWD.

Figure 1.1: The four principles of medicines optimisation (Royal Pharmaceutical Society, 2013)
1.7.Gaps in knowledge

There are some unanswered questions concerning PLWD and medicines use. Research is required to explore these gaps in knowledge to raise awareness of these issues and endeavour to provide recommendations to optimise medicines use in this patient population. One area that affects medicines use that needs to be understood better is medication swallowing issues in PLWD, how this impacts medication management and adherence and how these issues can be overcome by more appropriate formulations (Stegemann et al., 2012). There are not many studies conducted on swallowing SODF in dysphagic patients (Kelly et al., 2010). Research has been focused on nutrition and swallowing difficulties and has not taken into account that patients may find it difficult to swallow specific formulations (Watson, 1994; Rothenberg et al., 2007; Easterling and Robbins, 2008; Pouyet et al., 2014). In addition, there is the assumption that patients living at home can manage their medicines well and are not questioned by HCPs about their swallowing abilities (Strachan and Greener, 2005). Knowing the prevalence of swallowing difficulties in PLWD can raise awareness of this problem so that HCPs can include it in their assessment of PLWD, especially when prescribing medicines to ensure that they are taken in a safe and effective manner. This can be achieved by looking at the different formulations and their ease of use in PLWD, and gathering both their perspectives and the caregivers’ perspectives as well. Furthermore, the process of how PLWD and their caregivers tackle any issues they encounter with the administration of formulations that are difficult to swallow, along with their justification, can also assist in forming recommendations for better prescribing and pharmaceutical practices, as well as optimise the switch between appropriate formulations. The use of all dosage forms, not only those taken orally, should also be studied in this population to gain a better scope of issues concerning medication use. It has been documented that patient satisfaction with medication formulations is associated with better adherence (Barbosa et al., 2012). Furthermore, formulations that offer ease of use can increase caregivers’ satisfaction with treatment and reduce medication-related stress (Winblad et al., 2007). This issue should not only be explored in the community, but also in the care home setting, as the barriers to medicines use, especially relating to formulations and dysphagia, may differ due to dementia severity and prescribing patterns. There has been little research on modifying medications, such as crushing tablets, in care home settings with regards to medication administration errors in patients with
swallowing difficulties (Stuijt et al., 2013). As the population is ageing, optimising their therapy will rely on better understanding the use of different formulations and administration methods.

Another area that may negatively affect medicine use that has not been studied thoroughly in PLWD is the transition from self-management to caregiver-led management, as well as looking at the causes and the impact it has on both the patient and the caregiver (Cotrell et al., 2006; Arlt et al., 2008; Maidment et al., 2012). Most of the studies conducted on medication management have looked at elderly patients without cognitive impairment (Cotrell et al., 2006). A recent review on the role of informal caregivers of PLWD highlighted the complex role the caregiver undertakes and the scarcity of the literature on their role with administering medications to patients (Gillespie et al., 2013). Understanding this transition and the factors associated with it can help in identifying ways to provide more efficient means of medicines management for PLWD. It can also shed light on ways to optimise the transition for both the PLWD and the caregiver. This may help improve the quality of life of the patient and hence the caregiver as well. There is also a paucity in the literature regarding the involvement of PLWD in the decision making process from their treatment perspective (Hirschman et al., 2005; Smebye et al., 2012). Gaining a better understanding of their involvement may assist in enhancing the relationship between caregivers and patients, maintaining the patient’s autonomy as well as improving their quality of life (Smebye et al., 2012).

One of the research priorities in dementia presented by the James Lind Alliance in partnership with the Alzheimer’s Society was to find the most effective ways of supporting caregivers of PLWD at home (Alzheimer’s Society, 2013). Gathering family caregivers’ views is as important as those of the patients; gaining the perspective of the caregiver and understanding their experiences with their medication management duties can shed light on different aspects. Caregivers observe PLWD and manage and administer medications and may therefore have a different perspective to offer. Furthermore, caregiver satisfaction is associated with better patient compliance to treatment (Bernabei et al., 2012). Also, increasing ease of use of medicines for caregivers and PLWD and providing better support with medicines management can reduce caregiver burden and stress, thereby enhancing their quality of life as well the care recipient’s (Belle et al., 2006). Caregiver burden is linked to a low quality of life, negatively influencing the PLWD (Maidment et al., 2013). Reducing caregiver burden
may delay the transition to care homes and avoid the costs of institutionalisation. Recent figures show that the placement of people with dementia in care homes is costing the UK approximately £7 billion per annum (Alzheimer’s Society, 2007). The importance of informal caregivers of PLWD can be seen in one study that showed that patients with caregivers were 20 times less likely to be admitted to a care home (Banerjee et al., 2003).

Optimising medication use requires a comprehensive understanding of the issues affecting medicines management and administration in PLWD and their caregivers. This can be achieved by conducting a thorough search of the available literature on this topic. The next chapter outlines the literature review and the relevant findings.

**1.8. Thesis outline**

The thesis aims to inform optimisation of medication use in PLWD and alleviate caregiver burden through the identification and examination of the factors associated with the challenges with medication use as dementia progresses. Chapter 2 provides a review of the literature to understand the issues previously found in this patient/caregiver population and to identify priorities regarding specific objectives, as well as ascertain the optimal research method to fulfil the research question. The aim and objectives of the current research are presented at the end of the chapter. Chapter 3 presents the research design and methods employed to achieve the research objectives, as well as the rationale for their use. Chapter 4 reports the background characteristics of the participants from both the community and care home settings and details their medication use. Chapter 5 provides an examination of the findings from PLWD and their family caregivers and highlight areas that require optimisation. Chapter 6 examines the findings from the care home setting, and the factors associated with challenges to medication use from the perspectives of carers and nurses. An analysis of medication use changes in the context of progression of dementia and care setting is provided in Chapter 7. Chapter 8 discusses the major findings in the context of previous literature, and their implications for future practice and research. Recommendations based on the findings are provided for healthcare practice and policy and the pharmaceutical industry, in order to optimise medication use for PLWD and their caregivers.
Chapter 2: Literature Review

2.1. Introduction

Safe and effective medication use is a priority for all patients, especially older patients, due to their co-morbidities and diverse needs. This includes tailoring the drug formulations and optimising their medication management (Orwig et al., 2006; Stegemann et al., 2010). This is even more vital in PLWD due to their decline in cognitive abilities. The medication management role of family caregivers of older people and PLWD, the tasks they undertake and the factors affecting them has already been explored in a recent review (Gillespie et al., 2013), but the problems faced by PLWD and their caregivers with medication use were not the main focus of the paper. Optimising medication use requires a comprehensive understanding of the issues affecting medicines management and administration in practice, both in the community and care home settings.

The research question for this review is ‘What are the challenges to optimal medicines use faced by people living with dementia and their caregivers?’ The medication use process is defined here as the management and administration of medications, which includes decisions and concerns about medications. The term ‘caregiver’ encompasses both family caregivers and carers or nurses in care homes. This is to better explore issues across different care settings, levels of training and stages of dementia. The review highlights the scope and range of problems experienced by PLWD and their caregivers. It focuses on problems that relate directly to medicines management and administration and identifies the gaps in knowledge, which in turn can help inform future research.

2.2. Method

2.2.1. Search strategy

A literature search was conducted to identify studies relevant to the research question using bibliographic databases such as PubMed, EMBASE, International Pharmaceutical Abstracts, Scopus, PsycINFO, Cumulative Index to Nursing and Allied Health Literature (CINAHL), MEDLINE and Science Direct. Additional searches were made using International Journal of Pharmacy Practice (IJPP) abstracts and Google (Google was used as an additional tool to identify any studies that may
have been missed in the database search). No time limit restrictions were imposed when conducting the search; all databases were searched from time of inception until January 2015. In addition, the references from the retrieved studies were manually searched for any other relevant studies. The findings of this review were published earlier in 2016 (Alsaeed et al., 2016b). An update to the search was conducted to include new research published between January 2015-July 2017. The search strategy and the terms used can be found in Table 2.1.

Table 2.1: Search strategy and terms

| Subjects 1 | ‘Dementia’ OR ‘Alzheimer’s’ OR ‘Mild cognitive impairment’ AND |
| Subjects 2 | ‘Caregiver*’ OR ‘Carer*’ OR ‘Care home*’ OR ‘Carer centre*’ AND |
| Medications | ‘Medication*’ OR ‘Prescription*’ OR ‘Pharmaceutical*’ OR ‘Drug*’ OR ‘Formulation*’ OR ‘Dosage form*’ AND |
| Problems | ‘Barrier*’ OR ‘Challeng*’ AND |
| Medication use | ‘Medication administration’ OR ‘Medication management’ OR ‘Medication use’ |

2.2.2. Eligibility criteria

Studies that provided either the PLWD, their caregiver’s or both of their perspectives on challenges to medication use were deemed eligible. There were no restrictions on method type; studies that used qualitative, quantitative or a mix of both methods were included. The term ‘caregiver’ encompassed both family caregivers and carers or nurses in care homes (nursing or residential). Family caregivers were defined as family members or friends who provided unpaid medication assistance. Abstracts of posters were also included as they provide information on ongoing-work that is being conducted in this area, as there is limited published data available. Studies were excluded if they did not mention whether people had a form of cognitive impairment, or if they were not written in the English language. Table 2.2 shows the eligibility criteria used.
Table 2.2: Eligibility criteria for included studies

<table>
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<th>Eligibility criteria</th>
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<tr>
<td>Qualitative, quantitative, or mixed-methods</td>
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<tr>
<td>Perspective of PLWD, caregiver, or both</td>
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<tr>
<td>Included issues with medication use</td>
</tr>
<tr>
<td>Caregivers included family caregivers and carers or nurses from care homes</td>
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<tr>
<td>States that patients have form of dementia</td>
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<td>In the English language</td>
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2.2.3. Outcomes

The primary outcome for conducting this literature review was to determine what barriers to medication use, either with medication management or administration, have already been studied in this patient population. The secondary outcome was to study the method of data collection and analysis adopted in each study, in order to determine the best method for acquiring the data and analysing the findings for the present study.

2.2.4. Data extraction and analysis

An inductive thematic approach was taken when reading the articles to generate themes; information relating to problems encountered with medication management and administration to PLWD, as well as recommendations and suggestions to improve medication use, were extracted from the articles. Challenges and factors impacting medication use were extracted and recoded into themes. Quotes from studies were extracted to illustrate each theme. Information such as the study design and setting, country, type and number of participants, sampling and recruitment and methodology was recorded on data extraction sheets. These were developed and reviewed with the research supervisors. The Consolidated Criteria for Reporting Qualitative Research (COREQ) was used to appraise the qualitative studies (Tong et al., 2007); only 12 were appraised properly using this criteria as the rest were abstracts. This method of assessing qualitative studies has been used previously in published systematic reviews (Tong et al., 2008; Morton et al., 2010; Prorok et al., 2013). Appendix 1 contains the quality of reporting in the studies based on the COREQ criteria. Appraisal of
qualitative and quantitative studies involved an assessment of the research methods, study design and sampling.

2.2.5. Search strategy results

The total number of citations retrieved in the 2015 search from the data bases was 2657. A search using Google UK and Google Australia yielded 4 further studies that also met the inclusion criteria, bringing the total number to 2661. The titles of all citations were reviewed and 2378 studies were excluded. The abstracts and full text of the remaining 283 citations were then reviewed according to the inclusion criteria, and 270 were excluded for the following reasons: duplicates (n=64), irrelevant (n=206). A review of the full text of the remaining 13 papers ascertained that they fulfilled the eligibility criteria. After a manual search of the reference lists and citations of the retrieved articles, 3 further studies were deemed relevant. This search was repeated in August 2017 to include new research and a further 3 studies were included. Figure 2.1 represents a flowchart of the literature review process. The following section offers a summary of these studies and their implications on the present one.

2.3. Results

2.3.1. Selection of studies

The literature review yielded 19 studies that reported problems with medication use in PLWD and their caregivers. The participants in 15 of the studies were either PLWD, their caregivers or both (Hutchings et al., 2010; Taylor and Weiss, 2010; Kaasalainen et al., 2011; Carder, 2012; Jansen et al., 2012; While et al., 2012; De Witt Jansen et al., 2013; Erlen et al., 2013; Maidment et al., 2013; Poland et al., 2014; Gillespie et al., 2015; Smith et al., 2015; De Witt Jansen et al., 2017; Look and Stone, 2017; Maidment et al., 2017). The participants in the other 4 studies were older people in general, some of whom had dementia or cared for a PLWD (Travis et al., 2000; Lau et al., 2009; Reinhard et al., 2012; Mirk et al., 2013). Seven of the studies were conducted in the United States of America (USA), nine in the UK, two in Australia and one in Canada. All of the studies were conducted fairly recently, with the earliest published in 2000 and the latest published this year. Tables 2.3 and 2.4 summarise the main characteristics of the studies; the majority of the studies retrieved used
qualitative methods, two adopted a mixed methods approach and one relied on quantitative methods.

Figure 2.1: Flowchart of literature review process
2.3.2. Study participants

The overall sample size from all 19 studies was 2291. As the sample sizes from the quantitative studies are much larger than those of the qualitative studies due to the methods used, the total sample size from the 16 qualitative studies was calculated separately. The aggregate sample size from the 16 qualitative studies was 412, with a mean sample size of 26 participants. The demographics of the PLWD and their family caregivers differed between the studies. PLWD participants were aged between 65-94 years and tended to be females; family caregiver ages ranged from 33-86 years with the majority being female spouses or daughters.

2.3.3. Quality of studies

The quality of reporting varied between the qualitative studies; some criterion were rarely reported, such as relationship with participants, while others were consistently reported such as methodology, sampling and reporting of findings. The number of items ranged from 14 (While et al., 2012; Gillespie et al., 2015) to 32 (Maidment et al., 2017) out of a total of 32 items, with a mean of 19 items. Some of the studies utilised more than one method of data collection, which strengthened the study findings and provided a more flexible method to accommodate participants (Travis et al., 2000; Hutchings et al., 2010; Carder, 2012; Maidment et al., 2013; Gillespie et al., 2015). Some of the studies included were conference abstracts and therefore limited information was available in regard to methodology and sampling (Taylor and Weiss, 2010; Jansen et al., 2012; De Witt Jansen et al., 2013; Maidment et al., 2013; Mirk et al., 2013).

2.3.4. Barriers to medicines use in PLWD

Six major themes were generated from the 19 studies; organisation and scheduling logistics, formulations and administration procedures, impact on caregiver, impact on PLWD, partnership between caregiver and PLWD, and how this partnership interfaces with formal care. Each theme had sub-themes that clarify how each one affects medicines use in PLWD and their caregivers. Table 2.5 summarises the themes, sub-themes, and quotes derived from the studies to support each theme.
Table 2.3: Characteristics of qualitative studies

<table>
<thead>
<tr>
<th>Author</th>
<th>Country</th>
<th>Type (number) of participants</th>
<th>Method of data collection</th>
<th>Methodology</th>
<th>Aim of the study</th>
</tr>
</thead>
<tbody>
<tr>
<td>S Travis et al. (2000)</td>
<td>USA</td>
<td>Family caregivers (23)</td>
<td>Interviews</td>
<td>Content analysis</td>
<td>To learn the issues surrounding medicines administration to elderly patients from the perspectives of family caregivers</td>
</tr>
<tr>
<td>DT Lau et al. (2009)</td>
<td>USA</td>
<td>Hospice providers (22), family caregivers (23)</td>
<td>Interviews</td>
<td>Content analysis, thematic coding</td>
<td>To identify family caregiver medication management skills for home hospice patients</td>
</tr>
<tr>
<td>D Hutchings et al. (2010)</td>
<td>UK</td>
<td>Family caregivers (11), PLWD (12)</td>
<td>Interviews, focus groups</td>
<td>Thematic analysis</td>
<td>To learn PLWD and caregivers’ experiences of using cholinesterase inhibitors</td>
</tr>
<tr>
<td>DA Taylor and MC Weiss (2010)</td>
<td>UK</td>
<td>7 case groups; each group consisting of the PLWD, their main caregiver and the PLWD’s prescriber</td>
<td>Interviews</td>
<td>Interpretative phenomenological analysis</td>
<td>To explore the perspectives of medicines for dementia from PLWD in the early stage of the condition, their main caregiver and their prescriber over time.</td>
</tr>
<tr>
<td>S Kaasalainen et al. (2011)</td>
<td>Canada</td>
<td>HCPs (26), family caregivers (20), PLWD (11)</td>
<td>Interviews</td>
<td>Grounded theory</td>
<td>To explore the personal experiences relating to medication management from the perspectives of PLWD in the community, their family caregivers, and HCPs who are involved in their care</td>
</tr>
<tr>
<td>PC Carder (2012)</td>
<td>USA</td>
<td>Paid carers at care homes (16)</td>
<td>Interviews, observation</td>
<td>Grounded theory</td>
<td>To identify how care home staff members decide to administer PRN medications to residents with dementia</td>
</tr>
<tr>
<td>B Jansen et al. (2012)</td>
<td>UK</td>
<td>Bereaved caregivers (6), HCP (6)</td>
<td>Interviews</td>
<td>Narrative analysis</td>
<td>To explore caregivers’ and HCPs’ experiences with treatment options for PLWD at end-of-life care</td>
</tr>
<tr>
<td>Author</td>
<td>Country</td>
<td>Type (number) of participants</td>
<td>Method of data collection</td>
<td>Methodology</td>
<td>Aim of the study</td>
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<tr>
<td>C While et al. (2012)</td>
<td>Australia</td>
<td>Family caregivers (9), PLWD (8)</td>
<td>Interviews</td>
<td>Grounded theory</td>
<td>To explore the personal experiences relating to medication management from the perspectives of PLWD in the community and their informal caregivers</td>
</tr>
<tr>
<td>B De Witt Jansen et al. (2013)</td>
<td>UK</td>
<td>Nurse home managers (3), nursing staff (8)</td>
<td>Interviews</td>
<td>Thematic analysis</td>
<td>To explore nursing home managers’ and staff members’ experiences of administering medicines to residents with dementia</td>
</tr>
<tr>
<td>A Mirk et al. (2013)</td>
<td>USA</td>
<td>Family caregivers (19), elderly people (27)</td>
<td>Medication management visit</td>
<td>Not reported</td>
<td>To identify barriers to effective medication management among elderly patients and informal caregivers</td>
</tr>
<tr>
<td>F Poland et al. (2014)</td>
<td>UK</td>
<td>Family caregivers (9)</td>
<td>Focus group</td>
<td>Thematic and narrative analysis</td>
<td>To gain caregivers perspectives on medication issues and how they are dealt with</td>
</tr>
<tr>
<td>F Smith et al. (2015)</td>
<td>UK</td>
<td>Family caregivers (14), PLWD (5)</td>
<td>Interviews</td>
<td>Framework approach (thematic analysis)</td>
<td>To examine the scope and range of medicines-related assistance provided by family caregivers of PLWD and the problems arising from it</td>
</tr>
<tr>
<td>R Gillespie et al. (2015)</td>
<td>Australia</td>
<td>Family caregivers (29)</td>
<td>Interviews, Focus groups</td>
<td>Thematic analysis</td>
<td>To explore the views of ethnic minority family caregivers of PLWD and their medication management experiences</td>
</tr>
<tr>
<td>Maidment et al. (2017)</td>
<td>UK</td>
<td>Family caregivers (11), PLWD (4), HCPs (16)</td>
<td>Interviews</td>
<td>Framework analysis</td>
<td>To identify and understand the key challenges with medication use in PLWD and their informal caregivers and explore the role of the pharmacist</td>
</tr>
<tr>
<td>B De Witt Jansen et al. (2017)</td>
<td>UK</td>
<td>Registered nurses (24)</td>
<td>Interviews</td>
<td>Thematic analysis</td>
<td>To explore nurses’ experiences of pain management for people with advanced dementia in palliative care, and to identify the challenges, facilitators and areas requiring improvement.</td>
</tr>
<tr>
<td>Author</td>
<td>Country</td>
<td>Type (number) of participants</td>
<td>Method of data collection</td>
<td>Methodology</td>
<td>Aim of the study</td>
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<tr>
<td>Look and Stone (2017)</td>
<td>USA</td>
<td>Family caregivers (29)</td>
<td>Focus groups</td>
<td>Thematic analysis</td>
<td>To explore how family caregivers manage medications for their older adult care recipients</td>
</tr>
</tbody>
</table>

Table 2.4: Characteristics of studies that employed quantitative or mixed methods

<table>
<thead>
<tr>
<th>Author</th>
<th>Country</th>
<th>Type (number) of participants</th>
<th>Method of data collection</th>
<th>Methodology</th>
<th>Aim of the study</th>
</tr>
</thead>
<tbody>
<tr>
<td>SC Reinhard et al. (2012)</td>
<td>USA</td>
<td>Family caregivers (1,677)</td>
<td>Online survey</td>
<td>NA</td>
<td>To learn the responsibilities of family caregivers relating to medical tasks and the difficulties encountered</td>
</tr>
<tr>
<td>J Erlen et al. (2013)</td>
<td>USA</td>
<td>Family caregivers (91), PLWD (91)</td>
<td>Interviews, questionnaires, telephone follow-up</td>
<td>Not reported</td>
<td>To examine medication management deficiencies, as well as medicine taking issues, encountered by PLWD and their caregivers in the community</td>
</tr>
<tr>
<td>I Maidment et al. (2013)</td>
<td>UK</td>
<td>Alzheimer’s Society Research Network Volunteers (20), family caregivers</td>
<td>Focus group, survey</td>
<td>Not reported</td>
<td>To explore the role of family caregivers relating to safe medication management and the issues involved</td>
</tr>
<tr>
<td>Theme</td>
<td>Sub-themes</td>
<td>Illustrative quotes</td>
<td></td>
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</table>
| **Organisation and scheduling logistics**<sup>2,5, 13-14,16,17,19</sup> | - Scheduling multiple medications throughout the day and giving them on time  
- Acquiring, storing, and tracking medications  
- Coordinating personal medication schedules with those of the PLWD |  
*Caregiver:* ‘I just dread that if I would make a mistake . . . I have a lot of tablets so I don’t want to make a mistake with my own as well as my husbands’<sup>24</sup>  
*Caregiver:* ‘It is actually coordinating all the bits and then sometimes they [the Dr’s] will write you three months or four months or five or six. But there is no consistency to it. So, unless you monitor it and watch it carefully yourself, you are going to end up running out of things.’<sup>4</sup>  
*Caregiver:* ‘The medication was delivered to my mum by the pharmacy. But suddenly they stopped…I live the other side of London. So I had to spend another day phoning around to get everything done’<sup>13</sup> |
| **Formulations and administration procedures**<sup>4,10,12-16,19</sup> | - Giving medication to a disoriented/difficult PLWD  
- Deciding when to hold, adjust, or discontinue a medication, especially PRN medicines  
- Learning how to administer different types of formulations and medicines that may be painful or embarrassing  
- Having a good understanding of the medicines being given such as difference between brand and generic names  
- Employing strategies to aid medication use  
- Dealing with polypharmacy and medication complexity (number and frequency of medications)  
- Having dexterity problems, poor vision, or swallowing difficulties |  
*Caregiver:* ‘[If] she doesn’t want it, she won’t swallow it, then I have to crush it up, I have to mix it with banana and she seems to swallow that. And then sometimes with the puffer she will blow it the other way…you know she’ll spit up pills. Sometimes I know she hasn’t taken the medication because I find it on the floor. Gotta watch her – she’s clever.’<sup>9</sup>  
*Care home staff:* ‘The challenge is they can’t take it orally a lot of the time because their swallow deteriorates and they frequently get aspiration pneumonia so whatever oral pain relief they would have been on previously, they can’t take anymore.’<sup>18</sup>  
*Caregiver:* ‘The nurse called the drug lorazepam and I didn’t think I had it. It turned out to be Ativan but I didn’t know there are two names.’<sup>5</sup>  
*Care home staff:* ‘I think visual cues are really helpful, because sometimes people will tell you, ‘My leg hurts,’ but they’re holding their back, or…they’re really meaning hungry.’<sup>12</sup>  
*Caregiver:* ‘when she lived alone and had to take her blood pressure tablets on her own and I came in the afternoon, the tablet was still in the dosage box and I didn’t know what to do. I did not know if it could hurt her to give the tablet at that moment or if I had to wait until the next morning.’<sup>13</sup> |
<table>
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<tr>
<th>Theme</th>
<th>Sub-themes</th>
<th>Illustrative quotes</th>
</tr>
</thead>
</table>
| **Impact on caregiver**<sup>1-4, 6-16,17</sup> | • Managing medications and administration impacted on caregivers’ time and lives by restricting activities and causing burden  
• Medication management described as emotionally difficult and frightening  
• Reluctance in relying on others for support  
• Difficulties accessing support to ensure safe and effective medicines use  
• Role taken on by caregiver without choice, support, skills, or medication knowledge. (feelings of personal responsibility)  
• Caregivers’ concerns and feelings regarding medicines use change as dementia progresses  
• Skills/training needed by formal caregivers when dealing with PLWD | Caregiver: ‘I do that [fill the tablet box] every Sunday morning because I get very tired in the afternoon. I have to do it when I’m really functioning . . . I have so much medication and that’s why I think I have to do things when my mind is really clear.’<sup>4</sup>  
Caregiver: ‘I don’t know what I would do [if I was ill] . . . to be honest I think I would just have to get out of bed and do it myself . . . Our Dr would probably say to me, well we will have to get somebody to help you then.’<sup>4</sup>  
Caregiver: ‘Well, this caused me a lot of burden and stress in the beginning. Like, really max. Even though I actually understood what I was doing’<sup>4</sup>  
Caregiver: ‘Don’t forget that the clinician and pharmacist can have little or no understanding of the practicalities’<sup>8</sup>  
Caregiver: ‘I really do wish you wouldn’t ask me how I’m coping because the word coping implies that if I’m not, it’s my fault.’<sup>8</sup>  
Caregiver: ‘Sometimes I feel fed up but what can I do? That is my duty…I forget my medicine but I never forget his.’<sup>17</sup> |
| **Impact on PLWD**<sup>4, 6,10,13,15-16</sup> | • PLWD want to retain autonomy/independence  
• PLWD refuse to take medications due to denial (early stage) or delusions (severe stage)  
• PLWD affected by transition in care and change in environment | Caregiver: ‘Mum had been in hospital for a month and that was the longest time she’d been not looking after herself . . . the habit of her remembering to take medication every day had been broken and I didn’t know how it would start up again.’<sup>4</sup>  
PLWD: ‘I used to have the medication and I’d take it myself. I don’t know [what changed]; I think it was a bit of a scam. I think it’s so they can employ more nurses’<sup>4</sup>  
Caregiver: ‘I think she felt a loss of independence when the dementia hit. But not only that but as soon as her own control over her own medication, that she was so used to, was taken out of her hands….so it’s giving the autonomy to the patient as far as possible.’<sup>18</sup>  
Caregiver: ‘when we got the blister packs he was so angry with us he said ‘what do you think!? Do you think I can’t manage medications!?’<sup>16</sup> |
<table>
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<tr>
<th>Theme</th>
<th>Sub-themes</th>
<th>Illustrative quotes</th>
</tr>
</thead>
</table>
| **Partnership between caregiver and PLWD**<sup>4,8,9,13,16</sup> | • Trust needed between patient and caregiver  
• Transition from self-management to caregiver-led management  
• Inclusion of caregiver and PLWD in decision-making | Caregiver: ‘At first she was taking them every time and then it sort of degraded. She took them most times. Then it degraded a bit more and she took them sort of okay but not really that often. She was getting worse as time was going on.’<sup>4</sup>  
Caregiver: ‘Now, the most difficult time was the changeover between him thinking he could do it and then me giving him his medication. It took quite a lot of mental gymnastics and a lot of encouraging, me ringing up the GP and specialists as well and they say certain things and then he’d believe them. But he wouldn’t believe me, because he thought I was ganging up on him.’<sup>4</sup>  
Caregiver: ‘it is really difficult. Mum… forgets. What I’ve done is sort of sit down and explain things, and her own family doctor has tried to explain things. I want mum to know what is going on.’<sup>13</sup> |
| **Interface with formal care**<sup>4,5,8,9,11,13,16-19</sup> | • Need to communicate effectively with HCPs about medication-related issues (communication barriers and facilitators)  
• Trust and continuity between HCPs, caregivers and PLWD  
• Accessibility of HCPs  
• Inclusion of both caregiver and PLWD in discussions and decisions | PLWD: ‘If I want to know [about my tablets] I can go to the chemist and I ask them. They always say if you don’t know what it is about, come and ask us and we’ll explain it’<sup>4</sup>  
Caregiver: ‘So that’s when I changed doctors because he said, because of [my husband’s] age, what’s the point’<sup>4</sup>  
Caregiver: ‘If I didn’t have the relationship with the GP that I do, mum wouldn’t be at home; she’d be in a nursing home because I wouldn’t cope’<sup>4</sup>  
Caregiver: ‘the doctor doubled the dosage without even telling us, we only found it out by collecting the tablets at the pharmacy.’<sup>13</sup>  
Caregiver: ‘our GP was talking only to me as if she was not there. My mother thought he was saying she was mad because he was not talking to her. I was so angry.’<sup>13</sup> |

Theme 1: Organisation and scheduling logistics

This theme describes the issues encountered by caregivers with their medication management tasks and the skills required by them to effectively and safely provide medicines to the PLWD. One of the major barriers faced by caregivers and PLWD highlighted in most studies was difficulties in obtaining medicines and maintaining regular supplies of medicines at home (Travis et al., 2000; Lau et al., 2009; Taylor and Weiss, 2010; Mirk et al., 2013; Gillespie et al., 2015; Smith et al., 2015; Maidment et al., 2017; Look and Stone, 2017). It was evident that managing medications was a challenging task that necessitated various activities such as ordering and collecting prescriptions and/or supplies from various sources.

Scheduling logistics were also seen by caregivers as a daily stress, with the most common challenge being able to arrange their own medication schedule to correspond with that of the patient’s (Travis et al., 2000; While et al., 2012). There is also the added challenge of fitting both medication schedules in alongside the caregiver’s routine. Polypharmacy and complex medication regimens can complicate this task further as caregivers stated this caused difficulties in monitoring when prescriptions needed to be filled and maintaining sufficient amounts of medications at home (Lau et al., 2009; Gillespie et al., 2015; Smith et al., 2015; Look and Stone, 2017; Maidment et al., 2017).

Managing multiple medications and the procurement and maintenance of medicine stock at home were all highlighted by caregivers as a barrier to the medicine use process. Caregivers had to develop strategies, such as keeping a diary to assist with medication management (Smith et al., 2015; Look and Stone, 2017) or putting stickers on prescriptions to remind them to renew them (While et al., 2012), to overcome these challenges to ensure that medicines were available for the PLWD and were given in a timely manner.

Theme 2: Formulations and administration procedures

This theme encompasses a variety of concerns in regard to information relating to the medicines and their administration from the perspectives of both the caregiver and the PLWD. All of the studies included in the literature review discussed issues relating to this theme. Poland et al. (2014) obtained the views of both caregivers of PLWD and health care professionals (HCPs) on medication management and the challenges
encountered. They illustrated how simple tasks, such as preparing Fybogel™ laxative by suspending granules in water for oral administration, can become complicated and cause distress to the caregiver and delay medicine administration; one caregiver stated that the formulation sets too quickly to be swallowed by the patient. This highlighted the impracticality of some medications. Difficulties in administration of medicines can cause caregivers to modify medications without consulting HCPs, which may result in compromising the efficacy and safety of medications (Erlen et al., 2013; Mirk et al., 2013; Gillespie et al., 2015). Tailored formulations need to be prescribed to PLWD to aid the administration process, such as prescribing liquids to patients with swallowing difficulties (Kaasalainen et al., 2011). In the study by Travis et al. (2000), 32% of caregivers’ accounts related to difficulties in administration of medicines, caregivers of PLWD experiencing more stress than those of other caregivers. This was due to this patient groups’ cognitive decline and challenging behaviour problems which can potentially make medicine administration a difficult task (Travis et al., 2000; Kaasalainen et al., 2011; De Witt Jansen et al., 2013; Gillespie et al., 2015). Other more general issues identified were complicated instructions, such as how to give medicines, and making decisions on when to give or withhold medicines, especially those which are Pro Re Nata (PRN).

Knowledge concerning the medicines was also an important issue that affected caregivers’ decisions about administration (Lau et al., 2009; While et al., 2012; Maidment et al., 2013; Poland et al., 2014; Gillespie et al., 2015; Smith et al., 2015; Maidment et al., 2017). Caregivers of PLWD highlighted the importance of patient information leaflets, but still faced difficulties in making judgements regarding medicines use (Smith et al., 2015). One study demonstrated the importance of caregivers being aware of dosages in case of labelling errors (Taylor and Weiss, 2010). Poor vision and manual dexterity were other barriers to medicine use (While et al., 2012; Mirk et al., 2013; Gillespie et al., 2015). A complex medicine regimen with four or more medicine doses that require adjustment by the caregiver and a variety of dosage forms can also be a barrier to optimum medicines use, adding stress to the caregiver (Kaasalainen et al., 2011; Reinhard et al., 2012; Maidment et al., 2013; Mirk et al., 2013; Gillespie et al., 2015). Some caregivers stated that they need to develop some strategies to overcome some of these barriers, such as the use of multi-compartment compliance aids, reminders, giving all the tablets in the morning or placing medicines near their bed (Hutchings et al., 2010; Kaasalainen et al., 2011;
While et al., 2012; Gillespie et al., 2015; Smith et al., 2015; Look and Stone, 2017). Some of the strategies adopted by caregivers were not always safe and effective, as demonstrated by Gillespie et al., (2015) where caregivers placed medications for the PLWD in unlabelled easy-to-open containers to assist them in overcoming their dexterity problems and to maintain their independence.

One study focused on the factors affecting the decision to administer PRN medicines to residents with dementia by paid carers in care homes (Carder, 2012) and found that the decision process can be complicated, and can be influenced by various issues. PLWD were not always able to verbalise why they were requesting a certain medication, such as for pain relief. The paid carer would have to be familiar with the patient to be able to successfully interpret their request by studying their behaviour and nonverbal cues. These were similar findings to the study conducted by De Witt Jansen et al., (2017) focusing on the administration of pain relief by nurses to PLWD in palliative care. They also identified route of administration and type of formulation as a barrier in severe dementia. De Witt Jansen et al., (2013) conducted another study at nursing homes to explore the experiences of staff in administering medicines to dementia patients. The authors found several barriers to the medication management and administration procedures that can either be attributed to factors relating to the PLWD or factors relating to the work environment. Disease severity, cognitive capacity, physical disability and difficult behaviours were all barriers. Environment-related factors were interruptions by colleagues or the PLWD’s family members, distractions and the ratio of staff to residents. Staff members all agreed that the solution to overcoming barriers to medicine administration at nursing homes was effective communication with everyone involved in the process; from the residents and their relatives to the HCPs. This finding was similar to Carder’s (2012) study and De Witt Jansen’s (2017) study.

Theme 3: Impact on caregiver

Caregivers can sometimes feel ill-prepared for the role they have taken on (Maidment et al., 2013; Poland et al., 2014). Taking on this role and managing medicines can disturb their daily routine and affect what activities they can take part in, especially if they do not live with the PLWD (Hutchings et al., 2010; Reinhard et al., 2012; Smith et al., 2015). Furthermore, it can cause them anxiety when they cannot cope with the
pressures involved in this role; this may make them feel that they are inadequately supporting the care recipient (Poland et al., 2014).

Caregivers’ concerns regarding the PLWD and coping with their medicines changed along the progression of dementia. At the mild stage, caregivers were focused on starting anti-dementia medications and acquiring information regarding the condition (Jansen et al., 2012). As the condition progressed to the moderate-severe stage, caregivers were more anxious about the issues they faced with the administration of medicines and how to make adherence to medications easier. At this stage, the burden of caregiving became more evident, since the role they adopted with medication assistance changed as the PLWD’s cognitive abilities deteriorated. At the early stages of the condition, they may take on a minor role with managing medications by requesting blister packs to be made by the pharmacist (Gillespie et al., 2015). At the moderate to severe stages, the caregiver takes on a much greater role and develops strategies for safe and effective medication use.

Staff administering medications to PLWD at care homes stated that the skills required to care for PLWD differed from those needed to care for other residents; for example, there was a need to be more patient and empathic (De Witt Jansen et al., 2013). When PLWD start refusing medications, staff members had to make ethical judgments on the administration of medicines, and felt that the pharmacist was the best source of assistance in this case. Caregiving staff at care homes identified the need for more efficient training concerning medication administration to dementia patients, such as the appropriateness and acceptability of available formulations and effective pain management. They also expressed a need to rely on their skills in understanding each individual resident to better care for them (Carder, 2012; De Witt Jansen et al., 2013, 2017).

Managing and administering medicines has a direct impact on the caregiver, which can affect their role regarding medicines use. The responsibility involved negatively affects the caregivers’ quality of life, restricting their time and activities elsewhere, thus causing caregiver burden (Jansen et al., 2012; While et al., 2012; Smith et al., 2015; Gillespie et al., 2015). This role has been taken on by friends or family members; it was deemed a personal responsibility by themselves, by PLWD, or by society (Reinhard et al., 2012). Family caregivers may take on this role without any form of support and without prior knowledge of what the role involves (Reinhard et
al., 2012; While et al., 2012). Some caregivers stated that they were not provided with any information about the prescribed medicines and no support or information regarding medicines use, such as medication use reviews (Taylor and Weiss, 2010). Caregivers feel that they can only depend on themselves and any past experiences that may assist them; in fact, caregivers become so engrossed in the role that they are reluctant to have someone else take on the responsibility of the PLWD’s medicines (While et al., 2012; Smith et al., 2015). This was not always the case, as some caregivers felt relieved when other family members assisted in managing medications or finding information on medicines (Gillespie et al., 2015).

Theme 4: Impact on PLWD

The PLWD is central to any discussion on challenges to medicines use; the caregiver may be responsible but the PLWD is profoundly affected. PLWD and their caregivers all stress the importance of the PLWD retaining their independence and autonomy (Kaasalainen et al., 2011; Poland et al., 2014; Gillespie et al., 2015; Smith et al., 2015). This can have a positive effect on PWLD taking their medicines as they still feel in control of at least one aspect of their lives.

The PLWD’s cognitive abilities and severity of dementia have a strong influence on how they take their medications. One study illustrated how PLWD dealt with medicine management as dementia progressed (Kaasalainen et al., 2011). PLWD can sometimes refuse to take medicines when they are distressed or confused due to their condition. At the early stages, they may refuse because they are in denial and do not want to relinquish control over their lives (While et al., 2012), or have the belief that what they are experiencing is a usual part of the aging process (Gillespie et al., 2015). This can lead to anxiety over their loss of independence. As dementia progresses, their reasons for refusing to take medications may be attributed to delusional beliefs and paranoia of being poisoned, challenging behaviour or believing that they do not require these medicines (While et al., 2012; Gillespie et al., 2015; De Witt Jansen et al., 2017; Look and Stone, 2017; Maidment et al., 2017). People at the severe stages of the condition were found to be mostly compliant, but their barriers to medicine taking were now due to difficulties remembering how to take medicines or swallowing them (De Witt Jansen et al., 2013; Look and Stone, 2017). In addition, any changes to their environment or transition in their care may have a drastic effect on their abilities to manage and take their medicines (While et al., 2012).
Theme 5: Partnership between the caregiver and PLWD

The partnership between the caregiver and the PLWD is crucial to medicines use. Some caregivers feel they need to empower the PLWD by allowing the PLWD to feel more in control of their medicines, and this strengthens the relationship between them (Poland et al., 2014). Caregivers need to be vigilant to discern when PLWD need help, as their transition from self to caregiver-led management is often variable and difficult to predict (While et al., 2012). This constant task of assessing the PLWD’s capabilities to manage and take their own medicines has been described as very taxing by some caregivers (Gillespie et al., 2015). Some of the signs that might indicate that the caregiver needs to provide assistance with medicines includes the PLWD forgetting to refill prescriptions, forgetting when and how to take the medications and forgetting the information given to them by their GP or pharmacist (Gillespie et al., 2015). Administration of some medicines can also pose some problems; some dosage forms can cause discomfort, pain or embarrassment when being administered, such as suppositories, inflicting stress on the caregiver and affecting their relationship with the PLWD.

This transition affects both the PLWD and their caregiver; the PLWD is either reluctant to release their autonomy or welcomes the assistance, and the caregiver needs to make the transition as smooth as possible (While et al., 2012). Caregivers have to balance their efforts of allowing the PLWD to retain their autonomy with their feelings of anxiety at doing so, such as ensuring that the PLWD is involved in information and decisions about their medicines (Smith et al., 2015).

Gillespie et al., (2015) found that some caregivers did not trust the PLWD to manage and take their medications as instructed and always had to be vigilant. Trust is required between both, especially when the PLWD is transitioning from self to caregiver-led management. The relationship needs to be transparent, with both parties working together to ensure that medicines are being taken in a safe and effective way.

Theme 6: Interface with formal care

This theme describes the relationship between HCPs, such as GPs, pharmacists and staff at care homes, and the caregiver and PLWD. Some caregivers felt that HCPs do not fully comprehend the role that caregivers have taken on and the burden and stress involved with it (Poland et al., 2014). This can lead caregivers to not share their
medication-related concerns, thereby increasing their burden (Lau et al., 2009). Furthermore, caregivers felt they were not being involved by the GP in discussions and decisions about the PLWD’s medication, such as when medications were changed or new ones prescribed (Jansen et al., 2012; Gillespie et al., 2015; Smith et al., 2015). The opposite also occurs, where the GP completely disregards the PLWD in the consultation and talks about them directly to the caregiver, causing distress to the PLWD (Smith et al., 2015). There is also the issue of the limited consultation time, causing some caregivers not to voice their concerns or ask for more information, as well as the inaccessibility of some HCPs (Smith et al., 2015; Maidment et al., 2017).

Gillespie et al., (2015) explored caregivers’ views from ethnic minority groups in Australia on support from HCPs. Some caregivers voiced their contentment with their relationship with their HCPs, sometimes relying on them to advise and mediate, as the PLWD looks up to them and would therefore comply with their instructions. With regards to services and support from pharmacies, not all caregivers had access to a pharmacist that provides assistance, even when they know that the person has dementia. Maidment et al, (2017) advocated the potential role of the pharmacist in optimising medication management for PLWD and their caregivers. This was through encouraging a more active role of the pharmacist within GP surgeries, allowing their access to PLWD’s files, and having a named pharmacist for dyads.

A strong relationship between the dyad and HCPs where communication is invited is necessary to facilitate medicines management (Kaasalainen et al., 2011; Maidment et al., 2017). Caregiver and patient support, such as education, should also be provided to ease the hassles involved with the management of medicines and empower both the caregiver and PLWD (Kaasalainen et al., 2011; Maidment et al., 2017). Both PLWD and their caregivers value their relationship with their HCPs and its continuity; they need to trust the HCPs to be able to depend on them (While et al., 2012).
2.4. Data collection and methodology

2.4.1. Qualitative studies

The literature review includes sixteen studies that have utilised qualitative methods. These were in the form of interviews (Travis et al., 2000; Lau et al., 2009; Taylor and Weiss, 2010; Kaasalainen et al., 2011; Carder, 2012; Jansen et al., 2012; While et al., 2012; Mirk et al., 2013; De Witt Jansen et al., 2013; Smith et al., 2015; De Witt Jansen et al., 2017; Maidment et al., 2017), focus groups (Poland et al., 2014; Look and Stone, 2017), or both (Hutchings et al., 2010; Gillespie et al., 2015).

The qualitative studies included in this review utilised five different methods for data analysis; content analysis, thematic analysis, grounded theory, narrative analysis and interpretative phenomenological analysis. The use of each one depends on the research question being asked. Content analysis ‘focuses on the characteristics of language as communication with attention to the content or contextual meaning of the text’ (Hsieh and Shannon, 2005). The aim is to organise large amounts of data into smaller categories, which are evident from the text or from analysis, through the use of a coding scheme (Hsieh and Shannon, 2005). The coding scheme is developed by the researchers as they analyse the data; there are no preconceived themes. Thematic analysis is one of the most commonly used analysis methods for qualitative data (Bryman, 2012). This method utilises a framework to organise themes and subthemes that are generated from the data. This method is advantageous as it is both deductive and inductive; it relies on the research aim and topic guides as well as participant responses. Grounded theory was first described in 1967 by Glaser and Strauss and has become the most cited approach in qualitative research (Bryman, 2012). In grounded theory, data are coded as soon as they are collected, with theories emerging rather than being predetermined. Coding is formed from the researcher’s interpretation and refined through constant comparison, wherein data are collected and analysed constantly to update and improve on future data collection (Starks and Brown Trinidad, 2007; Bowling, 2014). Narrative analysis employs unstructured interviews to promote story-telling; the emphasis of this approach is on the story rather than the smaller parts of the discussion as in the other approaches (Bowling, 2014). Interpretative phenomenological analysis relies on both how the individual interprets a personal experience and how the researcher interprets it; it is inductive in nature (Smith, 2004).
All these methods share a similar basis of coding to either generate themes or organise data in categories. Some methods are interconnected; thematic analysis can also be applied in grounded theory. Some researchers can also apply certain characteristics from different methods to produce a better analytical method that fits their research question (Lau et al., 2009; Hutchings et al., 2010; Poland et al., 2014).

2.4.2. Quantitative and mixed methodologies

Three studies included in the literature review used either quantitative methods (Reinhard et al., 2012) or a mixed-methods approach (Erlen et al., 2013; Maidment et al., 2013).

Reinhard et al., (2012) used an online survey targeted towards informal caregivers in the USA to discover the medical and nursing tasks they do daily. Of the 1,677 caregivers who responded, 30% cared for someone with a form of dementia. This was a nationally representative sample, but the representativeness is limited as it was very general and did not include sub-groups. The questions were general and were not tailored to specific populations, such as caregivers of PLWD. Furthermore, the authors had no way of verifying if the care recipients did indeed suffer from dementia as they depended on the account of their caregivers. In addition, using a survey is not the best method to capture rich data; participants cannot elaborate or explain their answers further. Moreover, participants may not have understood questions or not filled in the survey correctly which can reduce the validity of the findings. The questions also failed to identify specific difficulties with medicines as the topics discussed were general.

Erlen et al., (2013) used questionnaires, interviews and telephone follow-up to discover deficiencies in medicine taking from the perspectives of 91 caregiver-PLWD dyads in the USA. The large sample size and the variety of methods used to recruit participants ensure the representativeness of the sample. The Mini Mental State Exam (MMSE) was used to verify that patients had cognitive impairment. Sociodemographic data was provided to illustrate the characteristics of the sample. The authors were vague about the interviews their findings; the study results were all quantitative. There may be some bias in the sample selected as the authors relied on self-reporting, and it is possible that the dyad had already experienced a medication-related event that triggered them to participate. The information captured is not as rich
as obtaining data from interviews or focus groups; the authors stated the medication-related deficiencies experienced by caregivers without any elaboration.

In the study by Maidment et al., (2013) in the UK, caregivers of PLWD were invited to participate in a focus group discussion to generate issues they faced with medicines management. Also, 20 Alzheimer’s Society Research Network Volunteers were asked to fill in a survey. The study details and in-depth findings were not available as this was a conference abstract. The authors used 2 methods to capture different types of data which strengthens the study. However, the study is limited by the small sample size and the exclusion of dementia patients; PLWD views are just as important as their caregivers’.

2.5. Discussion of the literature review

This review has shown that some data are available with regard to challenges to medication use generally in older people. However, not all studies were exclusive to a dementia population; some included a wider sample of older people, some of whom had dementia; others were caregivers of PLWD. Medicines use in this population may provide added difficulties for caregivers as a result of issues relating to cognitive impairment (Poland et al., 2014; Look and Stone, 2017). There is a distinction between the care provided in the two types of care homes; this may have an implication on the findings because of the level of training of staff members. Although six different themes were generated from the studies, there is some overlap.

Administering medicines is a huge component of being a caregiver of PLWD and has many barriers associated with it (Travis et al., 2000; Reinhard et al., 2012). It is further complicated by polypharmacy, a variety of dosage forms and difficulty to interpret instructions (Maidment et al., 2013). Travis et al., (2000) demonstrated that while all caregivers faced hassles when administering and managing medicines, those caring for cognitively impaired individuals had worse experiences. This can be attributed to the patient refusing to take medicines, causing the caregiver to get frustrated (Reinhard et al., 2012; Gillespie et al., 2015). Barriers to medicines management and administration for caregivers of PLWD were not limited to dementia-specific medicines, but to all medicines and dosage forms being administered (Poland et al., 2014). Something as simple as applying eye drops can turn into a lengthy process. Even making decisions about whether the person requires pain relief can pose difficulties as it is sometimes difficult for the PLWD to express
their pain. The administration of medicines can also be hindered by the PLWD developing difficulties swallowing or forgetting how to take medicines (Gillespie et al., 2015; Smith et al., 2015).

In care homes, better communication with the healthcare team, the PLWD and their family was stated as important to the administration of medicines (Carder, 2012; De Witt Jansen et al., 2013, 2017). Furthermore, staff administering medicines had to possess certain skills to be able to understand each PLWD individually to make the process of medicine administration safe and effective (Carder, 2012; De Witt Jansen et al., 2013, 2017).

The degree of cognitive impairment is a major barrier and affects various activities, including medicines administration and negotiating the transition from self to caregiver-led management. While two studies attributed barriers to medicines management to dementia severity (Jansen et al., 2012; Kaasalainen et al., 2011), another study associated them with regimen complexity (Erlen et al., 2013).

The partnership between the PLWD and their caregiver was a critical component of the medicines use process; it was seen as a continuous struggle due to issues such as the PLWD refusing to take medicines and their need to retain their independence (While et al., 2012). Their transition to caregiver-led management may not go smoothly as they can resent the help offered. In addition, caregivers cannot always discern the stage at which the PLWD can no longer manage their medicines safely and effectively (Poland et al., 2014; Gillespie et al., 2015).

Caregivers took on the caregiving role but lacked the knowledge required to make certain decisions (While et al., 2012). The role often entails making complex judgements regarding medicines use for the PLWD, adding more to their stress (Maidment et al., 2013, 2017).

Study findings also illustrated how caregivers lacked medication-related support (Travis et al., 2000; Taylor and Weiss, 2010; Poland et al., 2014; Gillespie et al., 2015; Smith et al., 2015; Maidment et al., 2017). Family caregivers sometimes modify medicines, such as by crushing tablets, or by concealing them in food to ease medicine administration to those who have difficulties swallowing or refuse to take medicines. They may not realise that this can affect the therapeutic outcome, leading to lack of quality, safety and efficacy of the medicine (Gillespie et al., 2015).
General support and services aimed at PLWD and their caregivers have been highlighted as requiring improvement (National Audit Office, 2007). There is a need for improved systems regarding the provision of medicines-related information, such as the importance of the treatment, expected side effects and administration procedure, to ensure optimal medicines use and adherence (While et al., 2012).

Findings emphasise the importance of maintaining a *good relationship between the dyad and HCPs*; effective communication and trust can assist the caregiver in coping with the pressures, thereby allowing the PLWD to be cared for at home for a longer time (While et al., 2012; Poland et al., 2014).

The literature reviewed highlights the role that HCPs could play in overcoming some of the issues discussed. This can be through better communication, inclusion of both PLWD and their caregivers in discussions and decisions, and provision of detailed and individualised medication information. The role of the pharmacist was stressed as being integral to this (Maidment et al., 2017). Pharmacists are an accessible and approachable source of information and support. There is a need for consistency in the advice and reviews administered to PLWD and their caregivers to ensure there is no confusion. Pharmacists may also have a major role in care homes by supplying advice to nurses and carers on medication administration and formulations, as well as reviewing medicines. Older people have been shown to benefit from pharmacist-led interventions (Ryan et al., 2014).

### 2.5.1. Conceptual model

The findings of the literature review assisted in the development of a conceptual model to be used as a basis in the present study (Figure 2.2). The themes that emerged from the literature review provided the main factors. These are followed by sub-factors that also affect medicines use; these were either mentioned briefly or not at all. The themes and sub-themes in this conceptual model provide the framework for the areas of interest that are explored in the present study.
2.5.2. Implications and justification for the present study

This review has shed light on some gaps in knowledge, which can be addressed in future research. This includes how PLWD and their caregivers cope with deteriorating cognitive decline and other physical difficulties that arise due to progression of dementia that might affect medication use. Various studies have suggested that the direction of future research should focus on medication use in the dementia population and ways to help them and their caregivers, such as by supporting them with medication management and medication-related knowledge (Maidment et al., 2012; Gillespie et al., 2013; Prorok et al., 2013; George and Steffen, 2014).

PLWD and their caregivers

All of the studies illustrated the burden caregivers of PLWD experienced with medicines management. They also showed that it was crucial that caregivers were supported as PLWD depended on them to not be institutionalised. According to the World Health Organization (WHO), studies should focus on how medication administration affects caregivers (WHO, 2012). This justifies focusing this research on PLWD and their caregivers, especially relating to barriers to medicines administration, as it contributes greatly to caregiver burden.

Gaining the perspectives of both the PLWD and caregiver are essential in exploring all the issues, as previous research has shown that PLWD have differing views than those of their caregivers and are able to contribute to research (Werezak L and Stewart N, 2002; de Boer et al., 2007; Miranda-Castillo et al., 2013). The endorsement of patient-centred care, and the inclusion of care recipients in decision-making has been the focus of current research as they have a great effect on medication adherence (Ryan et al., 2014). Furthermore, the production of successful, tailored interventions and services requires the input of the users, who in this case are the PLWD and their caregivers (Aggarwal et al., 2003; Abetz et al., 2009; Miranda-Castillo et al., 2013; Singh et al., 2014). Poland et al., (2014) demonstrated how the involvement of caregivers of PLWD can assist in determining topics relevant to them to enhance research validity and the development of efficient interventions that are feasible to implement.
PLWD reach a point where a caregiver is needed to assist them with their medicines, and sometimes, medication-related issues need to be discussed in the context of the relationship between the PLWD and their caregiver. Their partnership plays a major role in promoting optimal medication use and developing tailored support (Francis et al., 2006; Thorpe et al., 2012; Roland and Chappell, 2015).

Dementia and medicines

An issue relating to medicines administration that needs further exploration is how the variety of formulations affect medicines use, such as modification of medicines to ease administration, and the processes and decisions involved. Difficulties with swallowing and dysphagia were briefly mentioned in some studies (Erlen et al., 2013; Gillespie et al., 2015; Smith et al., 2015). Understanding the scope of the issues with swallowing difficulties and its consequences on the administration of medications and specific formulations can help in generating tailored recommendations. Regulatory bodies, such as the European Medicines Agency (EMA), are interested in recognising what medicine-related aspects require improvement for the geriatric population; The Food and Drug Administration in the USA place importance on user perspectives as they provide beneficial information that may not have been investigated previously (FDA, 2006). The findings from the present study can inform such regulatory bodies and pharmaceutical companies to make considerations for appropriate formulations for optimal and safe medication use.

Prescribing appropriate formulations for PLWD may help in their maintaining their independence for longer and delay their transition to care homes. This is a crucial barrier that will be explored in the present study. This study will not focus on dementia-specific medicines, but will include all medicines being administered to the PLWD, as medicines used to treat dementia, such as memantine and donepezil, will not cover the whole scope of barriers. Furthermore, medication-related support needs to be tailored to caregivers of PLWD and the patients themselves; their perspectives on what is needed at different points of disease progression requires exploration to achieve this. One study described how disease progression is linked with barriers and facilitators to medicines management (Kaasalainen et al., 2011). The present study aims to explore this further as Kaasalainen et al., failed to elaborate on the findings and recommendations. Furthermore, the study was based within one particular region in Canada; therefore the findings may not be generalizable to the population in the
UK, as they can be attributed to the different health systems. By examining the implications of choice of different routes of administration and dosage forms, and including the views of both PLWD and their caregivers, recommendations can be given to achieve patient-centric care regarding effective medicines use for PLWD.

Dementia and formal care

As dementia progresses and family caregivers are no longer able to care for the PLWD at home, their care shifts from the community to care homes. Caregivers in care homes, such as nurses, are also faced by barriers when administering medicines to people with dementia (Carder, 2012; De Witt Jansen et al., 2013, 2017). This setting should not be overlooked, hence its inclusion in the present study. It is important to identify barriers from all severities and aspects to be able to encompass all situations. Training and procedures can sometimes differ between care homes, such as administration of PRN medicines (Carder, 2012). The inclusion of different types of care homes in the present study will assist in exploring issues that are encountered at a variety of sites.

Interface with formal care regarding medicines use is also explored in the present study. Understanding the relationship between the caregivers and PLWD and their HCP and the barriers to communication that may occur is essential to optimising the medication use process; non-adherence to treatment has been shown to be linked to a breakdown in this relationship (Ryan et al., 2014).

Implications for the present study

Dementia is a debilitating condition that affects both the patient and their caregiver; the number of people who will suffer from it will steadily increase as the population is ageing. Although efforts are being taken to raise awareness of the disease, the focus has been on its diagnosis and management. Medication use may be a minor aspect of the disease but if overlooked, can drastically affect the patient.

Medicines are prescribed and dispensed to PLWD with little regard to how they and their caregiver feel about the use of these medications and the issues they may encounter. The present study considers all medicines and formulations, as their acceptability and the ability of the caregiver and PLWD to use them appropriately can also affect their safe and effective use (Royal Pharmaceutical Society, 2013).
Furthermore, oral dosage forms and swallowing are also explored as the swallowability of oral medicines is significant to determining the acceptability of medicines, especially in older people, and hence their adherence to their regimen and achieving their therapeutic outcomes (Liu et al., 2014). By employing qualitative methods to examine all medicines being used by PLWD in both the community and care home setting, a better understanding of the scope of issues surrounding the medication use process is achieved, and targeted interventions can be formulated.

The findings will also inform the relevant regulatory bodies that are concerned with geriatric medicines. Pharmaceutical companies will also benefit as the information regarding which medicines and formulations pose the most difficulty, and how PLWD and caregivers modify them. This can help in identifying more appropriate formulations, or improving instructions on how to modify medicines without damaging the medicine or harming the patient. Prescribers, pharmacists and nurses need to understand the importance of asking about how medicines are being taken or given to ensure they are being adhered to and administered safely and effectively, leading to acceptability both for PLWD and their caregiver. There is also a need for better service and support provision, and future research should focus on interventions to improve medicines use for this population; there are various interventions on improving medicines use in different patient populations, but there is scarce data on how PLWD and their caregivers can improve how their medicines are used (Ryan et al., 2014). The present study is able to inform future pharmacy services and interventions tailored to this patient population by identifying and examining all the issues surrounding the medication use process from the perspective of the PLWD and their caregiver. Recommendations can then be given to achieve patient-centric care regarding optimal medicines use for PLWD.
Factors affecting optimal medicines use in PLWD

Organisation and scheduling logistics
- Managing multiple medications (obtaining, storing, tracking)

Partnership between caregiver and PLWD
- Decision-making
- Switching from self to caregiver-led management

Impact on PLWD
- Retain autonomy
- Severity of cognitive impairment

Impact on caregiver
- Burden associated with medicines administration and management
- Lack of medication-related support and services

Formulations and administration procedures
- Formulations and routes of administration
- Modifying medications
- Difficult instructions
- Dysphagia
- Polypharmacy and regimen complexity

Interface with formal care
- Relationship/communication between HCP and PLWD and caregiver

Figure 2.2: Conceptual model on factors affecting optimal medicines use in PLWD (Alsaeed et al., 2016)
2.6. Aim of the present study

To identify and examine the factors contributing to the challenges to medication use from the perspective of PLWD, at different levels of disease severity, and from their caregivers in the community and care home setting in order to help maintain optimal therapy for this patient population, with a focus on the use of appropriate drug formulations. In addition, to make recommendations for assistance for PLWD and caregivers to help alleviate caregiver burden and improve the medication use process along dementia progression.

2.6.1. Specific objectives

A literature review was undertaken to identify the issues found in this patient population previously, and to find the gaps in literature. Preliminary fieldwork was also conducted to better inform the research. Details of the preliminary fieldwork can be found in chapter 3. Table 2.6 lists the specific objectives which correspond to the domains in the conceptual framework developed from the literature review. The table also illustrates how each objective was measured. Detailed information on how each objective was measured can be found in chapter 3.
<table>
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<th>Table 2.6: Specific objectives</th>
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<tr>
<td><strong>Objectives</strong></td>
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<tr>
<td>1. To identify the frequency, range and suitability of medicines and formulations used at the different settings and any transition in formulations used (e.g. tablets/capsules to liquids to patches).</td>
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<tr>
<td>2. To gather and examine PLWD and caregiver views and experiences of medication management and the perceived advantages and difficulties in the community and care home setting, and any changes with progression in dementia.</td>
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<tr>
<td>3. To identify and examine the problems faced by family caregivers at home and nursing/carer staff in care homes regarding challenges with medicines administration and changes encountered with dementia progression</td>
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<tr>
<td>4. To identify the extent of emergence of swallowing difficulties in each care setting and its implications on medicines use in both care settings.</td>
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<tr>
<td>5. To identify and examine the factors associated with the changes in the caregivers’ and PLWDs’ role regarding medicines management and decision-making along dementia progression and its impact on them and the care recipient.</td>
</tr>
<tr>
<td>6. To identify and examine the factors associated with the interface with formal care that affect medication use from the PLWDs’ and family caregivers’ views and suggestions for improvement. To also identify how interactions within the care home affect medication use.</td>
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<tr>
<td>7. To produce tailored recommendations to optimise medication use and alleviate caregiver burden.</td>
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Chapter 3: Methods

3.1. Introduction

This chapter details the methods and justifications, as well as the ethical approval process and considerations taken. It also provides the research design with sampling and recruitment procedures, in addition to the data collection methods and tools, and data analysis process.

3.2. Preliminary fieldwork

3.2.1. Aims of the preliminary fieldwork

Preliminary fieldwork is vital in research; it assists in determining the important issues related to the population being studied. The following were the aims for conducting the preliminary fieldwork:

- To gain insight into issues that relate to medicines use in the elderly
- To refine the aim and objectives of the present study
- To pilot the instruments and documents to ensure their feasibility and acceptance
- To pilot the data collection method of the present study to ensure data will achieve objectives

As part of the preliminary fieldwork, the researcher assisted in the facilitation of two public engagement events for elderly people, attended a conference on swallowing difficulties, led a discussion with two elderly volunteers about medicines use, and gained a former PLWD family caregiver’s views on the topic guides and study documents.

3.2.2. Details of the preliminary fieldwork

Patient and public involvement in research, especially in health research, is imperative to better inform research and produce relevant findings that will benefit service users (Brett et al., 2014). With that in mind, the researcher assisted in facilitating a public engagement event at UCL School of Pharmacy in 2013 on ‘How to Improve Medicines for Older People’ (Orlu-Gul et al., 2014). This event involved 78 people that included elderly members of the public, academic researchers and experts from
industry and regulatory agencies. The discussions revolved around medicines management, using different medicine formulations, and the partnership between the caregiver and patient at home. The researcher was also involved in another public engagement event at the same venue in 2014 on ‘What are the Important Questions for Research into Ageing?’ (Alsaeed et al., 2016a). The topics discussed were ways in which elderly people can be actively involved in research and age inequalities. Although this workshop was not as relevant to the present work as the one conducted earlier, information was attained that is deemed applicable and provided useful perspectives.

The issue of swallowing difficulties in the elderly, which was brought up in the first public engagement event attended, and dysphagia in PLWD is linked to medicines use and issues surrounding it. Therefore, the researcher attended the 5th United Kingdom Swallowing Research Group Conference in February 2014 to learn more about dysphagia and new research involving it.

A semi-structured discussion took place at UCL School of Pharmacy with two participants who volunteered through the Age UK London branch. Although both participants were former family caregivers, the discussion helped immensely in piloting the interview schedule. In addition, thematic analysis of the audio-recorded transcription produced data that helped in refining the study’s objectives, as well as topic guides, which are discussed in the next section. The themes in common between the literature and the interview guide were caregiver burden, compliance to medicines, caregiver support/empowerment, relationship with the general practitioner (GP), medication-related problems and autonomy/decisions. New themes that emerged dealt with the impact of dementia progression on the caregiver and PLWD, the effect of the caregiver’s health on caregiving and how the caregiver’s role changes. All these themes were taken into account when developing the new topic guides for the present study.

The topic guide was not piloted in care homes due to the need for approval from an ethics committee, as well as time constraints.
3.2.3. Implications of the preliminary fieldwork

All the fieldwork conducted has informed the study in different aspects. Attending the first public engagement event and facilitating with the group discussion shed light on issues that are pertinent to the present study. The challenges discussed by participants included physical difficulties (such as swallowing, visual and dexterity problems), cognitive difficulties, medicine related difficulties (such as polypharmacy, lack of advice, and medication reviews) and other shared difficulties (such as the relationship with and role of the pharmacist and GP). Some important points that were introduced were inappropriate formulations, lack of communication between patients and caregivers and HCPs, lack of advice to patients about medicines use (such as altering formulations), and whether they had difficulties swallowing medicines (Orlu-Gul et al., 2014). All the issues discussed have provided a justification for the present study and have been taken into account with developing the aim, objectives and topic guides of the present study.

From the discussions in the second public engagement workshop, it was noted how willing older people are to be involved in research, especially with PhD students. They are also willing to complete questionnaires, as long as there is no confusing language. A very interesting concern was also raised, which was that of ‘carer’ terminology. People taking care of their family member felt disrespected by being called an informal/unpaid carer, as they felt it held negative connotations and belittles what they do. This led to the decision to use the term ‘family caregiver’ instead of the terms ‘informal carer/unpaid carer’.

The two day conference helped in understanding the different ways swallowing can be measured, the outcome measures used, swallowing-related quality of life measures, and the strong association between dysphagia and poor quality of life for both the patient and caregiver. What was surprising was that the issue of swallowing medicines and dysphagia was only mentioned in one workshop, while all other research was focused on speech and diet. This highlights a gap in the existing literature regarding swallowing difficulties and medication use in PLWD, and makes the present study even more significant as the subject has not been examined thoroughly.

Leading the discussion with the two volunteers has not only helped in piloting and refining the interview schedule, but also illustrated how the number of people
involved, in this case two people, does not affect the quality of discussion. The two participants did not know each other beforehand and they managed to provide significant data as well as personal experiences. This indicates that having two people participating in an interview will still produce rich and viable data. The discussion also assisted in refining the objectives. The caregivers emphasised the changes that occurred along the progression of dementia in the care recipient and how it impacted them. This was an interesting point as it highlighted the importance of the trajectory of dementia on medicines use, as well as on the partnership between the PLWD and their caregiver.

A former family caregiver of a PLWD volunteered through the Age UK London branch; he assisted in examining the topic guides and documents aimed at PLWD and their caregivers that were used in the present study. He offered his views and recommendations on minor improvements to the information leaflets and participant reply slips, which were taken into account. The suitability of the word ‘dementia’ was discussed; the caregiver preferred to avoid it as it had negative connotations. He associates it with the word ‘demon’ and throughout the discussion he replaced it with the term ‘memory loss’. This demonstrates that some people feel uncomfortable with the word. Based on that, the term ‘dementia’ was replaced with ‘memory problems/issues’ when interviewing family caregivers and PLWD. He also assisted in providing recruitment ideas; he supplied the contact details of a dementia advisor, and also suggested attending dementia cafés run by the Alzheimer’s Society. These suggestions were immensely helpful and will be discussed in the subsequent sections.

### 3.3. Study design

In order to achieve the research objectives, a qualitative approach was implemented for the study design. The methodology included the use of qualitative joint and individual interviews and observations. To enable a comprehensive examination of issues from perspectives of PLWD and their caregivers, in relation to care setting and dementia severity, participants were recruited from the community and care homes in London. Figure 3.1 shows a diagram of the study design. Both parts of the study (community and care home settings) were conducted concurrently. The study adopted a cross-sectional element, with a follow-up of the community participants. The follow-up approach was applied with family caregivers via telephone; PLWD and their caregivers were asked if they would allow the researcher to call at a later date, in
3-8 months’ time, to ask further questions. This was to identify any changes that might have occurred with their medications and health state. This, in turn, will highlight if and how PLWD and their caregivers require support due to changes in medication use, as dementia progresses. Furthermore, it will inform how ongoing support might be tailored.

The topic guides were developed using information gathered from reviewing the literature and the results from the discussions in the preliminary fieldwork. Three schedules were created; one aimed for PLWD, one for their family caregivers, and one for staff at care homes. This is elaborated on in section 3.8.1.

In the community study, individual and joint interviews with family caregivers and PLWD were used; semi-structured interviews included open and structured questions. Interviews were conducted at a place of the participants’ convenience, which in all cases was their home. Conducting interviews at the participants’ home allows for a relaxed and familiar atmosphere where they feel more at ease to talk about their thoughts and experiences. Interviews with family caregivers and the PLWD were done simultaneously to make both participants comfortable. By interviewing family caregivers and their care recipients, the researcher was able to study their accounts of problems and their partnership in the context of medicines use. Separate topic guides caregivers and PLWD were developed, as the issues discussed differ slightly and some questions were only aimed at caregivers. After data collection was completed and initial analysis was conducted, participants who consented to be followed up were sent letters to remind them that the researcher would be in contact with them in the following week to set a convenient date for follow-up questions. A telephone interview was conducted with the researcher taking notes and audio-recordings when feasible. Details of the follow-up interviews can be found in section 3.8.1.

The second part of the study was conducted at a small number of care homes around London. At the care home setting, PLWD will most likely have moderate to severe dementia, and may lack the capacity to consent. Furthermore, consent from the PLWD’s family would be necessary for inclusion in the study, which would further delay recruitment. That is why in this setting, the health care professionals (HCPs) administering medicines to the patients with dementia were asked to participate in individual/joint interviews to discuss the issues associated with medicine giving and how they tackle them.
The researcher conducted observations of medicines being administered to dementia residents at each care home; observations were of the morning and lunch rounds at each care home in one day. Observations were recorded as field notes in a data collection tool; these included interactions between staff and residents observed, details of medication administration processes, and any other aspects of interest that might assist in analysing the findings. Observations and field notes assisted in achieving objectives 1-4 by identifying the suitability of formulations administered, the difficulties encountered with medication management and administration, and swallowing difficulties. Furthermore, this allowed the researcher to be familiar with the system adopted at each care home and to observe the actual administration of medicines and the range being used in dementia patients. The notes were written in full on the same day to reduce the risk of memory bias (Bowling, 2014). After the observation period, the researcher carried out individual/joint interviews with eligible staff members involved with medicine administration. Combining observations with interviews helped in understanding the whole process of medicines management in the different care homes (Gilmartin, 2015a). Furthermore, it allowed the researcher to place the interview questions into context after observing the HCPs administer the medications. As staff were engaged with their work, it would be difficult to allocate a time when staff can participate in a group discussion. Thus, the interviews were flexible in that they would depend on the availability of participants; the researcher allowed for individual interviews as well as joint interviews when feasible.

A request was made to audio-record the interviews using a digital audio-recording device, to be transcribed later by the researcher. Audio-recording provides many advantages such as allowing better examination of what the participants say, allowing the researcher to focus on the participants during the sessions rather than writing notes, and provide an important aspect which is how the participant is answering. Those who did not wish to be audio-recorded were not excluded, and the researcher was prepared to take notes during their interview (all participants agreed to be audio-recorded). Thoughts and feelings concerning the interview, such as disruptions and rapport, were noted by the researcher, to assist in anticipating issues that might arise in subsequent interviews, as well as to provide context to the findings. Field notes were typed within 24 hours to ensure all information observed is retained. Transcribing of interviews was completed within a week of each interview.
Caregiver burden is an important aspect to measure; it demonstrates how caregivers are affected by the role they have adopted. As this study focuses on medicines use and its impact on the caregiver, the Family Caregiver Medication Administration Hassles Scale (FCMAHS) tool was chosen (Travis et al., 2003). It is the only caregiver tool that looks specifically at hassles related to medicines management and administration. Other information gathered includes patient and caregiver sociodemographic characteristics and medications being taken. The present study did not use a scale to measure disease severity. This is because some scales, such as the Mini-Mental State Examination (MMSE), can be awkward and distressing to administer to PLWD (Hughes et al., 2002). The number of hours spent caregiving can be used to determine the severity of the patient’s dementia. This information was obtained using the Caregiver Activity Scale (CAS) (Davis et al., 1997). Furthermore, family caregivers were asked how long they can leave the PLWD unsupervised; this provides an indication of how severe the dementia is. In addition, family caregivers were also asked to class the severity of dementia in their opinion. This triangulation of methods was used to provide a broad view on dementia severity.

The study is designed in this manner to gain a holistic perspective on medicines use as dementia progresses, and enable recommendations addressing the needs of PLWD and their caregivers to be made. By using these methods at the corresponding settings, the researcher was able to discern any differences in the way medicines are provided and the knowledge involved in the different settings. In addition, it provided a wider view on the spectrum of problems faced by PLWD and those who care for them at different stages of dementia severity. This assists in understanding the context of the problems, and ensures the provision of tailored recommendations. This may help to optimise therapy for each setting, improve clinical outcomes and reduce caregiver burden. In addition, the findings assist in anticipating the problems that may occur for future PLWD and their caregivers.
• Nursing and residential care homes in London

• PLWD and their family caregivers in their own homes in London

**Sampling and recruitment**

• **Care home setting:**
  • Eligible care homes identified via CQC website
  • Called care home managers and gained consent (4 care homes)
  • Visited care homes to gain background information and set date for the study day

• **PLWD and caregivers in the community:**
  • Letter packages distributed by dementia advisors and given at dementia cafés
  • Received reply from participants by mail or phone
  • Contacted participants at convenient time and set date for interview (called day before interview to confirm)

**Data collection**

• **Care homes:**
  • Observation of two medications rounds (structured data for qualitative analysis)
  • Semi-structured individual/joint interviews

• **Community:**
  • Semi-structured individual/joint interviews
  • Structured data using instruments (FCMAHS,CAS)

**Data processing and analysis**

- Qualitative interviews and observations
  - Audio-recording
  - Transcribing
  - NVivo 11
  - Generating codes
- Structured data
  - SPSS version 21
  - Descriptive statistics (sum, mean, standard deviation)
- Thematic framework analysis (iterative, deductive/inductive, constant comparison)

**Figure 3.1:** Diagram of study design
3.4. Rationale for chosen methods

A mixed qualitative approach, using interviews, observations and structured qualitative data, was chosen as it is the most suitable to achieve the research aim and objectives. This is supported by the literature review; the majority of the studies employed qualitative methods in the form of interviews and/or focus groups. This indicates the suitability of this approach for the present study as the objectives of the data collection were similar. Quantitative methods, such as the use of surveys or questionnaires, will not be able to capture in-depth information, are rigid in structure, have a low response rate and there is a risk of participants misunderstanding the questions or the questions posing a cognitive burden on them; this may all negatively affect the quality of responses (Bruce and Paterson, 2000; Ryan et al., 2001; Bowling, 2014). Furthermore, quantitative methods were found to be uninformative when assessing ease of use and suitability of formulations, such as the use of surveys to ask participants about issues encountered with certain medications (Messina et al., 2015).

With individual and joint interviews, the researcher is able to ensure that all those recruited are included and to elicit responses from them. The use of a mix of qualitative methods also assists in gaining different types of data in the same data collection phase. The structured element is composed of two questionnaires that are completed by the family caregiver after each interview. Details of the instruments can be found in section 3.9. These structured surveys provide a different way of data collection that complements the interviews by providing an overview of information that is used alongside the participant perspectives.

Gaining the perspectives of family caregivers and PLWD about medication use is important in health research and in the development of health services. This assists in understanding the issues relevant to them which will help develop tailored recommendations (Abetz et al., 2009; Bowling, 2014; Orlu-Gul et al., 2014). Individual and group interviews rely on interacting face-to-face with the participants to gain their perspectives. They also allow for clarification of what is said, unlike quantitative methods. The present study employed the use of both individual and joint interviews, as seen in the study by Hutchings et al., (2010) as this ensures that all participants are included and accommodated. PLWD were interviewed with their family caregiver, as previous research has shown that they may feel anxious and uncomfortable sharing information with groups of people (Bamford and Bruce, 2002).
The method of data collection was more flexible with care home staff as it depended on their time, as the researcher did not want to cause further stress. Conducting group discussions with the care home staff can assist in reducing the time spent with data collection, transcription and analysis, as well as increase sample size as more participants can be included. The use of both individual and group discussions assisted in ensuring the flexibility of the methods, and therefore the feasibility of the study.

Participants in the community were followed up after 3-8 months from the time of the first interview. This was deemed a sufficient amount of time for change to occur, as illustrated in previous research (Werezak L and Stewart N, 2002).

Qualitative observation was also utilised in the care home setting. Applying observation and using this triangulated approach provides in-depth understanding of the medicines administration procedures and systems in care homes, as well as interactions between staff members and residents (Barber et al., 2009; Carder, 2012; Bowling, 2014; Gilmartin, 2015a). In addition, observing and taking field notes complements the interviews, as they provide context and may include interactions or issues that may not have been in the interview guide or were not provided by the staff when questioned.

The qualitative analysis method was also chosen based on previous studies. This was demonstrated in the study by Hutchings et al., (2010) where the authors employed a thematic-framework approach. This method utilises both a deductive and an inductive aspect to analysis; the thematic framework will rely on the objectives as well as new emerging themes from the data (Bowling, 2014). Furthermore, the conceptual model developed from the literature review provided the framework for the thematic analysis, which assisted in gaining a holistic view on issues relating to medication use.

Gaining the perceptions of PLWD may not always be feasible due to severity of cognitive decline and therefore ability to consent. However, it is still imperative for the views of PLWD with the capability to consent to be included as some want to be involved in research and are able to. They can also provide a different perspective to medication issues from their family caregivers (Werezak L and Stewart N, 2002; National Collaborating Centre for Mental Health, 2007).
3.5. Ethical considerations

Ethical issues should be considered before embarking on research. This is more crucial when the study population is vulnerable, which is the case in the present study. Ethical concerns not only deal with the participants, but also affect the researcher, data protection, confidentiality and anonymity (Bowling, 2014). Consent was taken by the researcher before the start of each interview, with the participant signing a consent form (Appendix 2). As this study recruited and interviewed PLWD, there was the ethical issue of informed consent. The person’s capacity to consent was assessed in line with the Mental Capacity Act 2005 (“Mental Capacity Act 2005: Code of Practice,” 2007). Consent was considered valid if it was informed, competent, uncoerced and continuing (“Mental Capacity Act 2005: Code of Practice,” 2007; National Collaborating Centre for Mental Health, 2007). If the person was deemed unable to consent, their caregiver’s consent on their behalf was not accepted. The PLWD should be able to make their decision independent of their caregiver to be eligible for inclusion. PLWD who expressed interest to be included were assessed with regards to their ability to consent before going forward with the interview.

As evident from previous studies, it was not always possible for PLWD in the community to participate. This is due to the difficulty in recruiting people with dementia to take part in studies. Careful consideration should be taken due to their cognitive decline and the sensitivity of the subject discussed. In addition, PLWD might be in denial of their diagnosis, feel uncomfortable with the subject matter, or have nothing to add to the study, or are unable to consent due to dementia severity. Efforts were made to recruit as many as possible through their caregiver. The subject of dementia is very sensitive and participants may feel anxious or upset when they recall certain experiences. A survey conducted in 6 European countries, including the UK, on family caregivers of PLWD (n=618) reported that 64% of caregivers were in denial about the diagnosis and 58% thought that the symptoms the patient was experiencing was a normal part of the ageing process (Bond et al., 2005). In addition, people aged 65 and over fear the diagnosis of dementia more than other chronic diseases such as cancer or heart disease (Alzheimer’s Society, 2008). In the consideration of not wanting to cause any distress, the researcher did not use the term ‘dementia’ or ‘patient’, and instead mentioned ‘memory problems’ or ‘memory issues’ (Alzheimer’s Society, 2008; Hutchings et al., 2010). The same consideration was taken with the caregivers by not using the terms ‘informal carer’ or ‘unpaid carer’
as the label might not be favourable (Martin et al., 2012). These considerations with terms are reflected in the information leaflet, invitation letters and topic guides for PLWD and their caregivers. Also mentioned in an earlier section, assessing degree of cognition with tests such as the MMSE were not used as they have been known to cause distress to both the PLWD and their family caregiver (Hughes et al., 2002).

It was anticipated that care home staff members would be unable to commit to research due to their busy schedule. For that reason, they had the option of individual interviews as well as group interviews. Furthermore, they might have felt that participating in this study may affect them or their job, either in a negative or positive way. This is more an issue during the observation period because they might have thought that the researcher was looking for errors. They were assured that observation was only taking place so that the researcher familiarises themselves with the care home and its processes regarding medicines administration. The staff were informed that their participation is voluntary. If at any point they refuse and would like to withdraw, they would no longer be observed, but the data obtained beforehand would still be used.

Before every interview, the participants were asked if they understood the study and what their involvement meant. They were informed that they could skip any questions they did not feel comfortable answering and/or terminate the interview at any point. This was to make sure that the participant felt comfortable and in control. The researcher was vigilant in looking for non-verbal cues from the PLWD (such as restlessness and agitation) that may indicate their discomfort and wish to withdraw. If the researcher felt that the participant was uncomfortable, then the interview would be stopped. If participants did not wish to continue, they were told they could leave the study, but any information collected up till that point would be used.

The researcher’s safety was also considered. The researcher visited unfamiliar areas alone and visited participants’ homes to conduct interviews. The researcher made sure to contact someone beforehand to inform them of her location, and re-contacted them at the end of the interview in accordance with UCL’s Lone Working Policy.
3.5.1. Data protection

Interviews were audio-recorded and transcribed verbatim by the researcher. All identifying information was coded to ensure anonymisation. The participants were identified only by a participant ID number on any electronic document used. All documents were stored securely and only accessible to the research team. The study complied with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so.

All paper records were locked in a cabinet at the Pharmacy Practice department at the School of Pharmacy, UCL. All computer files are password protected and accessible only to the research team. All audio recordings will be deleted when the study has been completed. Participants will have the opportunity to receive the study findings after it is completed.

3.5.2. Ethics application and approval

Following the upgrade viva voce (oral examination), the study materials and application to the relevant ethics committee were prepared and sent to UCL Joint Research Office (JRO) on October 31st 2014; sponsorship approval is required from UCL before proceeding to the ethics committee. After various amendments were made, approval from the UCL JRO was received on December 17th 2014 (study reference number 15/LO/0177).

The study documents and application were sent to the National Research Ethics Service (NRES) Committee South East Coast-Surrey Research Ethics Committee on the 14th of January 2015 and a date was set for the full review, which was February 3rd 2015. The researcher attended the meeting which was held at Royal Surrey County Hospital. A provisional letter was sent 2 weeks after the meeting stating the need for minor amendments (Appendix 3.1). Once the specified documents were amended accordingly, they were resent on the 27th of February 2015. Favourable approval was given on the 17th of March 2015, but due to a technical error, the researcher was not informed of the decision until the 15th of April 2015 (Appendix 3.2). The research ethics committee was emailed to request the inclusion of additional sites to the study (care homes and Alzheimer’s Society branches).
3.5.3. Permission to use the questionnaires

Two structured questionnaires were used for family caregivers in the present study. The Caregiver Activity Scale (CAS) was available freely online. The researcher contacted the author of the Family Caregiver Medication Administration Hassles Scale (FCMAHS) to ask for permission to use the scale as well as receive it by email. The author kindly replied back and approved the tool’s use in the present study and attached it in the email.

3.6. Population

3.6.1. Sampling strategy

The number of PLWD in the UK in 2015 was 800,000, with numbers expected to double by 2040 (Department of Health, 2015). Eighty-four percent of PLWD are residing in England (Alzheimer’s Society, 2014). London has approximately 72,000 people living with dementia, with late-onset dementia affecting 7.3% of London’s elderly population (Alzheimer’s Society, 2014). In 2007, 54.8% of PLWD in London were at the mild stage, 32.3% at the moderate stage and 12.9% at the severe stage (Healthcare for London, 2009).

London is divided into 32 boroughs; each borough differs in the population demographics of PLWD and services and support available (Healthcare for London, 2009; Alzheimer’s Society, 2014). Three different boroughs in the London area were chosen for this study; Croydon, Lambeth, and City & Hackney. The Borough of Westminster was initially chosen instead of Lambeth, but recruitment challenges meant another borough had to be chosen. Each of the boroughs differs in their geographical area (inner and outer London), prevalence of dementia, and socioeconomic and ethnic diversity; this assists in providing a sample that is diverse and representative. Croydon is an outer London borough, with around 50% of its population black, Asian or an ethnic minority (BAME) in 2013 (London Datastore, n.d.). Hackney and City of London are combined as one borough by the Alzheimer’s Society. They are both inner London boroughs, with 43.6% and 27.5% of their population BAME respectively in 2013 (London Datastore, n.d.). Lambeth is also an inner London borough, and 41.5% of its population were from BAME groups in 2013 (London Datastore, n.d.). The percentage of PLWD in 2013 in each borough chosen
compared to all of London (n=72009) is 1.9% in City & Hackney, 2.5% in Lambeth and 4.9% in Croydon (Alzheimer’s Society, 2014).

The study population includes PLWD at different levels of disease severity, their family caregivers, and nurses and paid carers at the chosen care homes. A family caregiver is defined as an adult family member or friend who provides unpaid support with medicines for a PLWD. Formal carers in the community are not included in this study as it is not always the same person providing the care, and their experiences differ greatly from those who are family or friends (Bruce and Paterson, 2000). Also, family caregivers are more likely to be residing with the PLWD and may have taken on the role from the start, and are thereby able to provide detailed responses about the care provided along the progression of dementia (Smith et al., 2001). In addition, the primary family caregiver has been shown to spend more time caregiving than secondary caregivers and would therefore provide more information regarding medication use (Neubauer et al., 2008).

The community and care home settings have been chosen for the study for a variety of reasons. Older people are encouraged to stay at home for longer, so it is important to look at the community setting to include the majority of PLWD (Royal Pharmaceutical Society, 2014). However, care homes should not be excluded as approximately a third of PLWD in the UK live in care homes (Alzheimer’s Society, 2007). Furthermore, looking across the two care settings can ensure the participation of PLWD at different degrees of dementia severity, and caregivers from different socio-economic and cultural backgrounds, to ensure a more representative sample. It can also shed light on the differences in problems encountered when administering medicines in each setting, as it has been shown that the prescribing and administering of medicines, and acceptability towards different formulations, differ (Treloar et al., 2001; Liu et al., 2014). In addition, the issue of medicines management and administration to residents with dementia is not represented well in the research. The inclusion of care homes serves to widen the scope of medicines use and assist in understanding the issues from all dementia severities and environments. This can then allow for tailored recommendations for each setting.

Purposive sampling, a non-random method of sampling, was employed to ensure that the participants are relevant to fulfil the research objectives and to gain the perspectives of a range of participants (Tong et al., 2007; Bowling, 2014; Palinkas et
Qualitative research does not require a set sample size; saturation sampling was employed to ensure sufficient data are collected so recruitment can stop when no new data emerges (Fusch and Ness, 2015). A sample of 30 caregivers of PLWD in the community and 10 PLWD was aimed for to achieve the research objectives. The sample size was based on the studies from the literature review, as the sample size of the PLWD and caregivers are either less or similar to the one chosen for the present study. The sample size of the care home staff depended upon the number available at the participating care homes; between 2-3 staff members from each of the six care homes were anticipated to be sufficient.

The present study endeavoured to include PLWD as participants as the literature review emphasised the importance of gaining their perspectives. Not all the studies included PLWD; this can be attributed to the difficulty of recruiting and gaining the consent of PLWD for interviews. In addition, there is the belief that they would not be able to participate or add information owing to their cognitive decline. This will not hinder their recruitment in the present study, as previous studies have shown that PLWD are sometimes able to fully participate in research, and their perspectives are highly valued (Innes et al., 2005; Kaasalainen et al., 2011; Werezak L and Stewart N, 2002; While et al., 2012). Furthermore, the Mental Capacity Act states that PLWD should be seen as competent, and invited to take part in research (“Mental Capacity Act 2005: Code of Practice,” 2007). PLWD will only be recruited from the community, as those in care homes may most likely have progressed further in their disease state and cannot consent. Furthermore, recruiting PLWD from care homes requires more resources and time than those available for this study (Goodman et al., 2011).

There are two types of care homes, nursing homes and residential homes, and they differ in the type of care they provide (Barber et al., 2009). Residential homes employ formal carers to administer medicines to the patients, while nursing homes provide 24 hour nursing care. In addition, the amount and quality of care differs in both types of care homes (Centre for Policy on Ageing, 2012). Therefore, the study included both types to achieve a more diverse sample as well as assist in providing a holistic view on medication use. Furthermore, the two settings (community and care homes) and the use of two types of care homes are used in this study to be able to look at PLWD at different points of disease severity to get a better picture of medicines use in this patient population. This is because patients at home are usually at the mild to
moderate stage of dementia and can be cared for by their family, while those in care homes have most likely progressed to moderate or severe stages of the disease. Care homes were contacted and those that refused participation were eliminated and another care home was chosen in their place.

3.6.2. Eligibility criteria

Eligibility criteria for PLWD:
- Having mild cognitive impairment (MCI) or dementia
- Lives at home
- English speaking
- Willing and able to give informed consent for participation in the study

Eligibility criteria for family caregivers:
- Male or female aged ≥18 years old
- Family caregiver (unpaid)
- English speaking
- Must provide some assistance to the patient with medicines use, even if minimal
- Willing and able to give informed consent for participation in the study

Eligibility criteria for care homes:
- Registered as a nursing or residential care home on the Care Quality Commission website
- Must have residents with dementia
- Staff willing to give informed consent for participation in the study

Exclusion Criteria for all participants:
- Unable to speak English
- Under 18 years of age
- Unwilling or lack the capacity to consent
3.6.3. Sampling procedure

In the community setting, the PLWD and their family caregivers were recruited through the Alzheimer’s Society. This offered ease of recruitment and good response rates. Furthermore, recruiting through the Alzheimer’s Society ensured that participants either have dementia or are providing care to someone with dementia. This organisation has contact with many PLWD and caregivers, thus providing the study with a sample of participants from different socio-economic and cultural backgrounds. The researcher also attended four different dementia cafés to meet PLWD and their caregivers.

People were only excluded according to the criteria stated in the previous section. This study did not include a specific age group, specific medications or a predetermined caregiver profile, as these characteristics were not obligatory to achieve the study objectives. Although the study endeavoured to include people with different dementia severities, it did not restrict the sample to a specific dementia type. This allowed for relatively easier recruitment. The severity of dementia was based on the caregivers’ time spent caring for the PLWD, so the severity was an estimate. To be able to know the exact severity, the PLWDs’ medical notes would need to be retrieved; this would have required more time and additional ethics approvals.

Care homes were identified through the use of the Care Quality Commission (CQC) website and were purposively selected to include a varied sample of homes caring for residents with dementia, providing different types of care, and different home sizes. The CQC holds a directory of care homes across the UK that have been inspected and rated accordingly. Care homes are rated on five aspects: safety, effectiveness, respect, responsiveness and management. The care homes that participated had different scoring according to the CQC website which enabled a more diverse sample.

3.7. Recruitment

3.7.1. Caregivers and PLWD in the community

Recruitment of participants in the community was conducted through the Alzheimer’s Society. The head office in London was contacted and an application with details of the study and the assistance required from the Alzheimer’s Society was completed and sent, along with the ethical approval and Disclosure and Barring Service (DBS) check in July 2015. The application and DBS check can be found in Appendix 4. A
favourable reply was received by email in September 2015. Emails were sent to the Alzheimer’s Society branches from 3 different boroughs (Croydon, Lambeth, and City and Hackney) detailing the study and requesting to meet with the dementia advisors to further discuss recruitment.

Once contact was established with the managers of the 3 London branches of the Alzheimer’s Society, meetings were set with the dementia advisors in November and December 2015. The researcher explained the study and its importance, as well as provided prepared letter packages to be distributed to potential participants by the dementia advisors. The letter package contains separate invitation letters for the caregivers and the PLWD they take care of, with reply slips and information leaflets. The caregiver will make the decision about whether the care recipient is able to participate before giving them the invitation letter and information leaflet. The leaflets explain the purpose of the study, what the participant’s involvement would be, confidentiality issues, a picture of and information about the researcher, and the participant’s rights. These papers can be found in Appendix 5. The dementia advisors were also given a list of the eligibility criteria of participants. It was made clear to the dementia advisors distributing the letter packages to eligible participants that participation is voluntary. The researcher was available to answer any questions they had. The researcher also asked to be kindly invited to dementia cafés that each borough organises.

Emails were received in January 2016 from each of the branches visited about the dates and times of the dementia cafés that can be attended. Four different dementia cafés were attended; one in Hackney, one in Southwark (people from Lambeth attend the café in Southwark), and two in Croydon (East and West) between January 2016-May 2016.

With the assistance of dementia advisors at each branch of the Alzheimer’s Society, potential participants were selected and given a letter package. The researcher also distributed letter packages to interested potential participants at the dementia cafés attended. The eligible caregivers and the PLWD they take care of had all the information in advance and had time to make a decision. Interviews were arranged for those who had consented to be included, by returning the reply slip in a prepaid envelope or by directly contacting the researcher. Those who had consented were telephoned for confirmation and to set an interview date. Written consent from both
the PLWD and caregiver was taken on the day of the interview. For PLWD, this must be done in accordance with the Mental Capacity Act 2005 (“Mental Capacity Act 2005: Code of Practice,” 2007; National Collaborating Centre for Mental Health, 2007). Hence their ability to consent needed to be assessed. This was achieved by checking that the PLWD had understood all the information regarding the study and their involvement, was able to make a decision about their participation, was able to retain, use and weigh up the information regarding their decision, and to communicate their decision to the researcher (Cohen-Mansfield, 2003).

3.7.2. Care homes

Care homes were identified through the use of the CQC website and were purposively selected for those with residents with dementia. The researcher began by contacting the managers of care homes that fitted the eligibility criteria within the same boroughs as the chosen Alzheimer’s Society branches. Contact was done via telephone and/or email to first introduce the researcher and the study. It was decided to widen the care home recruitment to all boroughs as response rates were low. Managers who showed interest through telephone/email were asked for a meeting to discuss the study further and potential involvement. During the meeting, the researcher collected demographic data and general information regarding medication administration and management systems. Care home managers were given an invitation letter and reply slip (Appendix 6.1), and those who agreed were asked to sign the reply slip. A date was set for the study day, and the researcher handed the manager letter packages to be distributed to carer/nursing staff before the study day. Letter packages contained an invitation letter and information leaflet so that staff were aware of the researcher and what they were doing in the care home. These can be found in Appendix 6. Each participating care home was contacted 3 days before the visit day to confirm that the researcher was coming and to ensure that it was still convenient.

Recruitment of community participants commenced from November 2015 and was completed by June 2016. Recruitment of care homes began from April 2015 and ended by June 2016. Recruitment continued until data saturation was achieved. This was decided when no new information emerged and coding was deemed complete (Fusch and Ness, 2015).
3.8. Data collection instruments

3.8.1. Topic guides

The topic guides were developed using information gathered from reviewing the literature and the results from the discussions in the preliminary fieldwork. Three schedules were created; one aimed for PLWD, one for their family caregivers, and one for staff at care homes. The schedule used in care homes for the individual/joint discussions differed as these were aimed at nurses and formal carers at care homes and focused more on medication administration. The interview schedules were reviewed by a former PLWD caregiver to discern the appropriateness and clarity of the questions before being used.

The topic guides consisted of the main questions and probes; the use of open-ended questions allowed the participants to talk more freely about their experiences. The value of the data collected depended upon the use of well-worded probes to clarify the information being said by eliciting further elaboration (Marshall and Rossman, 2010). Follow up questions were also employed depending on the participants’ responses; some responses required a further question to pursue a topic brought up by the participant. The interview questions indirectly assessed the acceptability of the formulations used by the caregiver and PLWD, which has been defined as ‘an overall ability of the patient and caregiver to use a medicinal product as intended (or authorised)’ (European Medicines Agency, 2017).

An iterative approach which is common in qualitative research was undertaken whereby reflections on the topic guides and initial analysis of transcripts were done after each interview to ensure the wording of questions was assessed, and that any emerging interesting topics were explored. This was also to ensure a comprehensive exploration of participant experiences and topics important to them. Changes to the topic guides were discussed in regular meetings with the supervisor(s). The three interview schedules can be found in appendices 7.1-7.3 with the relevant additions/changes detailed below.
Below is a summary of the changes made to the care home topic guide, and reasons why:

- Before the first care home visit, a probing question was added to identify issues when handling medications, reasons behind switching between formulations, and suggestions on how to make the medication use process easier. This was after exploring the literature further, and discussions with the supervisor(s).

- After the first care home visit, new questions were added to the topic guide based on initial analysis. These reflected the new topics that emerged that needed further exploration in the upcoming interviews. These included probing questions about the variety of medications administered, differences perceived between generic and branded medications, factors affecting the medication round (such as aggressive behaviour), partnership between staff and PLWD, the role of the pharmacist and the interactions between the multidisciplinary team. The additional questions were typed in bold black to differentiate them from the other questions.

- After the second care home visit, the topic guide was updated again to further clarify the role of the pharmacist and to explore the autonomy of the PLWD. These additional questions/probes were printed in bold blue to differentiate them from the other questions.

Below is a summary of changes made to the community topic guides and reasons why:

- From the first 2 interviews, it was found that using an ice breaker was not needed as the researcher would chat before each interview and it was sufficient to establish rapport and put the interviewees at ease.

- After interviewing 11 participants, initial analysis of the transcripts and discussions with the supervisor(s) resulted in the addition of some further questions on both interview guides. These included handling medications, dealing with behaviour issues when administering medications, issues with branded and generic medications, and strategies developed which assist with medication management and administration. The additional questions were typed in bold black to differentiate them from the other questions.
The questions used in the follow-up interviews were semi-structured and included specific changes to the PLWD’s medications, changes with medication use, and how dementia progression has affected medication use. At the end of the discussion, a summary of what other participants have been saying was provided and the participant asked if they would like to add to this to ensure a full exploration of perspectives and experiences. This can be found in Appendix 7.4.

### 3.8.2. Caregiver burden

Research on the development of validated scales to measure caregiver burden has been extensive. These instruments have been developed to measure any positive or negative changes when an intervention has been introduced. Each instrument has its advantages and disadvantages, and a comparison can be found in Appendix 8 of instruments used on caregivers of PLWD or elderly patients.

One of the issues hindering better comparison of scales is the differences in the definition of caregiver burden adopted and the concepts behind caregiver burden. Another issue is the measure of objective and subjective burdens. Some measures fail to provide a link between the two, causing difficulty in assessing burden accurately. Objective burden is defined as an observable and tangible burden associated with caring for someone, while subjective burden is the caregiver’s positive or negative feelings associated with their role (Hunt, 2003). Another problem with some measures is their length and their difficult wording. Furthermore, instruments should be specific to a patient population as an instrument for caregivers of patients with heart disease would not necessarily be appropriate and sensitive to caregivers of dementia patients as stress in both circumstances will differ. This highlights the need for a sensitive burden measure for caregivers of PLWD.

A tool was required in the present study to measure caregiver burden in order to achieve objectives 3 and 5. As this study focuses on medicines use, and one of the objectives is to understand its impact on the caregiver, the tool chosen was the Family Caregiver Medication Administration Hassles Scale (FCMAHS) (Travis et al., 2003). It is the only caregiver tool that looks specifically at hassles related to medicines management and administration. This scale is made up of 24 items with a scoring from 0-5, and captures caregiver burden regarding medicine use such as safety issues and polypharmacy concerns. The scale consists of 4 domains: information seeking/information sharing (containing 9 items); scheduling logistics (containing 7
items); safety issues (containing 5 items); and polypharmacy (3 items). The FCMAHS has a high internal reliability ($\alpha=0.95$), and sub-scale reliability ranges from 0.80 to 0.92 (Travis et al., 2003). It is also short and easy to administer. Furthermore, the scale provided a better understanding of which areas in the medication role the caregiver undertakes cause the most stress, thereby highlighting where interventions are needed. The FCMAHS can be found in Appendix 9.

3.8.3. Approximate dementia severity

As the current research aims to identify changes to medication use as dementia progresses, a sample with PLWD at different severities of dementia was needed. This was partly achieved by including both the community and care home settings as mentioned previously. To provide a further indication of dementia severity of the community participants, the researcher asked the caregivers to provide an estimate of the severity of the memory problems, as well as how long they are able to leave the PLWD unsupervised, as demonstrated in previous studies (Smith et al., 2001, 2015). Caregivers are a reliable source for this information as they are in daily contact with the PLWD and can determine an approximate disease severity by the amount of time they spend per week providing care for them (Langa et al., 2001). In addition, some scales, such as the MMSE, can be awkward to administer to PLWD and can cause them and their caregivers distress (Hughes et al., 2002). They may be in denial of their disease and may take offence to some of the questions asked. The present study did not use an instrument to directly measure the severity of cognitive impairment; some studies relied on caregivers to ascertain how severe the PLWD’s cognitive impairment was (Smith et al., 2001, 2015).

To circumvent this problem, the researcher employed an alternative method to measure approximate disease severity. As dementia progresses, there is a decline in the PLWD’s ability to perform activities of daily living such as eating, bathing and dressing (Feldman et al., 2005). Family caregivers need to assist with these activities, and research has shown how dementia severity can be linked to the number of hours family caregivers spend per week taking care of PLWD (Davis et al., 1997; Langa et al., 2001; Marin et al., 2000). Furthermore, hours spent caregiving has been used as an outcome measure in clinical trials in Alzheimer’s disease (Brodaty and Green, 2002). The study by Langa et al., (2001) used a representative sample of PLWD and their caregivers in the USA to illustrate this. The authors learned that elderly people with
normal cognitive function received an average of 4.6 hours per week of informal care, while people with mild dementia received an average of 13.1 hours per week, with moderate dementia an average of 39.4 hours per week, and those with severe dementia received an average of 46.1 hours weekly.

A variety of methods and instruments are available for use to measure time spent caregiving that employ the diary or recall method (Clipp and Moore, 1995; Davis et al., 1997; Wimo et al., 1998). Although the diary method is considered a gold standard, it is time-consuming, complicated and requires more resources, and therefore the recall method is preferred (van den Berg and Spauwen, 2006; Neubauer et al., 2008; Dumont et al., 2010).

The Caregiver Activity Survey (CAS) (Davis et al., 1997) was chosen to retrieve the information regarding time spent caregiving by family caregivers as it was deemed suitable (Wimo et al., 2013). This scale was developed to measure caregiver burden, but it fails to successfully measure it. It functions better as a tool to ascertain the number of hours spent caring and has been utilised in a longitudinal study to validate its use on caregivers of patients living with Alzheimer’s disease (Marin et al., 2000). The CAS consists of 6 domains; each corresponding to an activity a caregiver helps the PLWD with in a regular 24 hour period, as well as supervision. The CAS can be found in Appendix 10. Using all 3 methods (the CAS, asking about severity of memory problems, and asking how long the PLWD can be left unsupervised) assisted in providing a better consensus on approximate disease severity of the PLWD in the community sample.

3.8.4. Other instruments

Other data collection instruments were used in the present study. A data collection tool was developed to capture the sociodemographic characteristics of participants, one used for the care home participants and one used for the community participants. This information was needed to ensure the diversity of the sample.

The community data collection tool included the participant code assigned for the study, initials, age, sex, education, relationship with PLWD, employment status and ethnicity. The participants were asked about the occurrence of swallowing difficulties and its development during the interview; no test or scale was used to assess dysphagia as it was out of the scope of this study. The tool also included a section to
note the medicines that the PLWD is taking, both prescription and over-the-counter (OTC). The information includes the name of the medicine, formulation, and if a compliance aid is used. This was captured to describe the variety and numbers of medicines PLWD are taking in the community setting to achieve objective 1. The care home data collection tool included the code assigned to participants, initials, sex, age, ethnicity, education level, years working and job title. The data collection tools can be found in Appendices 11.1 and 11.2.

A data collection tool for observations and field notes in the care home setting was also developed. This was reflected on and updated after each care home visit to make it more user-friendly. The tool allowed for the collection of information about the medication round and the medication administration process, such as time of round, number and type of medications administered, and issues observed during the administration of these medications. This information assisted in providing context to the interview data as well as answer objectives 1-4. Furthermore, it allowed the researcher to refer back to the data collected during the interview with participants for elaboration. The final tool used can be found in Appendix 11.3.

3.9. Data processing and analysis

Interviews were audio-recorded using the Olympus DM-650 digital voice recorder. All transcripts were transcribed verbatim by the researcher; this was done within 3 days of the interview to ensure good recall of the interview content. All identifying information was coded to ensure anonymisation. Field notes and observations were typed within 24 hours to ensure everything was documented in a timely manner.

Management of the data can be done using computer-assisted qualitative data analysis software (CAQDAS) packages. These software packages assist in storing, organising, and handling the data. Examples of functions performed by these software packages include retrieving quotes, creating a coding framework, coding segments of data, and annotating transcripts (Burnard et al., 2008). The NVivo 11 software was chosen to help with data management and coding the qualitative data (interview transcripts, observations, and field notes).

There are diverse approaches to qualitative analysis, with thematic analysis seen as underpinning them (Braun et al., 2006). Compared with other qualitative analysis methods, thematic analysis is seen as a flexible technique that can ‘provide a rich and
detailed, yet complex, account of data’ (Braun et al., 2006). There are two approaches to analysing data, deductive and inductive. Deductive approaches rely on a predetermined framework to analyse data, whereas inductive approaches depend on themes and theories emerging from the data with minimal involvement of a set structure (Burnard et al., 2008). When using thematic framework analysis, it does not necessarily mean relying on the deductive approach, as there is flexibility to this analysis method, and both deductive and inductive approaches can be used to answer the research questions (Gale et al., 2013; Vaismoradi et al., 2013). To answer the research question and fulfil the study objectives, principles of thematic framework analysis were applied. As seen in the previous chapter, a conceptual model was developed through a review of the literature. The six domains of the model provided a framework to examine the perceptions and challenges to medication use, and provide a holistic view of all factors affecting medication use. Both deductive and inductive approaches were applied with constant comparison; this was to ensure that theories were not limited to what is already known, and that analysis is not rigid (Bowling, 2014). Constant comparison enabled an iterative approach whereby themes were searched and compared across participant and setting data sets (Glaser, 1965; Pope and Mays, 1995).

Before being transferred to NVivo, transcripts were re-read alongside listening to the audio-recording to ensure accuracy. This was also done so the researcher familiarises themselves with the data. Initial analysis and annotation of interesting text was done while transcribing before moving the qualitative data to NVivo. This assisted in generating broad codes and identified recurring themes and concepts by using principles of thematic framework analysis. Figure 3.2 details the stages of framework analysis that were applied. Analysis began as soon as data were transcribed, and was a continuous process. This was to maintain good time management as well as develop and update the ongoing data collection and inform the analysis (Bowling, 2014). During the initial analysis stage, codes were created that were deductive (based on the topic guide questions) and inductive (new ideas that emerged from the data). Codes are defined as ‘a descriptive or conceptual label that is assigned to excerpts of raw data’ (Gale et al., 2013). These codes were arranged in the framework developed and acted as a coding frame. The coding frame consisted of the codes arranged according to domain, with a description of each code and whether it was deductive or inductive.
The coding frame was reviewed by both supervisors before commencing with line-by-line coding in NVivo to ensure it was appropriate; it was updated accordingly following the review. Coding with NVivo was conducted on 2 separate interview transcripts, and the coding frame was continuously updated by adding new codes, dividing previous ones, and providing better descriptions of codes for clarity. The researcher sent one coded and one uncoded transcript with the coding frame to the supervisors; they reviewed them independently and compared coding to reach a consensus. These 2 transcripts and new coding frame were then discussed between the researcher and supervisors and updated with minor suggestions. The researcher went over the coded transcripts with the updated coding frame to ensure they were coded accordingly. Analysis continued on 3 separate transcripts before going through a similar review process by the researcher and supervisors.

The researcher continued with the indexing process by systematically applying the updated coding frame on all the data set. The textual data was synthesised and the codes refined continuously. Appendix 12 contains the final detailed coding frame consisting of the 6 domains and corresponding codes. The domains applied to all participants and settings, but certain codes were specific to participant type. Respondent codes were also created to indicate the sex and participant type (family caregiver, PLWD, nurse, carer). These codes were independent of the coding frame and were created to differentiate between coded segments for analytical purposes.

Once all the data were indexed in the coding frame and synthesised, the last stage of analysis was implemented. This stage involved a deeper approach to analysis involving interpreting the data, identifying concepts and refining themes across participant types and care settings to answer the research aim and objectives. Data from participants in the community setting were interpreted individually, as well as within the dyad to examine the partnership concept within the medication use process. This was also done to fully realise how PLWD and their family caregivers perceived medication use, as sometimes they may have differing views. All the community data were reviewed in light of the research questions and associations identified between concepts to realise the wider context of the findings. Constant comparison was employed to provide explanations by answering ‘how?’ and ‘why?’ questions. This assisted in improving the starting conceptual model to generate a refined and purpose-led one on areas requiring optimisation regarding medication use in the community.
setting. This model is presented in Chapter 5, and assists in indicating where and what recommendations are needed.

All the data from the care home setting (interviews and observations) were synthesised and analysed alongside each other. A similar analytical approach to that used with the community data was undertaken. Patterns across the data were identified and concepts were generated to create a conceptual model illustrating areas requiring optimisation with medication use. This model is presented at the end of Chapter 6.

To determine changes to medication use as dementia progresses, all the data across participants and care settings that reflect issues relating specifically to decline in cognition were reviewed. These were grouped and interpreted to identify associations and concepts. The findings from this analysis stage can be found in Chapter 7 with a conceptual model summarising the changes to medication use and suggested solutions.

Descriptive statistics were also needed to fulfil the research objectives. This was required for the structured qualitative data from the FCMAHS and CAS. These were analysed using SPSS version 21 as only minimal statistics were needed (sum, mean, and standard deviation).
3.10. Validity and reliability of the data

Validity and reliability are central to all research; this is especially the case in qualitative research where extra measures should be taken to ensure rigour of methods and analysis due to its subjective nature. Reliability in qualitative research differs than that in quantitative research; reliability of quantitative research refers to the repeatability of results using the same methods (Golafshani, 2003). Reliability in qualitative research involves the trustworthiness and consistency of the methods employed (Golafshani, 2003; Creswell, 2013). Validity in qualitative research relates to procedures used by the researcher to ensure the accuracy of results, and that they are a true reflection of the phenomenon studied (Pope and Mays, 1995; Creswell,
2013). Others argue that validity and reliability are synonymous in qualitative research and come hand in hand (Golafshani, 2003; Bryman, 2012).

Issues with reliability and validity can occur at any point in the research. These include not following the topic guide, not taking care when reporting observations, not reaching a consensus on coding between researchers, and behaviour of participants changing when observed (Smith, 2010). Measures and procedures were undertaken at each stage of the present study to ensure the validity and reliability of the data.

Triangulation of methods was used (interviews, observation, structured questionnaires) to ensure that data are obtained in different ways and from differing perspectives. Triangulation was also used to complement each of the methods used. This would assist in minimizing bias and verifying the consistency of the findings (Golafshani, 2003; Creswell, 2013; Bowling, 2014). In the community setting, the completion of the FCMAHS alongside the interview enabled comparison of challenges with medication use. Furthermore, using more than one method to assess approximate severity of dementia was also applied to ensure reliability of the findings. In the care home setting, observing the medication administration process and gaining staff perspectives through the interviews helped in gaining a wider scope of the issues. Some challenges were apparent when observing the rounds, and during the interviews the participants would elaborate on them further.

The researcher conducted follow-up interviews with the community participants to verify their previous answers and to also discuss what other participants have been saying. This can also be considered as a form of participant validation of the data.

The validity and reliability of the final topic guides were ensured as they were all informed by previous research from the literature review and preliminary fieldwork. Topic guides and documents were also assessed for suitability and clarity by a caregiver. These were also all reviewed by the supervisors. The researcher attended a variety of courses and read books to ensure qualitative research skills were suitable before commencing data collection. The courses dealt with conducting interviews, conducting focus groups, qualitative analysis skills, thematic analysis, and using NVivo.
During the interviews, the researcher ensured participants understood the questions by endeavouring to word them in an understandable way and repeating their answers back to confirm them. The researcher ensured community participants were at ease. This was done by establishing rapport, interviewing them in their home, assuring them of the anonymity and confidentiality of the documents, and that the researcher was a PhD student. Care home participants were also assured of anonymity and confidentiality and would therefore not affect them in any negative or positive way. The researcher recorded reflections, comments, feelings or issues that occurred during interviews and observations to assist in analysing the findings, as well as ensuring that the next interview is better conducted.

Observation does not rely solely on participant accounts of events or behaviour, which can be biased. The researcher had to ensure that there was no bias by not allowing their interpretation of observations to distort the findings. There may also be a risk of the Hawthorne effect, wherein participants change their behaviour due to the presence of the researcher (Bowling, 2014). The researcher was able to reduce the risk of this happening by explaining reasons for observation, which did not include identifying errors. Field notes were written from both care settings on participant behaviour, the environment, and interactions between people observed. These were analysed alongside the interviews. An example is how care home residents interact with staff when medications are administered. These notes provided triangulation of methods and validated the interview data by adding context.

Data collection and analysis were an iterative process; the topic guides and data collection tools were updated continuously along data collection to ensure reliability of the methods. Interviews were audio-taped and transcribed verbatim by the researcher to ensure accuracy of transcription and for quality assurance purposes. NVivo was used to manage data well and assist with coding and retrieving data. It also enabled an easier and accurate search of codes and themes across the data set. Reliability of the analysis was ensured by involving both supervisors at different stages of the data processing. Both supervisors independently reviewed the coding of 2 transcripts and compared sub-codes to reach consensus, reviewed and adjusted the coding frame at two different points along data analysis, and reviewed the final analysis of the findings. Furthermore, the framework used for analysis was not rigid and allowed flexibility in the interpretation of the data through constant refinement.
The researcher may unintentionally influence the findings and therefore the concept of reflexivity is imperative to ensure reliability and validity in qualitative work (Starks and Brown Trinidad, 2007; Smith, 2010). Having a clinical pharmacy background assisted the researcher in being objective and more mindful of certain medication and formulation aspects. This helped in asking relevant questions and understanding patients’ experiences with medication use. Bias was limited by relying on previous literature and the conceptual model as an analysis framework to ensure a holistic view on all medication use issues. Furthermore, the researcher endeavoured to adhere to principles of qualitative enquiry in all stages of the research and be open-minded and flexible when analysing, in order to allow for new and unfamiliar concepts. All participants were aware that the researcher was conducting this research as fulfilment of a PhD degree and that the researcher’s background was in pharmacy. This may have affected responses as participants were more sympathetic towards the researcher when they learned she was a student. This may also have affected their responses regarding pharmacy services as they may have felt obliged to provide positive experiences, although this was not the case.

The following chapter details the community and care home participant characteristics. It also reports recruitment challenges, conduct of observations and interviews, and the results from the FCMAHS and CAS questionnaires. Medication numbers and formulation varieties in each care setting are also discussed.
Chapter 4: Community and care home participant characteristics

4.1. Introduction

This chapter provides challenges faced with recruitment in each setting, and the perceived optimal methods. Response rates and characteristics of participants from the community and care home settings are also reported. The use of the Family Caregiver Medication Administration Hassles Scale (FCMAHS) to measure caregiver burden relating to medications and its results are also detailed. Furthermore, dementia severity of the community participants and how it was measured is described. The chapter concludes with a summary of medications used in each setting and its implications.

4.2. Recruitment challenges

Recruitment is always a difficult phase within research; this was so in the present study. With regards to recruiting within the community setting, which was done via the Alzheimer’s Society, a few barriers were encountered. The first challenge was the internal application process within the Alzheimer’s Society, which took 2 months to be approved by their head office. The next challenge was getting in contact with individual branches in London to ask for assistance with recruitment. One of the chosen London boroughs (Westminster) was not able to help as they were already taking part in another study; this delayed recruitment further.

Relying on the dementia advisors to recruit participants by distributing the letter packages to eligible participants was also another challenge as it was not productive (only 3 participants were recruited through dementia advisors). This was overcome by the researcher attending dementia cafés in each borough to talk to PLWD and caregivers and distribute letter packages personally. This assisted greatly with recruitment, as participants had a chance to ask questions and see the researcher, which may have helped as they were more familiar with the study and so would feel more at ease with participating. An interesting observation when attending the dementia cafés and speaking to PLWD and their caregivers was how they perceived the problems associated with medication use as normal and insignificant to be included in a study. Many of the caregivers felt they had to deal with any issues by themselves, without involving HCPs.
Regarding care home recruitment, the main challenge was finding care homes not involved in dementia research. In addition, the number of staff members available also played a factor in managers’ decisions. Moreover, contacting care home managers via telephone was more efficient than by email.

4.3. Community response rates

Chapter 3 describes the methodology of recruitment in detail. Letter packages were handed to dementia advisors for distribution; 38 in Croydon, 30 in Hackney, and 30 in Lambeth. The number of letter packages that were actually distributed could not be obtained from the dementia advisors, but only 3 replies were received from participants. Thus, an accurate response rate cannot be calculated in this instance.

The number of letter packages distributed personally to interested people at the various dementia cafés was 6 in Hackney, 22 in Croydon, and 6 in Lambeth. The number of participants that replied back and were included in the study were 18 (response rate = 53%). All but 1 dyad agreed to be followed up at a later date.

Reminder emails were sent to dementia advisors and managers but this did not provide an adequate technique for recruitment. Visiting dementia cafés frequently to enlist participants was a better method to achieve optimal response rates.

4.4. Care home response rates

A total of 39 care homes in London were contacted (6 in Westminster, 3 in Hackney, 9 in Croydon, 2 in Islington, 4 in Camden, 8 in Barnet, 3 in Bromley and 4 in Lambeth). Reasons why care home managers declined to be involved in the study included not being able to accommodate the study requirements due to staff numbers/capacity and busy schedules; already taking part in a research study; or simply not interested.

Six care homes agreed to take part after meeting with the managers, but 2 managers reconsidered and declined participation before data collection began due to low number of staff and busy schedules. The response rate was 15% (including the six care homes).
4.5. Demographics of community participants and conduct of interviews

The characteristics of the community participants, both caregivers and PLWD, can be seen in Table 4.1. Although most of the participants were Caucasian, almost a third were from BAME groups. The educational backgrounds of participants were also diverse. The majority of participants were from Croydon; this can be attributed to recruitment from two areas in Croydon and more PLWD and caregivers attending dementia cafés.

Nine dyads were interviewed together. Two family caregivers were interviewed alone as the PLWD they were providing care for was unable to participate; 1 PLWD was not able to communicate and the other PLWD was at a care home. One PLWD was interviewed on their own as they had a paid carer taking care of them. The paid carer was sitting during the interview and contributed some comments and opinions.

All of the first interviews were conducted at the participants’ homes. The duration of the home interviews ranged from 35 minutes 10 seconds to 139 minutes (average 72 minutes). Home interviews with the PLWD and their family caregivers were conducted together; this proved to be beneficial as sometimes the PLWD would rely on their caregiver for reassurance when answering, and other times the PLWD would provide additional information when the caregiver was answering. Furthermore, interviewing the dyad together provided a better environment and more thorough answers as both parties were present and could answer together and be more at ease with the questions and interviewer. There were some interruptions and distractions during the interviews due to phone calls and pets being present, but these were minimal. In 2 instances, the participants had an appointment to attend, which resulted in a shorter interview.

The follow-up interviews were conducted via telephone and the duration of the interviews ranged from 5 minutes 15 seconds to 37 minutes 26 seconds (average 12 minutes). It was difficult for the PLWD to follow questions on the phone, and some were hard of hearing. This resulted in the caregivers being interviewed and one PLWD who had mild dementia and a paid carer. He asked the paid carer to provide the information about medication changes as he is unaware of his medications. Eleven follow-up interviews were conducted; 3 interviews were hand-written and 8 were audio-recorded. It was not feasible to audio-record in those 3 instances due to where the researcher was at the time.
Table 4.1: Characteristics of caregivers and PLWD in the community

<table>
<thead>
<tr>
<th></th>
<th>PLWD (n=10)*</th>
<th>Family caregivers (n=11)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (mean [range])</strong></td>
<td>80.6 [72-89]</td>
<td>65.8 [57-89]</td>
</tr>
<tr>
<td><strong>Gender (female)</strong></td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Asian</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>African</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Afro-Caribbean</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Relationship to PLWD</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daughter</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>Spouse (wife)</td>
<td>-</td>
<td>4</td>
</tr>
<tr>
<td>Spouse (husband)</td>
<td>-</td>
<td>5</td>
</tr>
<tr>
<td><strong>Approximate severity of dementia</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td>Moderate-severe</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>Severe</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td><strong>Education level</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary school</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>College</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>University graduate</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td><strong>Borough</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hackney and City of London</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Lambeth</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Croydon</td>
<td>8</td>
<td>8</td>
</tr>
</tbody>
</table>

Note*: Participants interviewed consisted of 9 dyads, 1 PLWD, and 2 family caregivers

### 4.6. Family Caregiver Medication Administration Hassles Scale

As described previously in Chapter 3, the FCMAHS was used to assess caregiver burden specifically relating to medication management and administration. Using the scale was in part fulfilment of objectives 2, 3 and 5. Caregivers allocated a score from 0-5 for each statement; 0 corresponds to no hassle and 5 to one of the worst hassles. The total number of caregivers for each scoring category along each statement was calculated to better illustrate which domain corresponds with the highest burden. Table 4.2 reports the frequency of caregivers affected by each hassle for each of the 4 different domains within the FCMAHS. Nine of the eleven caregivers interviewed completed the FCMAHS; it was found to be not applicable for the other 2 as one caregiver relied on a paid carer to do the majority of medication-related activities, and the other caregiver’s mother was at a care home. Two of the caregivers required help with completing the FCMAHS by explaining each subscale.
The completion rate was 100% (there were no missing data). The scale consists of 4 domains and the potential overall score can range from 0 to 120; a high score indicates a higher perceived burden. The data were entered in SPSS version 21 and analysed descriptively. The mean medication administration hassles score was 20.4 (SD 17.7, range 0 to 56).

It can be seen from Table 4.2 that the majority of hassles were encountered in the information seeking/information sharing domain and the scheduling logistics domain. There were low scores in the last 2 domains as the majority were using blister packs prepared by the pharmacist, and the rest were using OP but had a system in place that made managing medications easier. One caregiver scored 0 for all the subscales and this corresponds directly to the findings of her interview.

Some caregivers elaborated further when filling the FCMAHS. Access to information was seen as a hassle by 4 caregivers. One caregiver stated that she prefers receiving information from the pharmacist as it is much quicker and less intimidating than the general practitioner (GP). Furthermore, her husband is on a number of medications which leads to scheduling difficulties.

The findings from the FCMAHS did not always correspond to the interviews. In one instance, a caregiver indicated that she had no hassles knowing when to hold, increase, decrease a dose or discontinue the medication; during the interview she mentioned the difficulties she had knowing how much of the Laxido sachets to give her husband. In addition, the same caregiver indicated on the questionnaire that she had no hassles with modifying medications. This did not correspond to her interview, in which she stated that she had once opened a capsule without advice and was surprised that it contained granules and not powder that she can mix with food. Using this tool alone may not provide accurate information as some caregivers provided fuller and sometimes contradicting information in their interviews. In addition, some sub-domains may be classed as “not a hassle” by caregivers as the situation has never arisen or that this aspect has been well managed. This is a limitation of the measure, and the interviews provide clarification and context to this data.

The FCMAHS has demonstrated that family caregivers of PLWD had difficulties with their role relating to health literacy and organisation and scheduling logistics. These issues were elaborated on within the interview and will be discussed in the subsequent results chapters.
<table>
<thead>
<tr>
<th>Hassle item by domains</th>
<th>Not a hassle</th>
<th>Hardly a hassle at all</th>
<th>A mild hassle</th>
<th>A moderate hassle</th>
<th>A severe hassle</th>
<th>One of the worst of all hassles</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Domain 1: Information</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowing what to do if an emergency occurs</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Finding clear information about the medication</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Knowing why a medication is being given and if it is having the desired effect</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Being comfortable talking to the doctor about medications</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Having someone available to answer questions</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Getting information within a reasonable time frame</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Feeling comfortable about making medication decisions</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Knowing what questions to ask the physician</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Understanding the directions and information I am given</td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td><strong>Domain 2: Scheduling Logistics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Giving medications on time</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Scheduling multiple medications throughout the day</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Arguing with the care-recipient about when to take medications</td>
<td>5</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Working medication schedules into my daily routine</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Coordinating my medication schedules with those of the care-recipient</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Sharing the responsibility with the care-recipient for keeping medication schedules</td>
<td>5</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Remembering to give medications according to schedule</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Domain 3: Safety Issues</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admitting to the physician or others that I made a mistake</td>
<td>7</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Knowing when to hold, increase, decrease a dose or discontinue the medication</td>
<td>6</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Understanding when medications can be crushed, mixed, dissolved, etc.</td>
<td>8</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hassle item by domains</td>
<td>Not a hassle</td>
<td>Hardly a hassle at all</td>
<td>A mild hassle</td>
<td>A moderate hassle</td>
<td>A severe hassle</td>
<td>One of the worst of all hassles</td>
</tr>
<tr>
<td>-----------------------------------------------------------</td>
<td>--------------</td>
<td>------------------------</td>
<td>---------------</td>
<td>-------------------</td>
<td>-----------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>Recognising adverse (bad) side effects</td>
<td>6</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Knowing how to give medication safely</td>
<td>7</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Domain 4: Polypharmacy Concerns</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Keeping medication prescriptions filled</td>
<td>5</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Planning ahead to keep prescriptions filled over weekends and holidays</td>
<td>5</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Managing medication prescriptions written by multiple physicians</td>
<td>8</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
4.7. Severity of dementia of PLWD in the community

Chapter 3 previously stated the rationale for the chosen methods to measure the severity of dementia in the community participants. The Caregiver Activity Survey (CAS) was used, as well as obtaining the amount of time caregivers can leave the PLWD unsupervised. Caregivers also provided an approximate severity based on their own opinion. The following sections state the results from each method to better provide an indication of severity.

4.7.1. Caregiver Activity Survey

The CAS was completed by 10 of the 11 caregivers; it was not applicable in 1 case as the caregiver had a paid carer to help with most activities stated in the CAS. Table 4.3 reports the time spent by each caregiver for each of the 6 domains. Each domain lists examples of activities and asks the caregiver to assign the number of hours and minutes within a 24 hour period they spend doing them. The data were entered in SPSS version 21 and analysed descriptively. The mean amount of time per day was 21 hours (SD 12.7, range 1.5 hours to 36.5 hours).

Some caregivers had difficulties filling in the CAS as some sections were felt to be irrelevant. These were indicated on the table with NA. An example was one caregiver whose husband was wheelchair bound; therefore she had to assist with everything. They also found it difficult assigning certain hours to activities. It can be seen that the majority of time is spent supervising the PLWD or communicating with them. Furthermore, there is some overlap between these 2 domains. This resulted in some caregivers’ scores adding up to more than 24 hours per day. Reasons for this discrepancy are explained in the discussion chapter, but it does indicate the burden that some caregivers experience with their role.
<table>
<thead>
<tr>
<th>CAS domain</th>
<th>C1H</th>
<th>C1L</th>
<th>C1C</th>
<th>C2C</th>
<th>C3C</th>
<th>C4C</th>
<th>C5C</th>
<th>C6C</th>
<th>C7C</th>
<th>C8C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communicating with the person</td>
<td>20 hours</td>
<td>14 hours</td>
<td>2 hours</td>
<td>2 hours</td>
<td>12 hours</td>
<td>5 hours</td>
<td>30 minutes</td>
<td>16-18 hours</td>
<td>10 hours</td>
<td>10 hours</td>
</tr>
<tr>
<td>Using transportation</td>
<td>2 hours</td>
<td>NA</td>
<td>1 hour</td>
<td>NA</td>
<td>0 hours</td>
<td>7 hours</td>
<td>1 hour</td>
<td>2-4 hours</td>
<td>NA</td>
<td>2 hours</td>
</tr>
<tr>
<td>Dressing</td>
<td>3 hours</td>
<td>3 hours 30 minutes</td>
<td>1 hour</td>
<td>NA</td>
<td>0 hours</td>
<td>2 hours</td>
<td>2 minutes</td>
<td>2 hours</td>
<td>30 minutes</td>
<td>2 hours</td>
</tr>
<tr>
<td>Eating</td>
<td>2 hours</td>
<td>3 hours</td>
<td>30 minutes</td>
<td>30 minutes</td>
<td>0 hours</td>
<td>2 hours</td>
<td>0 hours</td>
<td>1 hour</td>
<td>0 hours</td>
<td>4 hours</td>
</tr>
<tr>
<td>Looking after one’s appearance</td>
<td>1 hour 30 minutes</td>
<td>2 hours</td>
<td>20 minutes</td>
<td>30 minutes</td>
<td>15 minutes</td>
<td>1 hour</td>
<td>0 hours</td>
<td>2 hours</td>
<td>2 hours</td>
<td>2 hours</td>
</tr>
<tr>
<td>Supervising the person</td>
<td>1 hour</td>
<td>14 hours</td>
<td>10 minutes</td>
<td>12 hours</td>
<td>24 hours</td>
<td>4 hours</td>
<td>0 hours</td>
<td>4-6 hours</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Total amount of time per day</td>
<td>29 hours 30 minutes</td>
<td>36 hours 30 minutes</td>
<td>5 hours 15 minutes</td>
<td>36 hours 15 minutes</td>
<td>21 hours 1 hour 32 minutes</td>
<td>33 hours 30 minutes</td>
<td>12 hours 30 minutes</td>
<td>20 hours</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4.7.2. Other methods

To achieve a better consensus on the approximate severity of dementia, other methods were used alongside the CAS. Each caregiver (and in one instance a paid carer) was asked how long they can leave the PLWD unsupervised. This may be used to show a correlation with how severe the decline of cognition is. Each caregiver was also asked how they would class the PLWD’s dementia severity based on their opinion. Table 4.4 reports the amount of time the PLWD can be left on their own. The second column provides the approximate dementia severity reported by their caregivers.

<table>
<thead>
<tr>
<th>Participant code</th>
<th>Amount of time they can leave PLWD unsupervised</th>
<th>Approximate dementia severity reported by caregiver</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1H</td>
<td>Constant supervision</td>
<td>Severe</td>
</tr>
<tr>
<td>C2H</td>
<td>Constant supervision</td>
<td>Moderate-severe</td>
</tr>
<tr>
<td>PLWD2H (stated by paid carer)</td>
<td>Can leave alone for whole day</td>
<td>Mild</td>
</tr>
<tr>
<td>C1L</td>
<td>Constant supervision</td>
<td>Moderate</td>
</tr>
<tr>
<td>C1C</td>
<td>3 hours</td>
<td>Mild</td>
</tr>
<tr>
<td>C2C</td>
<td>Constant supervision</td>
<td>Moderate-severe</td>
</tr>
<tr>
<td>C3C</td>
<td>1 hour</td>
<td>Mild</td>
</tr>
<tr>
<td>C4C</td>
<td>2 hours</td>
<td>Severe</td>
</tr>
<tr>
<td>C5C</td>
<td>30 minutes</td>
<td>Moderate-severe</td>
</tr>
<tr>
<td>C6C</td>
<td>2 hours</td>
<td>Severe</td>
</tr>
<tr>
<td>C7C</td>
<td>3 hours</td>
<td>Severe</td>
</tr>
<tr>
<td>C8C</td>
<td>2 hours</td>
<td>Mild</td>
</tr>
</tbody>
</table>

4.7.3. Comparison of methods

Comparing the findings of all three methods to assess dementia severity can be seen in Table 4.5. As mentioned previously, the CAS was not seen as the best way to assess the amount of time spent caregiving due to overestimation and overlapping of domains.

Looking at the results from the supervision domain in the CAS and the answers caregivers provided when asked how long the PLWD can be left unsupervised, it is very clear that there is some discrepancy. In some cases, the caregivers would state that they could not leave them unsupervised because they were being overcautious.
and it did not relate to dementia severity. The same can be applied to how caregivers classed the severity in their opinion.

The triangulation of methods and the results achieved may not provide a precise answer but they demonstrate the diversity of severities of the participants’ dementia. The findings also show the need for a better method to assess the approximate severity of dementia in PLWD. Furthermore, the CAS was originally used as a caregiver burden measure and the amount of time caregivers spend with daily activities indicates the burden of their role.

<table>
<thead>
<tr>
<th>Participant code</th>
<th>Severity of dementia based on CAS score</th>
<th>Severity of dementia based on supervision</th>
<th>Severity of dementia based on caregiver</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1H</td>
<td>Severe</td>
<td>Severe</td>
<td>Severe</td>
</tr>
<tr>
<td>C2H</td>
<td>NA</td>
<td>Severe</td>
<td>Moderate-severe</td>
</tr>
<tr>
<td>PLWD2H (stated by paid carer)</td>
<td>NA</td>
<td>Mild</td>
<td>Mild</td>
</tr>
<tr>
<td>C1L</td>
<td>Severe</td>
<td>Severe</td>
<td>Moderate</td>
</tr>
<tr>
<td>C1C</td>
<td>Moderate</td>
<td>Mild</td>
<td>Mild</td>
</tr>
<tr>
<td>C2C</td>
<td>Severe</td>
<td>Severe</td>
<td>Moderate-severe</td>
</tr>
<tr>
<td>C3C</td>
<td>Severe</td>
<td>Mild</td>
<td>Mild</td>
</tr>
<tr>
<td>C4C</td>
<td>Severe</td>
<td>Mild</td>
<td>Severe</td>
</tr>
<tr>
<td>C5C</td>
<td>Mild</td>
<td>Mild</td>
<td>Moderate-severe</td>
</tr>
<tr>
<td>C6C</td>
<td>Severe</td>
<td>Mild</td>
<td>Severe</td>
</tr>
<tr>
<td>C7C</td>
<td>Severe</td>
<td>Mild</td>
<td>Severe</td>
</tr>
<tr>
<td>C8C</td>
<td>Severe</td>
<td>Mild</td>
<td>Mild</td>
</tr>
</tbody>
</table>
4.8. Demographics of care home participants and conduct of interviews

Four care homes around London were recruited and 8 participants in total were included in the study. Tables 4.6 and 4.7 report the characteristics of the care homes and the participants (care home staff) respectively. All care homes were privately owned. Two carers were interviewed from the first residential care home, one carer from the mixed care home, three nurses from the nursing care home and two carers from the second residential care home. All the care homes had residents with dementia. Care home codes consist of each borough’s initial (such as W for Westminster) and the type of care (R for residential).

All of the interviews were conducted in the care homes in a suitable and quiet area to accommodate the staff. Interviews were conducted individually except in one case where 2 carers were interviewed together due to time constraints. The joint interview assisted in providing detailed data by prompting the discussion of many relevant issues. Seven interviews were conducted in total, including the joint interview. The length of the interviews ranged from 20 minutes 34 seconds to 41 minutes 52 seconds, with an average of 30 minutes.

<table>
<thead>
<tr>
<th>Care home code</th>
<th>Type of care provided</th>
<th>London Borough</th>
<th>Current number /maximum number of residents</th>
<th>Availability/involvement of HCPs</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHWR</td>
<td>Residential</td>
<td>Westminster</td>
<td>33/42</td>
<td>GP attends care home rounds every Wednesday.</td>
</tr>
<tr>
<td>CHIM</td>
<td>Mixed</td>
<td>Islington</td>
<td>52/53</td>
<td>Multi-disciplinary team (consisting of GP, pharmacist and geriatric specialist) meetings every month. Two local GPs attend rounds every Monday and Wednesday. Pharmacist comes once a month to review medications.</td>
</tr>
<tr>
<td>CHIN</td>
<td>Nursing</td>
<td>Islington</td>
<td>64/64</td>
<td>Pharmacist comes once a week to review medications. GP attends rounds every Friday.</td>
</tr>
<tr>
<td>CHBR</td>
<td>Residential</td>
<td>Barnet</td>
<td>14/18</td>
<td>GP and pharmacist only attend when needed</td>
</tr>
</tbody>
</table>
Table 4.7: Characteristics of care home participants

<table>
<thead>
<tr>
<th>Participant code</th>
<th>Gender</th>
<th>Age (years)</th>
<th>Job title</th>
<th>Ethnicity</th>
<th>Education level</th>
<th>Years working</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>Male</td>
<td>52</td>
<td>Carer (residential care manager)</td>
<td>Caucasian</td>
<td>Vocational qualification</td>
<td>18</td>
</tr>
<tr>
<td>C2</td>
<td>Male</td>
<td>55</td>
<td>Carer (residential care manager)</td>
<td>Caucasian</td>
<td>Vocational qualification</td>
<td>39</td>
</tr>
<tr>
<td>C3</td>
<td>Male</td>
<td>38</td>
<td>Carer (residential unit manager)</td>
<td>Caucasian</td>
<td>GCSE’s</td>
<td>8</td>
</tr>
<tr>
<td>C4</td>
<td>Female</td>
<td>47</td>
<td>Senior carer and deputy manager</td>
<td>Caucasian</td>
<td>NVQ level 3</td>
<td>28</td>
</tr>
<tr>
<td>C5</td>
<td>Female</td>
<td>30</td>
<td>Senior carer</td>
<td>Caucasian</td>
<td>Nursing diploma</td>
<td>8</td>
</tr>
<tr>
<td>N1</td>
<td>Female</td>
<td>55</td>
<td>Nurse</td>
<td>Asian</td>
<td>Nursing diploma</td>
<td>34</td>
</tr>
<tr>
<td>N2</td>
<td>Female</td>
<td>26</td>
<td>Nurse</td>
<td>Caucasian</td>
<td>Nursing degree</td>
<td>3</td>
</tr>
<tr>
<td>N3</td>
<td>Male</td>
<td>48</td>
<td>Nurse</td>
<td>African</td>
<td>Nursing degree</td>
<td>4</td>
</tr>
</tbody>
</table>

4.9. Medication use and observations

There are various types of medications and formulations being used in the different care settings, and one of the objectives was to identify the number and range of the different formulations in each setting. The following sections detail medication use in each care setting and the observation of medication rounds in each care home. More detailed findings of the observation of the rounds are found in the next results chapters.

4.9.1. Medications in care homes

Observation of medication rounds within each care home was conducted to achieve objectives 1-4. The breakfast and lunch rounds in each of the care homes were observed by the researcher and notes were taken on the number of medications, the type of medications, and how the PLWD and care home staff administering the
medication interacted with each other. Table 4.8 reports the number and percentage of formulations observed in each care home. A total of 223 medications were administered. Almost 70% of the medications were tablets, with only 14% being capsules and 5% liquids. Inhalers made up 3.6% of all medications, followed by topical medications, sachets, and other formulations such as injections and eye drops.

<table>
<thead>
<tr>
<th></th>
<th>CHWR</th>
<th>CHIM</th>
<th>CHIN</th>
<th>CHBR</th>
<th>Total number of each formulation (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of tablets</td>
<td>31</td>
<td>53</td>
<td>27</td>
<td>42</td>
<td>153 (69%)</td>
</tr>
<tr>
<td>Number of capsules</td>
<td>2</td>
<td>10</td>
<td>7</td>
<td>12</td>
<td>31 (14%)</td>
</tr>
<tr>
<td>Number of liquids</td>
<td>1</td>
<td>2</td>
<td>5</td>
<td>3</td>
<td>11 (5%)</td>
</tr>
<tr>
<td>Number of inhalers</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>8 (3.6%)</td>
</tr>
<tr>
<td>Number of topical</td>
<td>0</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>7 (3%)</td>
</tr>
<tr>
<td>medications</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of sachets</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>5 (2%)</td>
</tr>
<tr>
<td>Other (ear drops, eye</td>
<td>0</td>
<td>5</td>
<td>2</td>
<td>1</td>
<td>8 (3.6%)</td>
</tr>
<tr>
<td>drops, patches,</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>injections, nasal spray)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total number of</td>
<td>37</td>
<td>82</td>
<td>44</td>
<td>60</td>
<td>223 (100.2%)*</td>
</tr>
<tr>
<td>medications observed in</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>each care home</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Discrepancy due to rounding up

4.9.2. Observation of medication rounds

Residential care home in Westminster (CHWR)

The care home consists of 4 units and each unit has 2 carers in charge; one carer takes care of the medication administration and the other takes care of the residents’ needs (feeding, clothing, etc.). None of the residents at this care home self-medicate and only 2-3 residents are aware of what their medications are. The average number of
medications per resident is 7. The care home uses multi-compartment compliance aids (MCAs) prepared by the pharmacy they liaise with for the solid oral dosage forms (SODF). Three carers, each one from a different unit, were observed administering medications to 12 different residents in total. The 2 carers interviewed from this care home were not observed administering medications; the carers who were observed all declined to be interviewed due to busy schedules.

**Mixed care home in Islington (CHIM)**

The care home is made up of 4 floors; the ground floor is a day centre, the first floor is the residential unit, and the second and third floors are nursing units. The residential unit had 1 team leader (a carer) who was in charge of administering medications to all the residents; other carers took care of cleaning and feeding the residents. The patients at this care home were not capable of taking their medication themselves. The average number of medications per resident is 5. This care home also utilises MCAs prepared by their pharmacy. One carer was observed on one unit (the residential unit) administering medications to 17 different residents. The same carer was interviewed after observation; this assisted in putting the information provided into context as the carer would refer back to the round and what was observed.

**Nursing care home in Islington (CHIN)**

The care home consists of 4 floors; the ground floor is for younger patients who require more care (such as those with PEG tubes), and the other floors are for patients with dementia, stroke or Parkinson’s. Although none of the patients self-medicate, some of the nurses provide the medications to some patients without waiting to observe whether they have taken them or not. Each floor had 1 nurse who would administer medications to all the patients on the floor. The average number of medications per resident is 8. Unlike the previous care homes, this care home uses original packaging medications (OP) as opposed to MCAs. Each patient had a locked cupboard in their room containing their medications. A total of 3 nurses, each one on a separate floor, were observed administering medications to 10 different patients in total. All 3 nurses were interviewed after observation.
Residential care home in Barnet (CHBR)

This care home is made up of 2 floors; the ground floor consists of the dining area and sitting room and a few of the residents’ rooms with the rest of the rooms upstairs. None of the residents self-medicate, and carers observe to ensure all medications are taken before moving on to the next resident. One carer (either the deputy manager or a senior carer) administer the medications to the residents, while the other carers take care of cleaning and feeding. The average number of medications per resident is 7-8. This care home was similar to the others in that it relies on MCAs prepared by their pharmacist. One carer (the deputy manager) was observed administering medications to 13 different residents. The deputy manager and a senior carer were interviewed following observation.

4.9.3. Medications in the community

The number and range of medications used by the community participants were recorded during the interview. Changes in medications were also gathered at follow-up with reasons why. This was to fulfil objective 1 and to identify changes to medication use as dementia progresses. Table 4.9 provides a report on the number of medications per participant, the medication names and formulations and frequency, and whether they use OP or an MCA. Diversity in the number and type of medications is evident. Furthermore, the results show the complexity of regimens demonstrated by the number and frequency of dosing; this contributes to caregiver burden. An interesting observation was that some caregivers would rather use OP over MCAs prepared by the pharmacist, even though they had a large number of medications to manage. This was due to a variety of factors such as having different doses on alternate days; having to break tablets in half; and personal preference towards how they manage the medications.

The maximum number of medications (including all formulations and both OTC and prescribed medication) at the time of interview was 15 and the lowest number was 3, with an average of 7 medications per person. The total number of medications was 85. The participants were on a variety of formulations; Figure 4.1 shows the number and percentage of formulations used by the PLWD in the community. It is predictable that the most common formulation was in tablet form (65%), followed by capsules (14%). Inhalers constituted 6%, with liquids and eye drops making up 3.5% each.
Before the interview by a week, one PLWD had one of their medications stopped by their GP (Accrete D3 tablet) due to his developing a contraindication. Another PLWD had their dementia medication changed from donepezil to galantamine; the caregiver realised her mother was suffering from side effects and decided to stop the medication and started the new tablets a month later.

At the follow-up telephone interview, caregivers were asked if anything had changed with the PLWD’s medications. Changes were diverse and include medications stopped without explanation to the caregiver; increases and decreases in doses; addition of new medications (such as antifungal tablets); and changes to class of medications (a participant had her amlodipine tablets changed to ramipril). Although not many of the participants had changes to their medications in the time between the initial and follow-up interview, it still highlights that circumstances change. The appropriateness of medications change and the addition of new medications may be required, while other medications become unnecessary. Regular medication reviews can ensure that unnecessary medications are stopped, unsuitable formulations switched, and caregivers and PLWD understand why medications are stopped, added or changed to increase awareness and avoid confusion.

![Figure 4.1: Number and percentage of formulations used by PLWD in the community](image-url)
<table>
<thead>
<tr>
<th>Number of medications per PLWD</th>
<th>Medication details (name, formulation, frequency)</th>
<th>OP or MCA (details)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>Hydrocortisone tablets TDS; levothyroxine tablets OD (different doses on alternate days); cyanocobalamin tablets OD; dutasteride capsule OD; folic acid tablet OD; lactulose solution BD; senna tablet OD; tamsulosin capsule OD; furosemide tablet OD; potassium chloride oral solution twice a week; testosterone injection once monthly (administered by nurse); colecalciferol capsule every 2 weeks; Daktacort cream OD; Daktarin cream OD; aqueous cream PRN</td>
<td>OP</td>
</tr>
<tr>
<td>5</td>
<td>Galantamine tablets BD; olanzapine tablets (5mg OM and 7.5mg ON); senna tablet OD; metformin tablet BD; calcium and vitamin D tablet OD</td>
<td>MCA (prepared by pharmacist)</td>
</tr>
<tr>
<td>10</td>
<td>Folic acid tablet OD; levothyroxine tablets OD (50µg and100µg); amlodipine tablet OD; aspirin dispersible tablet OD; finasteride tablet OD; lansoprazole capsule OD; memantine tablet OD; doxazosin tablet OD; enalapril tablet OD; simvastatin tablet ON</td>
<td>MCA (prepared by pharmacist)</td>
</tr>
<tr>
<td>5</td>
<td>Aspirin tablet OD; simvastatin tablet ON; amlodipine tablet OD; lactulose solution BD; ibuprofen tablet PRN</td>
<td>MCA (prepared by care home and given to her when she visits)</td>
</tr>
<tr>
<td>8</td>
<td>Simvastatin tablet ON; galantamine prolonged release capsules OD; mebeverine tablet TDS; latanoprost eye drops ON; atenolol tablets OD; amlodipine tablet OD; levothyroxine tablets OD; aspirin dispersible tablets OD</td>
<td>OP (caregiver places some tablets in a plastic compliance aid)</td>
</tr>
<tr>
<td>6</td>
<td>Omeprazole gastro-resistant capsule BD; indapamide tablets OD; donepezil tablets OD; amlodipine tablet OD; salbutamol inhaler QDS PRN; budesonide/formoterol Turbohaler BD</td>
<td>MCA (prepared by pharmacist)</td>
</tr>
<tr>
<td>12</td>
<td>Atorvastatin tablet ON; gliclazide tablet OD; pioglitazone tablet OD; memantine tablet OD; imipramine tablet OD; nifedipine prolonged-release tablet OD; ramipril capsule OD; metformin tablet BD; hyoscine butylbromide tablet TDS; budesonide/formoterol Turbohaler BD; salbutamol inhaler QDS PRN; hypromellose eye drops PRN</td>
<td>MCA (prepared by pharmacist)</td>
</tr>
<tr>
<td>Number of medications per PLWD</td>
<td>Medication details (name, formulation, frequency*)</td>
<td>OP or MCA (details)</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-----------------------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>4</td>
<td>Glucosamine capsule BD; fish oil capsules OD; vitamin D capsules OD; galantamine capsule OD</td>
<td>OP (Caregiver removes medications from OP and places in a plastic compliance aid every 2 weeks)</td>
</tr>
<tr>
<td>7</td>
<td>Formoterol Easyhaler BD; calcium and ergocalciferol tablet OD; bendroflumethiazide tablet OD; beclometasone dipropionate nasal spray BD; donepezil hydrochloride tablet OD; alendronic acid tablet once weekly; paracetamol tablets PRN</td>
<td>OP</td>
</tr>
<tr>
<td>6</td>
<td>Aspirin dispersible tablet OD; tamsulosin capsule OD; lansoprazole gastro-resistant capsule OD; laxido sachets (frequency and dose determined by caregiver) ; simvastatin tablet ON; memantine tablet OD</td>
<td>OP</td>
</tr>
<tr>
<td>4</td>
<td>Finasteride tablet OD; furosemide tablet OD; donepezil hydrochloride tablet OD; hypromellose eye drops PRN</td>
<td>OP</td>
</tr>
<tr>
<td>3</td>
<td>Ramipril capsule OD; aspirin dispersible tablet OD; atorvastatin tablet ON</td>
<td>OP</td>
</tr>
</tbody>
</table>

*Frequency: OD (once daily), OM (once in the morning), ON (once at night), BD (twice daily), TDS (three times daily), QDS (four times daily), PRN (as and when needed)
4.10. Summary of findings

The participants in both the community and care home settings included a range of personal characteristics and dementia severity. This assisted in providing a diverse sample across care settings to obtain a holistic picture.

In the community setting, PLWD were on an average of 7 medications; this was comparable to the care home setting. This could be attributed to the dementia severity of the PLWD in the community; more than half had moderate to severe cognitive decline. The majority were using SODF in the form of tablets (65%) and capsules (14%), whereas liquids (3.5%) and other formulations were rare. Medication use in the care home setting differed with regards to formulation variety; formulations such as solutions, suspensions, patches, and powders for reconstitution were used. This highlights that as dementia progresses and PLWD move from the home setting to care homes, formulations may change, such as some SODF being substituted with liquids or other formulations. In addition, it may indicate that prescribing decisions in the community setting are limited to certain formulations, whereas there is more variety in the care home setting.

The research aim is to identify the scope of issues relating to medication use, taking into account individual participant perspectives, care settings and progression of dementia. To be able to answer the research question and fulfil the objectives, the next results chapters (chapters 5-7) are structured to represent the results from the community setting, care home setting, and changes to medication use with progression of dementia respectively.
Chapter 5: Medication use in the community setting

5.1. Introduction

The dynamics between caregivers and PLWD were observed during the interviews; this related to how they worked together. Generally, the dynamics observed between the caregivers and PLWD work well and are based on their relationship. The PLWD and caregivers were interviewed together and the information provided was corroborated by each participant. In some rare cases, the PLWD would not completely agree with their caregiver. They would sometimes also interject while the caregiver answers their own questions or provide information that the caregiver had not considered. This is one reason why it is best including both parties when interviewing as PLWD may not be able to recall important events. It also highlights the importance of gaining both perspectives when discussing medications with HCPs.

The data from the community setting (the interview transcripts and notes) were analysed through coding and indexing using the thematic framework developed from the literature review. A thematic map based on the framework highlighting the themes and sub-themes generated through this first process of analysis can be found in Appendix 13. A further step of analysis was conducted to achieve the research objectives by identifying the priorities for family caregivers and PLWD from their perspectives. This chapter examines the findings in the context of the community setting and the partnership between the family caregiver and PLWD. This assisted in identifying and explaining when and how problems arise and the contextual factors to be taken into account when addressing medication-related problems. The analysis of the data in this manner fulfils the research objectives by answering the following questions:

- How does medication use contribute to caregiver burden?
- How is the PLWD’s autonomy maintained within medication use?
- What are the challenges associated with managing and administering medications?
- What factors associated with formulations are problematic for PLWD and their caregivers?
- How do interactions with HCPs assist or hinder medication use and in what ways can these be improved?
5.2. How does medication use contribute to caregiver burden?

It is widely documented that the caregiving role is burdensome, as seen in the literature review. The role and the medication-related activities that caregivers undertake may affect their everyday life and health; this may affect them negatively which may make them less able to take care of the PLWD at home.

The way caregivers perceived their role and responsibilities indicated how it affected their burden. Caregivers may sometimes feel they need to take care of the PLWD as they cannot rely on anyone else. Upbringing and culture was also found to aggravate this perception further. One caregiver was adamant about not putting her husband in a care home as it would be seen as a failure on her part. She even felt distressed about the idea of getting paid help.

The medication-related role was found to disrupt some caregivers’ lives, such as planning their social life or appointments. Some caregivers felt it had become part of their daily routine and had adapted to it. For other caregivers, administering and managing the medications may become overwhelming. Some caregivers felt like their life had become controlled by medication-related activities, and having to constantly plan ahead:

“Your whole day is, is, planned out for medication...because it’s a responsibility...you’re never free of this tension about are you administering it how it should be, that’s, that’s what I find difficult.” Caregiver 1, 74 years, Hackney

The medication-related role was also seen as very demanding and was described as a 24-hour job, causing stress to the caregiver. Some caregivers expressed resentment of this part of their role and wished they could relinquish their duties to the PLWD:

“I do it, I do it, but, you know, I said ‘why should I do it?’ before, I never do it before, why do I have to do it now? Of course I have to do it, you know? But before, it was free. She took her medication by herself, and you know, but now she can’t. I’m tired, blocked.” Caregiver 3, 87 years, Croydon
The medication-related role can also have a negative impact on the caregivers’ health. Caregivers themselves are getting older and have their own health needs. Some caregivers are also on medications themselves, and it can become quite a challenge remembering their own medications alongside the PLWD’s. Sometimes caregivers may put the PLWD’s medications and wellbeing before their own. One caregiver suffering from back problems refused surgery as he wanted to make sure he was always there to take care of his wife. He also ensures they have his wife’s medications when they are out. The stress associated with the role can also aggravate the caregiver’s health; this link was expressed by the participants. One caregiver’s mental health deteriorated and another caregiver developed gastritis. This burden associated with their medication-related role needs to be alleviated to ensure the caregiver’s health is not affected. They also need to distinguish their own burden from that of the PLWD:

“If I can say? I never really expected to end up taking control of how many tablets a day but, umm, that’s the way it’s planned out, you know. And I’ve personally have had, I don’t think it’s vital but, a few more hypos [hypoglycaemia] of late. Nothing too dramatic but, umm, I normally go, you know, some months without getting something.” Caregiver 2, 73 years, Croydon

Worrying about the PLWD’s medications, side effects and interactions may also affect the caregiver’s quality of life. This is linked to lack of information concerning medications, which increases burden and anxiety.

The caregiver’s health may also have an effect on the medication use process. Being sick or having certain illnesses, such as diabetes or back ache, can make managing and administering medications more problematic. The caregiver’s own ageing process also affects how well they can manage medications:

“Well I think it’s more strenuous for me because I too my health has deteriorated as well so it’s more taxing on me. So from that point of view, because if I don’t give it to him then he won’t have it. And it’s more taxing on me to remember and…not only remember but feel up to it, energetic enough to bother” Caregiver 7, 74 years, Croydon
Caregivers were found to have some negative perceptions of their caregiving role, and findings demonstrated how these perceptions affected their burden, such as feeling overwhelmed and isolated; these impact on their quality of life and burden as they worry about all aspects of the medication use process. Caregivers need reassurance about their role to know they are not isolated in their experiences. They should also be better prepared for this role by being provided with expectations of the tasks involved and skills needed. Receiving this validation and preparation may alleviate their burden. HCPs should also endeavour to meet the caregiver’s health needs alongside the PLWD’s and recognise they are both getting older and therefore may require further support. It is important to recognise the caregiver’s burden related to medication to be able to address the factors that increase this burden. This is to optimise the medication use process, alleviate caregiver burden and delay transition to a care home. Providing assistance and reassurance may help caregivers accept their role early on and reduce burden.

5.3. How is the PLWD’s autonomy maintained within medication use?

The concept of the PLWD’s autonomy in the context of the medication use process relates to the PLWD’s role in making decisions about their medications, such as being able to refuse to take a medication. The development of dementia in PLWD may result in their gradual inability to manage their medications; consequently this may mean that their caregiver becomes responsible for all medication-related aspects. These range from managing and administering medications to making decisions about medications. The PLWD’s autonomy is further discussed in Chapter 7 in the context of dementia progression.

Respecting the PLWD’s autonomy may be difficult in some cases, and some PLWD may still feel like they are being coerced. This was seen when one participant did not understand the benefit from taking the medications:

“They tell me to take it, you know I take. I don’t see what it done to me.”

PLWD 3, 83 years, Croydon
In other cases, the PLWD have accepted that they require assistance and are willing to rely entirely on their caregiver regarding medications. This compromise in their independence may cause them to not voice their opinions regarding the medications they are given. They may feel separate from the medication use process, and thus issues that arise may be unresolved, or preferences towards medications not voiced:

“I don’t know the names of the medicines and I don’t know anything. It’s just given to me and I take them” PLWD 1, 89 years, Croydon

PLWD did not always like to rely solely on their family caregiver; they may appreciate the help but they would rather do the things they are capable of themselves. This was seen in one PLWD who expressed her satisfaction of remembering her medications on her own, but was also frustrated when she could not recognise the medications. Another PLWD heard her husband saying how administering medications was difficult, and she replied she can do it herself, unaware that she has difficulties with medication use. However, she needs to be independent with her medications:

“Why you have to give me, I can’t take my tablets myself?” PLWD 3, 83 years, Croydon

This shows how much PLWD may value their autonomy, even within the medication use process. Even for those who have happily relinquished their autonomy, the implications of this were the disentanglement of PLWD from medication-related obligations, thereby increasing caregiver burden.

With regards to caregivers, they were aware of the importance of maintaining the PLWD’s autonomy within the medication use process. One caregiver perfectly summed the struggle of respecting the PLWD’s autonomy with medication use, especially with medication administration:

“I think it is possibly an inevitable thing that somebody will go through a stage where they don’t want somebody else telling them what to do and they can be very difficult if giving, with taking medication, accepting having medication given to them, you have to be negotiating all the time and rethinking your strategies on a daily basis, umm, can you give them the medication and persuade them to take it? Can you put it on a spoon and
persuade them to open their mouth? Will they then hide the tablets down the side of their gums because it looks as though they’ve taken it and then spit it out at a later stage? Umm, I’m not sure how you get somebody to be happy about losing control of their life at that point.” Caregiver, 57 years, Lambeth

Caregivers may try to provide the PLWD some semblance of independence when managing and administering medications to make the PLWD feel involved in the medication use process:

“It’s very important I think for her as well because she’s quite, she wants her independence so I think it upsets her if we do things too much for her” Caregiver 1, 60 years, Croydon

Management strategies adopted by caregivers and PLWD included placing medications in original packaging (OP) in certain places around the house to help them remember their scheduled time. One dyad coincidentally developed this strategy for the PLWD to remember to take her medications. This involves placing these medications around the rooms which they knew she will be in at the time she needs to take them. For example, the donepezil is placed on the mantle because she needs to take it at night before she goes upstairs, while some other medications are placed in the kitchen to be taken with breakfast. This strategy worked well, but the PLWD did not recognise the medications if they were not in their places or when the packaging changed:

“We’ve all got them in different places that I know when to take what, because where they’re positioned I know when to take them. I mean those packets are sometimes different colours so I don’t know which is which but when they are in their different places, I know what’s what and when to take it” PLWD 5, 88 years, Croydon
The importance of maintaining the PLWD’s autonomy was seen with one caregiver; she places the morning doses in a plastic compliance aid for her mother with a note next to it. She then relies on using the OP for the lunch and evening doses because she will be there with her mother and she can place the OP near her lunch or dinner plate:

“So I leave a note saying, next to the Mebeverine, saying ‘mum, have this half an hour before lunch’. I mean I could give it to her but I think she’s able that little bit of independence to read the note and help herself.” Caregiver 1, 60 years, Croydon

Finding a strategy to organise medications in a way that makes it easier on the caregiver as well as meets the needs of the PLWD and helps them feel somewhat in control of their medications is beneficial. The PLWD feels satisfied and happy with the process and it can empower them:

“She lays them out with the day and the time and everything and keeps them in the kitchen for me (laughs) so, well looked after.” PLWD 1, 89 years, Croydon

Other times, including the PLWD in the scheduling of Pro-Re-Nata (PRN) medications, such as paracetamol, was also seen as a shared responsibility and a way the PLWD retains some of their independence. Although it is valuable to consider the PLWD’s autonomy when organising medications, this does not always mean that medications will be taken. As one caregiver said, she allows her mom some independence with her medications by leaving them for her with notes, but her mother still sometimes forgets to take the medications:

“Umm...well the morning medication works well, it’s just the afternoon and the evening we have to be more vigilant to make sure that my mom takes it because sometimes she’ll see the note and then she’ll go upstairs to change her clothes and then I have to remind her to come down and take it” Caregiver 1, 60 years, Croydon
It can be difficult to keep reminding the PLWD as some caregivers feel like they are coercing them, which can lead to frustration to both parties. Developing strategies to respect the PLWD’s autonomy but at the same time administer the medications is imperative to ensure the PLWD’s wellbeing. There may sometimes be a struggle between the caregiver and PLWD; this was seen with even simple OTC medication, such as paracetamol, which can be difficult to negotiate with the PLWD to take, seen here and with 2 other PLWD:

“But I would never force it on her, I mean I’d say ‘oh silly woman, you know you’ve got a headache, why don’t you take a paracetamol?’ You know they are relatively harmless. Umm, but her attitude is ‘no! If I can avoid taking medication for that sort of thing’” Caregiver 2, 73 years, Croydon

The ways medications are presented and given to the PLWD differ from one dyad to the next. This depends on the preferences of the caregiver as well as finding a way that also suits the PLWD. PLWD may refuse taking medications if they feel coerced and not part of this process. These ways range from putting all the solid oral dosage forms (SODF) in a medication cup and standing by the PLWD to make sure they take the medications, to leaving them by their plate or tea cup. Methods chosen are also linked with the management strategy seen previously, such as leaving medication boxes in the room the PLWD will be in, or leaving them in a plastic compliance aid with notes. Another caregiver always gives the medications when he gives his wife her cup of tea. Not only is it a strategy to remember to give tablets because he associates it with when he takes her the tea, but it also helps his wife remember to take it and gives her some semblance of independence as she is not forced to take the medication. The PLWD preferences and behaviour need to be taken into account, such as always providing their medications with their favourite drink, to ensure they do not refuse medications.

In some circumstances, safeguarding the PLWD’s autonomy can cause some medications to be missed. One PLWD consistently forgets his tablets, even when they are in front of him. His wife does not want to always keep reminding him so he tends to forget his evening tablet. This may result in compromising the clinical effectiveness of his therapy, as well as wastage of medicines as they are thrown out. Caregivers may also be struggling to balance the PLWD’s autonomy and their need for medications, and prioritising which should be placed first:
“What matters most? It’s very difficult to be sure. I mean forcing somebody to take their medication probably is a step too far because the psychological effects of that are long lasting and the feeling that people are forcing you to do things is very, very distressing. So finding ways to get people to cooperate with having their medication may involve them sometimes not getting their medication I suppose.” Caregiver, 57 years, Lambeth

Other consequences of refusing or missing medications are the PLWD’s health deteriorating and requiring hospitalisation. With some other PLWD, their perceptions that some formulations are not essential may affect their medication use. One example is perceptions about inhalers which may lead to a case of asthma worsening, as one PLWD was said to be more breathless than usual. With another PLWD, allowing her some independence with her medications resulted in her being hospitalised. This shows the disadvantages of allowing freedom. This affected the caregiver who had to see his wife go through this ordeal, and also affected his wife who cannot make her own decisions and is forced to take medications in hospital, as her health deteriorated:

“Yeah, I would, I would make sure she takes the medicine because she’s been hospitalised several times because she hasn’t taken them and either refused or said she’s taken them and just hasn’t. And then, umm, you know, if it goes on for a week or more, she gets gradually worse and she ends up in hospital, where they forcibly give her medicines to stabilise her and then she comes back.” Caregiver 2, 64 years, Hackney

The PLWD’s autonomy and the desire to respect it can be a major factor within the decision-making process regarding medications. This is a complex process as the caregiver has to understand the PLWD’s preferences for the medication formulation, and strike a balance between their autonomy and their wellbeing. One example relates to the PLWD’s behaviour when refusing to eat food with their medications. The caregiver has to sometimes make decisions that put the PLWD’s wellbeing before their preferences and compromise their autonomy. This can have a negative effect on the partnership between the caregiver and PLWD. Caregivers have to make decisions about how to give medications when the PLWD refuses them. One caregiver started giving her husband donepezil without his knowledge as he refused the medication. She was concerned that his cognition was deteriorating, so she put his health before his autonomy. In some cases where the PLWD refuses medications, the caregiver
would decide to omit the dose. They make this decision without realising how it may affect the PLWD’s health:

“But for the moment, you know, as soon as it goes wrong I just back off and leave it until later. And you know for the odd day, I occasionally, very, very occasionally, you know if it turns out that later it’s difficult, well I might, I don’t know, might just leave it for one day and hope that there’s a cumulative effect.” Caregiver 6, 72 years, Croydon

This shows that caregivers may have to balance the PLWD’s health with their autonomy, and often put the PLWD’s health first, and that can affect their decisions. The type of medication may also be a factor, as caregivers accepted when PLWD would refuse PRN medication, such as for pain relief, but that was not the case with prescribed medication:

“See I would never; obviously never attempt to enforce something like that. I mean if she was refusing to take prescribed medication I might feel different, I would feel differently about it” Caregiver 2, 73 years, Croydon

This aspect of the decision-making process could be addressed by HCPs when medications are being prescribed or at appointments. Understanding how caregivers and PLWD make these decisions and how the PLWD’s autonomy factors in this process, as well as the challenges encountered, can assist with resolving the issues accordingly.

The findings have identified how the PLWD’s autonomy may impact the medication use process. The concept of preserving the PLWD’s autonomy can be seen as a spectrum; at one extreme the PLWD relinquishes their independence within the medication use process and thus affect their interactions within it, and at the other extreme the PLWD is provided with full autonomy which can cause medications to be missed and therefore increase the risk of their health deteriorating and hospitalisation. Both extremes may also increase caregiver burden as at one end they are in charge of all medication-related responsibilities, and at the other end they worry about coercing the PLWD with their medications. It would be best to reach a point in the middle of this autonomy spectrum; allowing some autonomy in the medication use process by ensuring the PLWD shares control of the medication-related aspects can have positive implications. These may lead to the PLWD feeling more satisfied and alleviating
behaviour issues that may have resulted from removing their autonomy. In addition, PLWD may be more willing to voice concerns or opinions regarding medications as they feel involved. It may also alleviate caregiver burden as tasks within the process feel shared between them.

The PLWD’s autonomy is significant to the partnership within the dyad, as well as to medication use. It was evident that both the PLWD and the family caregivers wished to conserve the PLWD’s autonomy for as long as possible, and this was exhibited through management strategies, sharing responsibilities, involvement in decision-making, and the administration of medications.

5.4. What are the challenges associated with managing and administering medications?

Caregivers and PLWD identified the practical challenges associated with medication use. There were some issues with obtaining medications, such as obtaining differing numbers of supplies of medications or prescriptions being delayed. The scheduling of medications forms a major component of the medication management process. Factors identified that affect this process include the dosing schedules and changes in medications.

The time of day medications are scheduled to be given and the dosing frequency may be seen as a challenge by some caregivers and PLWD. Dosing schedules where medications are only given in the morning and the evening were seen as optimal by most caregivers and PLWD. They found they can easily include them in their daily routine and utilise cues, such as leaving the medications near their breakfast or dinner plate. Medications given more than twice a day, such as including lunch time doses, may make the process more complicated for them as it may interrupt their day:

“Now that has to be with meals, so that does require a little bit more memory, especially when we go out for a meal. We went out for lunch today so I had to remember to take those with us.” Caregiver 4, 74 years, Croydon
Dosing schedules may also restrict the activities and routine of caregivers and PLWD. A change in their routine can also have an impact on scheduling medications. Attending social events or having to go to appointments can alter the scheduling routine and may cause medications to be missed:

“But I’m kind of building that into the routine because when she was having lunch at home it was easy, I just kept the tablet next to her lunch plate. So now before I leave the house to take her to her lunch club, I have to go to the kitchen and check that I haven’t forgotten anything then I give her her tablet before I leave. So it’s just as you say, building in cues whenever we want to remember.” Caregiver 1, 60 years, Croydon

Change in medications, such as the addition of new ones or temporary ones (e.g. antibiotics) may be seen as a hassle to some caregivers trying to fit them in the scheduling routine, especially when the PLWD is already on a number of medications. This then causes some caregivers to sometimes decide to omit a medication that they do not deem as important as others, especially if they need to be given at specific times:

“Particularly like the case of last week when my husband had antibiotic, you had to fit that in. And that was, sort of, they were 2 daily (twice daily dosage), and there was an 8-hour gap in between so you had to think ‘oh, ok, if I give that now and then…’, umm, you’re never free of this tension about are you administering it how it should be, that’s, that’s what I find difficult.”
Caregiver 1, 74 years, Hackney

Administration of medications may also pose difficulties for some caregivers. Environmental factors, such as noise and familiarity of surroundings, and the PLWD’s cooperation to take the medications may complicate the administration process. The importance of the PLWD’s autonomy was mentioned in previous sections, and it is also a factor when administering medications.

Caregivers have to sometimes individualise strategies for how to approach PLWD who display challenging behaviour. These can range from placating and coaxing the PLWD, to finding a suitable time to give medications. Understanding the PLWD’s mood would greatly assist with approach. Talking to PLWD and explaining to them
why they are taking medicines can be very helpful. It is not just the familiarity with the caregiver that is important, but also what is said and how it is said:

“Most things with her is if you keep explaining all the time what you’re doing she would be ok about it so you’d keep saying ‘it’s ok, remember that you need the oestrogen because of your pelvic floor, and so it’s ok this is just an oestrogen pessary, it’s going to help you to have stronger pelvic floor muscles’ and as long as you’re talking, explaining and being reassuring, she would be ok with that.” Caregiver, 57 years, Lambeth

The language and tone used was also reported to be important. This may agitate or aggravate the PLWD. One caregiver found that changing the way she instructed her husband to take his medication improved his willingness to take the medications, especially the capsules in the morning which he would sometimes refuse to take. Understanding his moods and behaviour better and changing her language and tone assisted greatly.

Instructions on how to administer medications were sometimes difficult to follow and this relates to a variety of factors including the PLWD’s behaviour and autonomy, as well as the approach when giving medications. Behaviour and PLWD’s preferences can dictate how the caregiver approaches them, and the method of administering the medications to them.

The findings show how the practical aspects of the medication use process, particularly the scheduling and administration of medications, may be challenging and may affect the PLWD’s health and increase caregiver burden. HCPs should take into account all these factors, including the management of both the caregiver’s and PLWD’s medications.

5.4.1. Lack of medication information

Lack of information concerning medications can negatively affect medication use, as well as add stress to the caregiver. Identifying areas where caregivers and PLWD lack information can assist in targeting these areas and ensuring caregivers and PLWD make informed decisions about medication use, thereby optimising medication use and decreasing caregiver burden associated with decision-making. Areas where lack of information affected medication use were about appropriateness of formulations,
modification of medications, medication interactions, side effects, and effectiveness and need for medications.

There was an evident lack of information on the importance of use of inhalers. One PLWD had stopped using her inhalers as she believes she does not need them, and that they may have an addictive effect:

“‘Because you know I’m alright. You know if I take it, you know, it will make me have to do it all the time. And I’m perfect so no thanks’” PLWD 3, 83 years, Croydon

All participants on inhalers did not seem to consider them as medications; when asked what medications they were on, they never mentioned them until the term inhaler was brought up. In one dyad, the caregiver did not enforce the use of his wife’s inhaler and eye drops in comparison with her SODF medications. This indicates that formulations that are not SODF or liquid may not be perceived as important.

Explaining the importance of medications and how they are helping the PLWD can make them more willing to use their medications. This was seen with one PLWD who became more positive about her medications when it was explained by her husband why she needed them, and that she may become worse if she stopped them. This shows that PLWD who seem to be avoiding their medications may be doing so unintentionally, because they have forgotten their need. If this information is provided continually when giving medications, it may make the medication use process easier.

Caregivers and PLWD also lack information regarding medication modification, as seen in the previous section. This lack of information means caregivers and PLWD continue with inappropriate practices with modifying medications that may have a negative impact on their medications, and consequently the PLWD’s health. One caregiver said she opened the capsule once and was surprised by the contents, and when asked if she had asked someone for advice, she said ‘no, should I have?’ This demonstrates that caregivers do not realise the implications of modifying medications or even the need to ask HCPs before doing so:
‘Well, I know that I could, I suppose I could take the capsule apart. I mean I did try and do that once (…) And I pulled one apart and was quite surprised that inside instead of it being a powder, which I thought would be quite easy to put into a spoon, there were all these thousands of little tiny granules and they went all over the place’ Caregiver 6, 72 years, Croydon

Making decisions to modify medications may be difficult for the caregiver and an added responsibility. While trying to ensure the PLWD takes their medications, they might lack the information regarding appropriate modifications. Caregivers sometimes lack information regarding medication interactions, either with other medications or with food. This can make the decision-making process more difficult and stressful for the caregiver. This is especially true for new medications. Sometimes caregivers hesitate to give a PRN medication, or even avoid it altogether. One caregiver asked if it is acceptable to miss a day or two of her husband’s furosemide to allow space for his antibiotic. This indicates that her informational needs are not being met:

“So what I have to do is sometimes give them with orange, and again I find that a worry because I think, I know some medications you can’t take grapefruit with so I’m thinking, does orange do the same sort of thing? But having said that, I think, it’s more important that he has the tablets than worrying about the small amount of orange he’s drinking.” Caregiver 1, 74 years, Hackney

When new medications are started, some caregivers may be unsure if they are suitable for the PLWD. For caregivers, decisions of starting and continuing these new medications can be a concern as they are not always sure they can assess the effectiveness. This is further aggravated by the caregiver’s lack of information about the medication, the overwhelming list of side effects on the medication leaflet, and the PLWD’s decline in cognition and hence their inability to sometimes voice that they are experiencing side effects. Sometimes when the PLWD is on a number of medications, the caregiver may worry about interactions, as well as scheduling. This can be exacerbated when a new medication is added, even if it is only temporary, such as an antibiotic. This can lead them to prioritise medications and omit those they deem unnecessary.
Caregivers may sometimes make decisions without the required knowledge, which may sometimes conflict with what is best for the PLWD’s health. This lack of information not only affects decisions, but may also increase caregiver burden relating to medication use. Decisions that were difficult for caregivers related to modifying medications, medication interactions, and starting and stopping medications. Their informational needs can be easily met by having the required information provided by GPs or pharmacists, either during consultations or MURs. Pharmacists can answer caregivers and PLWD’s questions when any new or temporary medications are added and assure them of their appropriateness and need, as well as ask about how to incorporate them in the dosing schedule to ensure they are taken. Fulfilling the dyad’s informational needs may assist in optimising medication use by ensuring caregivers make informed decisions about medications, and that PLWD realise the need for medications; this may also assist in alleviating caregiver burden.

5.5. What factors associated with formulations are problematic for PLWD and their caregivers?

The choice of formulation is important to ensure that medications are taken as prescribed and without problems. The characteristics of formulations, such as the type, size, shape, colour, taste and quantity need to be taken into account. For example large tablets, such as the Accrete D3 tablets, can sometimes be difficult to swallow. This can lead caregivers to modify medications for ease of use, sometimes without the required knowledge about the appropriateness of that modification.

Doses for older people are sometimes lower. Those requiring manipulation of dosage may be problematic. One example was a caregiver who breaks the 10mg hydrocortisone tablets and keeps them in a bottle. A few issues may emerge here as seen in the quote:

“Again it’s a little bit of a worry, like sometimes, umm, imagine I’ve broken say one in half, umm, like that one (showing me the halves she has already broken) it’s slightly smaller than that (showing me 2 different sized halves) and I’m thinking, now I must remember that the smaller one belongs to the half he had, we say, lunchtime. So this smaller one will be the one he has at 6pm. Things like that. Because I think, otherwise does it mean I’m giving him more or, that’s, that’s the sort of worry.” Caregiver 1, 74 years, Hackney
The findings demonstrated individual preferences regarding the characteristics of formulations such as taste, colour and size. The colour of medications may affect their acceptability by PLWD. An example is with Senokot tablets, which some PLWD considered distasteful due to their colour:

“I think it’s just the colour of these (senokot) that he’s not happy with, I mean they’re sort of... (Brown)... Yeah. And he’s not (acts like her husband when he’s given them, with disgust on his face) ‘what are they?’” Caregiver 1, 74 years, Hackney

Preferences may cause the PLWD to refuse medications; this becomes more complicated when the PLWD cannot verbalise why they are refusing and therefore the caregiver assumes it may be behaviour-related. Issues with preferences may be easily resolved with a change in formulation by asking about available alternatives. An example was seen with an effervescent formulation of potassium which the caregiver requested an alternative form and received a liquid formulation that the PLWD preferred and was able to take without problems.

For caregivers, formulation type was an important concern. This related to ease of use, ease of administration, swallowing ability and need for multiple dosing and monitoring. One caregiver would rather her husband stay on topical treatments than take the terbinafine tablets because she does not want to worry about side effects and monitoring for them. A few caregivers thought liquid medications could be easier to administer than SODF, but this depended on the PLWD’s swallowing ability.

Preferences for formulations may also relate to perceptions associated with branded and generic medications, products and packaging. Supplies from different manufacturers may mean that changes occur to medication packaging or to the medication itself, such as shape, size or colour. This may cause confusion to caregivers who are not always told that the medication is still the same. Even for caregivers who are aware of this change, repeated changes can be problematic or stressful:

“And you think it’s the same amount of tablets in and they’ve made the packets bigger and you think why have they done that? Which is a bit off-putting when you first get them because you get used to the same ones, don’t you? The same packaging” Caregiver 8, 70 years, Croydon
Changing from branded to generic medications may also cause some issues to the PLWD as well as their caregiver, such as experiencing side effects with generics, and the PLWD perceiving the medication as different and refusing. PLWD and their caregivers may think there is a compromise in quality when medications are changed. The perception that medications may be chosen for its cost rather than the PLWDs’ and caregivers’ preferences were also voiced:

“I mean they’re generic aren’t they? Most of them, they’re bought on the basis of cost by the pharmacist I presume. So they can’t dictate ‘well I want a red one or a pink one’ (his wife laughs) but I just wonder it’s got to come up so many times in the business of medication and tablets, clearly it’s not gonna happen because it hasn’t happened yet but I don’t see why they shouldn’t sort of put in a plea if you like to reconsider it, because I do think it’s a problem particularly for older people.” Caregiver 2, 73 years, Croydon

One formulation type that posed issues for participants, both caregivers and PLWD, were inhalers, as they may not be used regularly, and may be complicated to use and require correct technique. Not using inhalers correctly can lead to poor management of or exacerbation of symptoms. Inhaler use may also be challenging for caregivers as instructions are complicated and require effective coordination:

“The inhalers, we have one up the nose and one through the mouth. She forgets which is which, you know, ‘where do I do this?’ and ‘how do I do that?’ and I have to say, you know ‘count 5 and breathe in, breathe out’, do this, do that. And it surprises me that she asks me to, you know, take her through it each time. But then I find I forget as well! (We both laugh) I have to look at the instructions; I can’t blame her for not doing that on her own. So the two of us do it together and we get through it” Caregiver 5, 89 years, Croydon

Other formulations were considered difficult to handle and administer, such as injections, pessaries and eye drops. Caregivers may be unable to or decide to omit these formulations when they lack the adequate information and training to administer them correctly. This may affect the PLWD’s health, as well as burden the caregiver who may feel responsible. Some PLWD may also forget how to administer certain formulations, such as eye drops, themselves. The complexity of inhaler use was discussed in the previous section. Another formulation was pessaries, where one PLWD required help to administer them:
“She was prescribed oestrogen pessaries which then had to be administered by…she couldn’t administer, at no point did she reach the point where she was able to administer them herself although one could if one didn’t have dementia.” Caregiver, 57 years, Lambeth

The medications and packaging may be difficult for some caregivers and PLWD to handle. Small tablets and capsules were considered problematic to pick up and can easily slip or get stuck on their hands, especially when they had to break a tablet in half. Even though some SODF are this size for ease of swallowing, there is still the issue of handling, especially with caregivers and PLWD without full use of their hands. Sometimes, this can lead to medications being dropped and thrown away, raising the issue of medication wastage. It can also lead people to adopt inappropriate strategies, such as removing all their medications and placing them in one container. This can have negative implications for medication safety and stability, as some medications’ physico-chemical stability may be compromised if they are taken out of their protective packaging. This may lead to a change in integrity, colour and taste:

“When he was taking his own medication he used to have terrible trouble with the aspirin and moan and groan about it. He used to like to take them all out of the, out of this blister pack and put them into a little container so that all he had to do then was to unscrew it and take them. And he used to moan and groan about how his fingers were hurting when he took them out, because they’re really quite stiff” Caregiver 6, 72 years, Croydon

Medication packaging, whether in OP or pharmacy prepared blister packs, was deemed challenging to handle by some participants. Some medication blister foils can be difficult to handle, and some can be sharp and cause injury to caregivers when they are removing the medications, especially to those with less manual dexterity and thus rely on sharp instruments to cut the foil backing. This may cause harm to the medication and can cause injury to the caregiver:

“I mean personally I, I keep on finding different ways to push these out, I mean these you push them that side it’s a cardboard side so get a sharp pointed thing here and tear it from the back. It’s a bit of a performance.”
Caregiver 2, 73 years, Croydon
The findings have illustrated that certain characteristics may affect choice and preference of formulation for both PLWD and their family caregivers. PLWD preferences generally related to size, shape and colour of formulations, while caregiver preferences often related to ease of use.

Prescribing decisions should take into account formulation characteristics to ensure acceptability to both the caregiver and PLWD and to promote adherence. This is because some characteristics, such as taste and colour, may lead PLWD to refuse medications. Identifying the PLWD’s preferences entails finding a suitable alternative to ensure acceptability. Packaging can also be troublesome; medications and their packaging should be taken into consideration by HCPs. They should consider both the PLWD and caregivers’ abilities when issuing medications or a type of pharmacy prepared blister, as there are varieties. It may be difficult for HCPs to identify specific preferences; asking caregivers and PLWD about difficulties they encounter with medication use and formulations may assist in highlighting personal preferences. These questions can be asked within the consultation with the GP or with the pharmacist during a medication use review (MUR).

While the interchangeability of medications may be seen as trivial by some HCPs, the findings have shown that both caregivers and PLWD were affected by these common changes that did not take their preferences into account. This issue may be ameliorated if these changes between medications are explained, to ensure that the PLWD’s health is not compromised, as well as lessen their confusion.

If all these concerns and issues with formulations are discussed with HCPs, they can be taken into account for future prescriptions. HCPs could also be aware of potential issues with formulations and anticipate them for other PLWD. This may ease this part of the medication use process and therefore lower caregiver burden associated with it.
5.6. How do interactions with HCPs assist or hinder medication use and in what ways can these be improved?

Caregivers and PLWD interact with formal care along a variety of points, from diagnosis, to obtaining medication, to support and services. The findings identify which factors associated with formal care affect medication use, how they affect it, and what changes need to be made to improve care and thus optimise medication use. The factors identified were associated with the relationship between the dyad and HCPs.

The relationship the caregiver and PLWD have with HCPs may have an impact on medication use. The factors associated with this relationship, such as trust in the HCP and effective communication, can make the dyad feel supported and comfortable to discuss issues they might have with their medications or voice any concerns. Inclusion of both the caregiver and PLWD in discussions with HCP, such as the GP and pharmacist, is favourable as it assists in creating a stronger relationship and may also ensure that the dyads’ concerns are addressed. It was seen earlier that dyads may sometimes provide conflicting views, and sometimes the PLWD needs the caregiver to answer questions as they may not recognise all the medications they are taking and/or are unsure of past concerns, such as side effects. The PLWD’s inclusion in the discussion also respects their autonomy:

“They ask me, but if I’m, sort of hesitant and not sure what to say then she helps me, but most of the time I give the answers myself.” PLWD 1, 89 years, Croydon

PLWD valued inclusion in discussions about their health and medications. Their involvement makes them part of the medication use process and may make them more willing to take their medications:

“I think she (the doctor) doesn’t like me! ... She is not used to me and I am not used to her. Umm...yeah...one doctor is...umm...listening to you, the other doctor is not listening to you, so...” PLWD 1, 74 years, Hackney
Continuity of care and long-term relationship with the GP were important. Seeing the same GP helped foster communication and trust. GPs familiar with their medications were seen as helpful in prescribing decisions:

“But we try and see the same chap, not always possible, but the one who knows us. Because I think it’s quite important that they know the kind of medication you’re on and they know what you’re like” Caregiver 2, 73 years, Croydon

Pharmacists were valued for being approachable and available for informal chats, which encouraged them to voice any medication-related concerns:

‘When I was dealing with Boots they were alright but it was, umm, it was not very, umm, I won’t say friendly, that’s wrong, they were quite friendly. But they didn’t sort of get so much involved in what you were doing, they would just, you know, it was routine I think one would say.’ PLWD 2, 82 years, Hackney

Some caregivers valued and trusted pharmacists for their medication-related expertise. This highlights the potential role of pharmacists in supporting caregivers and PLWD:

“To be honest, I, I’m always, umm, I feel slightly better when the pharmacist said it’s ok rather than when the doctor, because, doctors, I think, are in one thing, but pharmacists have to know about all the, that doesn’t interact with that, but, you know, so, I think that’s better.” Caregiver 1, 74 years, Hackney

Having a paid carer can provide some relief to caregivers as they assist in alleviating some of the responsibilities. They can help with everyday activities such as feeding and bathing, as well as medication-related activities. The relationship and trust is, again, important:

“Yeah…I’m not taking all the time from the carers, no way. I just doesn’t (sic) trust them” PLWD 1, 74 years, Hackney
Paid carers may need to approach the PLWD in an appropriate way that makes the PLWD feel comfortable with them and therefore trust them to accept medications:

“Yeah, and she has to be sort of friends with them, not sort of adversaries or, you know, feel like they’re interrupting her regime” Caregiver 2, 64 years, Hackney

The lack of professionalism of some paid carers was highlighted, for example, inadequate training, tardiness (affecting the medication schedule), and mistreatment of the PLWD:

“They’ve often said to me ‘what do I do?’ and I go ‘there’s a big chart on the wall, you’ve got instructions in there, why the heck don’t you know what you’re doing?’ (says this in a frustrated tone). You know, you’re here to wash her, dress her, give her her pills, you should know that before you turn up at the door. Umm, and the other thing is their timing. Umm, we normally get the carers to come in at about 5-5:30. One turns up 20 to 8. Yeah, and we said, oh to the same carer, ‘she needs her pill with her breakfast, yeah, what time you coming?’ She said 6:30. I said ‘no it’s far too early, you know, she’s normally in 7-7:30’. ‘Oh well, I’ll turn up at 10’. And she turned up 20 to 11. She was also being abusive towards my wife as well as turning up late. Up to 40 minutes late” Caregiver 2, 64 years, Hackney

Some caregivers talked about their interactions with secondary care, such as memory clinics and care homes. These interactions, negative or positive, may also impact on the medication use process, such as providing expert information regarding medications and effective and sensitive communication. Thus, specialist services did not always meet expectations with regards to providing support and advice:

“But I suppose when something is so specialised like the memory service, my expectation was that they would from their experience with a, you know, with a small problem like memory they would have maybe studies that look at side effects of medications and they might have more information than we can get from the leaflets or from reading up ourselves, you know from direct experience. That was my expectation but...” Caregiver 1, 60 years, Croydon
Good relationships between the dyad and HCPs are imperative in optimising medication use. Involvement of both the caregiver and PLWD in consultations where they are able to voice their concerns can help HCPs provide tailored support and information, as well as target issues encountered in medication use. HCPs are the main source of support and information. Therefore, they should be approachable, have effective communication skills and anticipate issues that caregivers and PLWD might be experiencing.

5.7. Suggestions for optimising medication use by participants

Participants provided their suggestions on how the medication use process can be improved. This includes suggestions for pharmaceutical companies regarding medications and formulations that meet the PLWD and caregivers’ needs. These included improvements to characteristics of medications (such as size of SODF and developing medications that are easier to swallow), improvements to packaging, the availability of liquid formulations, and up-to-date leaflets:

“So syrups on spoons I suppose, it might be a good idea to develop the medications that are most common for elderly people who also happen to have dementia, to maybe develop syrups like we do for children.” Caregiver, 57 years, Lambeth

Examples of packaging improvements included making them user-friendly for people with reduced manual dexterity (such as easily teared blister foils). Blister foils with the days of the week were also found to be helpful, especially for PLWD who are still managing their own medications. Not all information can be considered as helpful, especially in leaflets. Caregivers may make inappropriate decisions based on this information. Information may need to be worded differently, or caregivers and PLWD need to be assured that the benefit outweighs the risk by their HCP:

“If you read that leaflet it’s quite terrifying, because you can harm this and harm that, and then I think, do I really need it?” Caregiver 1, 74 years, Hackney

Some caregivers thought that leaflets were not always tailored for them, and some information deemed important to them was missing. Examples include how medications are given or interactions with food or liquids, such as orange juice. Caregivers also needed information on dealing with the PLWD’s refusal of
medication, the effect of changing dosage time, and the window available for the
caregiver to administer the medication. This would assist the caregiver and lower the
stress associated with administering medications to PLWD who have fluctuating
behaviour. The size of the writing, font and colour should also be taken into
consideration as some older people find it difficult to read the miniscule writing on
leaflets.

Instructions also need to be less complicated, especially with inhalers and nasal sprays.
This added difficulty may make it challenging taking these medications, and more
often than not, they are forgotten by both the caregiver and the PLWD. Ensuring the
simplicity of medication instructions may assist in easing the medication use process.

Suggestions about HCPs included the availability of more knowledgeable pharmacists
so that caregivers can receive the answers they need about medication concerns from
them rather than having to see the GP:

“Yeah, I think it would be good if they could give us, because it would save us
going to the GP quite a lot if they could give us, answer some of our questions
and give us more information about side effects” Caregiver 1, 60 years,
Croydon

Caregivers also need the option to speak to the GP privately about the PLWD without
the PLWD being present to talk about their concerns without injuring the PLWD’s
feelings. This means that some concerns may not get voiced by caregivers and
therefore issues go unresolved:

“I think there were probably times when they should talk to me personally,
private, than to him because he’s like when I said he chewed the tablets or
something, I don’t want to be telling lies at him, if you know what I’m saying?”
Caregiver 7, 74 years, Croydon
Improving services and support being offered by memory clinics was highlighted. Training HCPs (GPs, pharmacists, paid carers) to be dementia friendly, and improving the current training and education was suggested, as they are not meeting caregiver and PLWD needs and standards for care:

“I think possibly, and I hesitate to say that all healthcare professionals should have dementia training because I know that dementia training could be very brief and not really adequate so it’s almost pointless.” Caregiver, 57 years, Lambeth

A suggestion by one caregiver was to develop a forum for other PLWD and caregivers where they can share their issues and how they were dealt with. This would help them learn from each other’s experience as well as be a form of support:

“That’s another sort of general point of mine which is that I wish there were some kind of central area where people who have the sort of problems that we do to go to and say what can we do? What is available to us for this, for that, and something else?” Caregiver 2, 73 years, Croydon

Participants provided a wide array of suggestions, all with the aim to improve the medication use process for both the caregiver and PLWD through better interactions and communication with HCPs and access to support and services that meet their needs. These may provide useful perspectives to inform service development.

The findings in this chapter identify the factors affecting medication use in the context of the caregiver and PLWD relationship in the community setting. Six main areas that require improvement were highlighted to optimise medication use in PLWD and lower caregiver burden. Figure 5.1 is a conceptual model of these six domains and their implications for medication use.
As dementia progresses and caregivers may no longer able to provide care, PLWD may transition from the community to the care home setting. The following chapter identifies and analyses the factors impacting on the medication use process in care homes to inform recommendations to optimise medication use (Chapter 6).
Chapter 6: Medication use in the care home setting

6.1. Introduction

The data from the care home setting (the interview transcripts and observation notes) were analysed through coding and indexing using the thematic framework developed from the literature review. A thematic map based on the framework highlighting the themes and sub-themes generated through the first process of analysis can be found in Appendix 14. These findings were analysed further to achieve the research objectives by identifying the priorities for care home staff in the context of the organisational factors within the care home setting to help understand and develop solutions to optimise medication use. The analysis of these findings in this manner fulfils the research objectives by answering the following questions:

- What organisational aspects within the care home affect medication use and how?
- How does the medication use process contribute to care home staff burden?
- How do interactions between staff and HCPs affect the medication use process, and how can these be improved?
- How do the interactions between care home staff and residents affect medication use?
- What factors associated with formulations are problematic and how?

6.2. What organisational aspects within the care home affect medication use?

Each care home organises the medication round differently; this was previously detailed in chapter 4. Obtaining and organising medications, as well as the logistics of the medication rounds may sometimes contribute to issues with medication use. The factors associated with these challenges are identified and examined below.

6.2.1. Obtaining medications

Residents in care homes are not always there permanently; some residents have just come back from hospital or are only there on a temporary basis. This transition raises a few issues regarding medications. Sometimes the medication supply is not sufficient for their stay at the care home. Wastage of medications may also occur when the medications are already available in the care home and the ones brought by the
resident have to be disposed of. The lack of communication between care settings results in medication wastage and more time spent on ensuring the medication supply is correct for the resident’s stay:

“When they come out of hospital, they bring in all the same medications back with ’em, without asking whether we’ve got it in stock all the time, so that just gets disposed of and sent back to the chemist, unless it’s changed and then we change it on the chart and that. But sometimes that makes more paperwork then.” C4, female, 47 years (CHBR)

For some care homes, procedure dictates that they have transactions with multiple surgeries and pharmacies to receive prescriptions for their residents. This can cause some delays in obtaining medications when there is a breakdown in communication between multiple providers. One carer illustrated how miscommunication with one of the surgeries led to prescriptions being sent to their old pharmacy instead of the new one, resulting in prescriptions getting lost or delayed.

When medications are received, care home staff have to be vigilant, as multi-compartment compliance aids (MCAs) are sometimes not correctly prepared by the pharmacy. This is more so when residents are in transition between hospital and the care home due to lack of awareness of changes to medications.

6.2.2. Organising medications

Medication management in care homes is either through the use of medications in original packaging (OP) or the use of MCAs prepared by a pharmacy. In all the care homes, medications that are PRN, e.g. paracetamol or ibuprofen, were always in OP. It was helpful when MCAs were filled according to the order in the medicines administration record (MAR) charts. When this was not the case it leads to frustration of staff as the medication round becomes longer and they feel rushed. Also, medications that were in OP had to be counted each time they were administered and logged on a separate sheet for auditing in the MAR chart file, which also made the process longer. Temporary residents or those arriving from hospital may have their medications in OP; this makes it more time-consuming on staff who are not used to medications in OP:
“But it, also does it affect how you give the medicines, umm, because sometimes, because a new patient comes in, they come with original packaging whereas you’ve got the blister packs already prepared” C3, male, 38 years (CHIM)

Preparing and administering medications was observed to require more time in comparison with the use of MCAs, regardless of the number of residents. This not only affects the timing of time-sensitive medications, such as those for Parkinson’s, but it may also affect the carer as it disrupts their schedule and might cause them to make mistakes due to medications managed in different containers.

Having OPs instead of MCAs was seen as safer to administer to residents in one of the care homes, as each resident would have a locked cupboard with their own medications in their own room. Furthermore, unused prepared medication (medications placed in a medication cup for administration) would be kept in their locker rather than the medications trolley, which can alleviate confusion. Some staff preferred using the OP rather than the MCAs as it was easier for them to recognise medications. Preferences were very individual and related to how well each carer or nurse can manage the medications.

6.2.3. The logistics of the medication round

Some care homes conducted medication rounds according to mealtimes, while others were flexible and took each resident’s timing of medications into consideration. It was observed that many factors can affect the medication round and are described in the following section.

The number and type of medications to be administered understandably makes the round longer. One example is medications to be administered via a percutaneous endoscopic gastrostomy (PEG) tube:

“Yeah, we got residents, 3-4 residents with a PEG feed, that takes longer as well, yeah, flushing, mix medication, some of them soluble medication for example you have to wait until they completely [dissolve], yeah so” N3, male, 48 years (CHIN)
Distractions were observed to interrupt medication rounds, such as residents requiring attention, assisting other members of staff, or responding to any emergency:

“It would be nice not to have the disruption of the telephone, umm, any MDTs that are coming in, umm, it would be nice if you kind of like had a bit of a, you know, protected time whilst doing medication, umm, that, that would be very helpful.” C3, male, 38 years (CHIM)

“If there’s an emergency and you have to lock the trolley and sometimes it’s all hands on deck if there’s an emergency in the middle of it.” C4, female, 47 years (CHBR)

Some residents may request information relating to their medications. Although it does not necessarily prolong the medication round, it distracts the staff member as they have to explain to them that it is confidential information that cannot be discussed in front of other people.

The findings identify the practical aspects of obtaining, organising and administering medications. Better communication between care settings and vigilance from care home staff may assist when obtaining medications and in reducing errors. Care home staff need to be familiar with medications in OP. The provision of clear instructions may make it easier to administer unfamiliar medications. The organisation of medications, distractions, and the number and type of formulation may all prolong the medication round. Staff administering medications may be able to prompt reviews to remove unnecessary medications. In addition, development of strategies to deal with distractions from residents and increasing staff awareness of the importance of running the round without disruptions may assist.

6.3. How does the medication use process contribute to care home staff burden?

Care home staff may experience stress with their role of administering medications; this may become aggravated when residents have dementia. The organisational aspects of the medication round detailed previously have a great impact on care home staff as they try to administer medications and efficiently manoeuvre through the medication round. The stress that it imposes on staff was evident through interviews and observations of the round. Even those with years of experience still found it challenging:
“Umm, really I am having about 10 to 12 years’ experience in this country. I work in nursing home quite a lot and people with dementia it’s, really it’s hard to give the medications, in that one stage it is very, very difficult, you know” N1, female, 55 years (CHIN)

Even with measures in place, such as staff wearing distinctive aprons with ‘do not disturb’ written on them, residents and other staff members may disregard them. The deterioration of residents’ health and arrival of HCPs can also distract the staff during the round:

‘As you saw today, umm, GP rounds, we were short of one member of staff, umm, and I have (one of the residents) who, ahh, has deteriorated quite significantly, especially since I last saw her, which was on Friday, umm, so that, and yourself being here, and umm, the DOLS (Deprivation of Liberty Safeguards) assessor was here, it’s just little bits, and the telephone, I feel that sometimes it’s just continuously ringing’ C3, male, 38 years (CHIM)

These disruptions may distract the staff member and may lead to medication errors occurring. Staff needed to be patient and focused in order to manage the round and residents:

“You just gotta have patience. You know you should never rush a drug round anyway, like a medication round anyway, you shouldn’t. You should just take time, don’t worry about what anyone else is doing around you, just, cuz that’s, you got to concentrate, you got to make sure that everything’s right before giving out the medication.” C5, female, 30 years (CHBR)
Residents displaying agitation and aggressive behaviour during medication administration were observed. This affected staff greatly and was evident from observations and interviews. One resident who had difficulty communicating became frustrated and started threatening the nurse administering the medications. The nurse looked understandably shaken and asked for a carer to calm the resident down:

“Umm, especially when they don’t know you, when they are...they don’t get used to you, like you know, you have been working with them, that’s the main problem for me, that’s why I always rely on the carers to help me. But if they know me and I always try to explain myself and you have to be very patient with them, it's very challenging behaviour sometimes. But I don't feel, I just feel that the main problem is when they don’t know you.” N2, female, 26 years (CHIN)

The challenging behaviour and attitude was found to be unpredictable. Staff found it difficult to foresee how the resident will behave:

“Umm, depends on them on the day really. Umm, sometimes it can be hard and challenging, but then other days they will just take it, which is quite nice” C5, female, 30 years (CHBR)

The responsibility of administering medications may be more than what some carers imagined it would be when they applied for the role. The implications of medication errors may overwhelm some staff, which may lead them to avoid administering medications and prefer other carer duties. This demonstrates the burden of this aspect of the caring role.

“So, when they sign up to do care work they didn’t envisage the responsibility of doing, administering medication, because it is quite plain to them when they sign the legal document the effects it could have if someone is overdosed, or you give the wrong medication, and it’s not just the physical effects of it, we fill out forms for CQC if someone does that. And then they have the stress and the worry of that” C1, male, 52 years (CHWR)

Training and competency also impacted care home staff when administering medications. The role and responsibilities of carers differed to nurses’; this can make them less confident about their abilities. They also felt that more was expected from
them as they had to administer medications alongside other carer duties. Carers also voiced how differences in qualifications in comparison with other HCPs made the role more difficult for them. The following carers were discussing this issue:

“And very difficult, if you’re doing medication and you’re a trained pharmacist it’s fine, if you’re medication and you’re a trained nurse, but our staff, although trained, they’re not actually nurses, they’re not doctors, they’re not, so some of them they’re, um, how do I say?” C1, male, 52 years (CHWR)

“They’re competent, but they’re also carers, so they’re also looking around to make sure that people are eating” C2, male, 55 years (CHWR)

“Yeah, so they’ve got that role, if you’re in hospital and you’re a nurse giving out medication you give out the medication. You’re not expected in the middle of you giving out medication to go and toilet somebody or to stop a fight between patients” C1, male, 52 years (CHWR)

That being said, nurses were also observed dealing with residents during the medication round when carers were unavailable. Like carers, nurses also find their role challenging.

It is evident how carers perceive their role in relation to other HCPs and how their qualifications and job title may not prepare them well for the challenges associated with medication administration. These misconceptions about the qualifications and job description could be rectified, and support and training provided to those who feel overwhelmed and ill-prepared for their role. Alleviating care home staff burden may enable them to remain in their position for longer, thereby maintaining staff levels and reducing staff turn-over.
6.4. How do interactions between staff and HCPs affect the medication use process?

Care home staff were generally satisfied with their relationship with the pharmacy team. The type of help they required varied greatly, from requesting more supplies to asking for advice about modifying medications. Staff may be more willing to ask for advice from the pharmacy if their experiences with them were positive and they feel supported by them:

“Yeah, he’s always there at a drop of a hat if we need him or we’re not sure. He comes and does inspections, he does, one of his staff does training with the staff and everything, he’s always there sort of he brings medication to us out of hours if we fax a prescription through, he’ll bring it in himself if he’s got no one to bring it in. he’s very good.” C4, female, 47 years (CHBR)

The importance of the role of the pharmacist within the care home and to the medication use process was also discussed:

“She has gradually gone through and reviewed all the residents within the home, obviously it’s an ongoing process because we have new admissions, umm, but she will look at, umm, all the medications that are prescribed, umm, if they’re still relevant, umm, if there’s any changes that can be made, umm so, I mean she has quite a big role, umm, within the home.” C3, male, 38 years (CHIM)

It was evident that staff relied heavily on the pharmacy and interacted with them frequently. The interactions were not always positive, which can make some staff disinclined to interact with the pharmacy. This may mean that pharmacists are not utilised for medicine information. Other participants would approach the pharmacist for help prior to the GP; this was attributed to trust, accessibility and a good relationship. Refusing or spitting out medications result in wastage, as well as issues for some staff when they try to order more medications to compensate. The pharmacy staff need to be aware of this and be more supportive when this occurs and provide extra doses when asked for.
Care homes that ensure that the multi-disciplinary team (MDT) has regular meetings that include care home staff may assist in making the medication use process easier for staff. This is through better and regular communication of concerns within the team to ensure issues are dealt with quickly and appropriately by including all the relevant HCPs’ opinions:

“So, it’s, it’s really, umm, helpful to have all of the MDTs in one place because otherwise you’re kind of pulling bits and phoning here and there and gathering information, umm, just to have, you know, the geriatric consultant, our local GP, HF of services for Ageing and Mental Health and, umm, C the pharmacist, umm, it’s, it’s very helpful to have, umm, these meetings because any concerns, sort of, come up, any changes, umm, you know, we can always, umm, put the relevant residents forward to, to discuss, umm, yeah it’s very helpful” C3, male, 38 years (CHIM)

These findings identify the contextual and organisational factors to be taken into account when addressing medication-related problems in this care setting. In addition, improving the communication and interactions between staff and other HCPs may assist in the relay of medication issues in a timely manner.

6.5. How do interactions between care home staff and residents affect medication use?

6.5.1. The relationship between care home staff and residents

The relationship between the staff and residents and its importance to the medication use process was observed. In the mixed care home, the carer observed was very kind to the residents, who were appreciative. He was attuned to how they took their medicines, which varied from resident to resident. This individualised approach of understanding the resident and being familiar with their preferences was observed with other staff as well. Familiarity is needed to understand how to approach residents individually and to also understand their behaviour and moods. Not having trust or familiarity may make the resident question the medications and make administering medications a long process:
“Very important, because they have to have trust in you with everything really, but especially with medication as well…No, if you don’t have that trust, they’ll probably refuse it more so therefore you’ll…that would make it long, the medication round longer, yeah if they didn’t have trust in you.” C5, female, 30 years (CHBR)

“Exactly, because if they don’t know you, the nurses who are come are not here regular staff, they find difficult than now what I am doing because I know them (the patients), some of them they’re (…) some of them we keep on going chatting as a friend in the room, so that’s helpful because of the relationship.” N3, male, 48 years (CHIN)

With dementia, residents may also value familiarity with their surroundings and staff members. Any changes in their normal routine or environment may make them agitated and affect the administration of medications:

“It’s important to have a routine with them, you know, and seeing the same, umm, faces that’s a very good point for them, you know, very important” N2, female, 26 years (CHIN)

A good relationship with residents also means that the staff know the residents well and know what to monitor for and when to refer them to the GP. In addition, it may help other HCPs to interact with the resident, especially those the resident is not familiar with:

“And it just helps everything run a bit, more smoothly, because you do, you do have, umm, you know, it’s the regular MDTs that are coming in but because they don’t come in all the time they haven’t built that close relationship with the residents so, it can be, you know, they become quite agitated and decline to see them” C3, male, 38 years (CHIM)

A positive relationship between staff and residents may make medication administration relatively easier. Furthermore, staff who are familiar with individual residents are in a better position to identify, monitor and report problems to HCPs, as well as liaise between HCPs and residents.
6.5.2. Approach when administering medications

Most residents with dementia in care homes may be at the moderate to severe stage of dementia, and their behaviour is a major contributing factor to the problems associated with medication administration. Residents in care homes may sometimes refuse medications. This may be attributed to their mood, the relationship with the person administering the medications, or their own beliefs. Residents may sometimes feel they have no need for medications as they can associate their transition into a care home with dying, while others consider medication useless. These perceptions and beliefs may cause them to refuse their medications:

“You know some of them they think they’ve been isolated and some of them they think they’re here already to die some of them say ‘why you give me the medication, I don’t need the medication now. Leave me alone’ yeah, so, that’s why going and come back again so it depends on the mood as well.” N3, male, 48 years (CHIN)

Sometimes, refusal of medications may relate to the resident’s preferences or their ability to swallow. Having a better understanding of how the resident feels about the medications may make the process easier on staff:

“Yeah probably they got problem with their throat, yeah, it could be…or the taste of medication sometimes, yeah, it depends, some of them as soon as they see tablets they’re feeling sick. Yes, yes as soon as you show them, yeah ‘these are your tablets’ they start feeling sick, so the medication in their mouth they start feeling sick” N3, male, 48 years (CHIN)

Behaviour and sleeping patterns may also affect when medications are given as staff have to return to administer the medications. This may mean doses are missed, especially if they need to be given at a certain time like antibiotics. Other implications include prolongation of the medication round, changing the scheduling times of other doses, and wastage when medications are disposed of when refused. This was observed in all the care homes. One example of one of the medications refused was Sinemet, which needs to be given at the same time each day. A constipation medication (Laxido) was also observed being prepared in a glass for administration, which was then placed in the resident’s locked medication cupboard when the resident refused it, to be administered at a later time. This highlights the issue of the
appropriateness of preparing liquid medications and keeping them for later administration:

“So you have to give like at 8 o’clock, 12 or 2 o’clock, then 4 o’clock, and to be honest you can’t give it at 8 o’clock and then 12 because the patient could refuse it or you know; it’s not, it’s not easy like that (…) really, so you have to, sometimes you have to count the hours, you know, this kind of things, to make it right.” N2, female, 26 years (CHIN)

Sometimes, gender may have an impact on residents’ behaviour when taking medications. Male residents were reported to be aggressive towards the female staff and tend to refuse medications from them.

Approach when administering medications may both elicit challenging behaviour as well as alleviates it as previously seen. If the resident is not familiar with the carer or nurse administering the medications, and the staff member does not establish rapport before administering medications, then the resident may become agitated, aggressive, and refuse medications:

“They get agitated, especially when they don’t know you, they don’t recognise your face. And you have to find a way to give it to them or just to come back and give it later. You have to adapt yourself to them, you know? And that’s the most difficult thing, sometimes when they get agitated and they don’t know you. You always ask for help with the permanent staff and….” N2, female, 26 years (CHIN)

Aspects of the medication use process may also affect the resident. The way medications are administered is an example, such as when carers or nurses have to wear gloves to administer a sublingual medication:

“And thinking you, we’re, we’re treating them like a leper. So it’s very hard, you know” C2, male, 55 years (CHWR)

Care home staff have to develop strategies to overcome challenging behaviour in the future. These strategies are individualised and include managing difficult residents, and communicating with them in a different way:
“Umm, behaviour, when they are not in a good mood, leave them for some time, I don’t dish out the medication then, I’ll go back to them, then make them, you know, I have a style of approaching people, I have my own style. So, mostly I, I didn’t get much trouble giving medications because I approach very, very in a better way. I just direct and I just know, I just talk to them, I greet them, I talk to them, ask them questions and then make them feel that there is somebody and then they feel something and I will ask them ‘is it ok to prepare your medication?’ then they will tell ‘yes’ I will do that.” NI, female, 55 years (CHIN)

“It’s very time consuming and also, they won’t open their mouth again afterwards so you have to find some other way, cracking a joke, making them laugh, so they open their mouth so you can actually see if they’ve got the tablet inside, so, hmm, there are difficulties…” C1, male, 52 years (CHWR)

Approach also relates with the residents’ abilities and cognitive decline, as well as preferences. Some residents preferred being approached from a certain side, which the staff have become aware of. It was observed how the staff changed the way they present the medications according to each resident; some would have all their medications tipped into their hands from the medication cup and taken all at once, while others preferred the medications to be lain out on the table in front of them for them to take one by one. One carer administered SODF on a spoon to make sure they are taken and overcome medications being dropped. Hence, staff have to ensure the residents are happy with each method and approach, and staff have to be attuned to each individual’s needs, likes and dislikes. This is complicated to determine and remember, but it may assist in making the medication use process continue smoothly.

The challenging behaviour may make it problematic for staff to manage residents, which was demonstrated through the administration of medications. It can also make it difficult to establish a rapport between them to ease medication administration. Familiarity and approach were essential to administering medications with minimal difficulties.
6.5.3. Respecting the resident’s autonomy

Care home staff respected the residents’ autonomy in simple yet effective ways. This was in the form of giving them a choice of drink or a spoon of food with the medications. Some staff would also provide the resident with a choice of whether or not they would like pain relief. Other ways care home staff endeavoured to respect the residents’ autonomy when administering medications was by offering to give medications at a later time. Providing some degree of independence makes the resident feel like they are making their own decisions, and may also make them more cooperative as they feel they are in control of that decision:

“She’ll do it one by one, we normally have water, orange or coffee lined up and she’ll choose which she takes it with. Whatever tablets she’ll think goes down easier with whatever liquid.” C4, female, 47 years (CHBR)

“You know, a spoon of jam do you wanna take that? So they still have the choice in that way” C2, male, 55 years (CHWR)

Safeguarding the residents’ autonomy and treating them with respect irrespective of their cognitive decline was important to staff:

“I think the one thing is you must always get the consent of them, you know, doesn’t matter, don’t take it for granted because they’ve got dementia doesn’t mean, there’s still a person inside that shell, there’s a person there” C2, male, 55 years (CHWR)

Care home staff can also have conflicting views on residents’ autonomy regarding medications. In one of the residential care homes, the staff would like to give the residents more autonomy with the medications, while the manager disagreed. Others felt that supervising the resident or putting the medications in their mouth felt forceful:

“They feel…it’s like you’re in…you’re not empowering them, you’re forcing them” C1, male, 52 years (CHWR)

Unfortunately, the consequence of ensuring that residents are not coerced is that medications are sometimes missed or not taken within their required time, such as Parkinson’s medications. Some residents may also refuse to eat, and that may mean
missing some doses. This may negatively affect the resident’s health and cause wastage of medications. Coaxing and encouraging patients was advocated by staff, but there are limits as staff did not want to force someone to take medications if they do not want them:

“So you still gotta treat them with dignity, and, and if they decline, fine, it’s ok at the moment and approach later, if they still decline, then you put decline, there’s no way you would force someone to take it, take medication or get angry with them. At the end of the day, that’s their decision” C2, male, 55 years (CHWR)

“Yes, they have to decide. And you have to encourage them to do it by themselves, to make them independent but you have to help them sometimes because they can’t manage by themselves and you have to let them because if not they are gonna get more agitated and they are gonna keep refusing medications and there is no point to keep asking that you come back ‘later’ or, you know sometimes some of the medications you have to give it at, like sinemet, it’s one of the important ones yeah?” N2, female, 26 years (CHIN)

“Yeah, sometimes they will tell that ‘I will take it, at my time’, ‘ok, it’s ok, when you are ready just let me know I will come’ so I’ll, if he’s able to take I can leave the medication with him, I trust, but not then I have to go again and again, ask ‘are you ready?’ ‘Yes’ then I will just dish out and give the medication” N1, female, 55 years (CHIN)

Another way of respecting their autonomy was by subtle supervision of medication taking. This was observed with one carer, who allowed residents to drink medications on their own. This provides the resident some semblance of independence with their medications and at the same time, the carer can still observe if they are taking the medications. There should be a balance between the resident’s autonomy and their capabilities. One nurse was observed leaving an inhaler with a resident to use, and later on asking her if she had used it.

Refusing necessary medications consistently may result in other measures being put in place. This occurred to one resident who was sectioned due to her refusal of a topical antibiotic cream which she required for a facial infection. She was deemed to lack capacity in accordance with the Mental Capacity Act by staff and her family. Another consequence of refusal of medications is covert administration of
medications. This means the resident has reached a stage where they lack the capacity to make their own decisions, are not involved in decision-making about their own health, and carers are unable to respect their autonomy:

“Umm, I think, umm, I think, that, you know, you have to consider individuals that don’t have the capacity, umm, to understand that, ah, when you are giving them the medication, but they are quite happy to, to, umm, to take it covertly. Umm, I think it’s, I think it’s important because otherwise someone’s wellbeing is going to deteriorate even further.” C3, male, 38 years (CHIM)

Findings demonstrate staff respect towards the PLWD’s autonomy. They exhibited this through their approach in administering medication to supervision of medication taking. Behaviour issues which may stem from decline in cognitive abilities and lack of capacity may result in the PLWD’s autonomy being overridden by covertly administering them their medications to ensure their health is maintained.

6.6. What factors associated with formulations and their use is problematic?

The choice of formulation was a major issue for care home staff, with many factors associated with it. These include the characteristics of the formulation, unsuitable formulations, individual preferences, swallowing ability, prescribing decisions and staff knowledge.

6.6.1. Characteristics of formulations

The characteristics of formulations, such as taste, size and consistency, may affect the acceptability of medicines. One resident was observed when the carer administered her iron syrup which she was unable to drink the whole amount at once. She was given the lactulose after in a measuring cup and she drank it after being coaxed. She gagged slightly when she was given tablets to swallow, which she spat in a tissue inconspicuously. The carer later said that this was not the first time she has done this. He explained she has problems because the Accrete D3 tablet is too big, the iron syrup is too sweet, and the memantine tablet is bitter. The GP was aware, but unfortunately nothing was done. This is an issue occurring at all the care homes:
“If they spit it, some of the residents will spit it out, because of the taste. And therefore you’re not sure how much has gone down, how much they’ve actually consumed or how much because you know (makes spitting sound) that’s it.” C2, male, 55 years (CHWR)

“Yeah, yeah, they do, thicker liquids they tend not to like” C1, male, 52 years (CHWR)

Size may also be an issue when medications are administered; even small SODF posed some problems. Small SODF were observed to be sometimes forgotten in the medicine cup or stuck on resident’s hands as they did not see them. Subsequently, some medications may be missed due to size if staff are not vigilant.

On the whole, staff considered capsules and liquids easier than tablets, but liquids should not always be considered the solution to SODF problems as they have their own set of challenges. Although liquids are preferred when residents have swallowing difficulties, they are considered more time-consuming to administer (when measuring out quantities) and care home staff have to make sure not to rush. In addition, some residents cannot drink large amounts at once and being fed from a medication spoon might mean administering an incorrect dose:

“But there is a problem when you measure it out and getting it into the figures in the spoon, so you leave some behind. Or a problem actually, if you like use a measuring cup and it’s like 20 mL of lactulose, you know some of our residents they can’t tilt their head back properly” C1, male, 52 years (CHWR)

Residents may also have beliefs and perceptions about liquid formulations that may affect their willingness to take their medications:

“It depends on the resident as well because the lady I give the medications said the tablets are too big, she was on a liquid medication but she thought her self, liquid medication make her loose stool so whenever she sees any liquid medication she won’t take it. So she skip for 3 days and then we requested the GP to change the medication. Now when we give tablets she’s quite happy.” N3, male, 48 years (CHIN)
Dispersible and effervescent formulations may also pose some problems. In a residential care home, a carer was observed preparing a soluble paracetamol formulation in a glass of water, which turned murky white as she was mixing it. The medication did not appear completely dissolved before the carer administered it. The resident was observed having difficulty drinking it due to its taste, and she could not finish it. The issues that arise here were inability to completely drink medication due to taste and the risk of medicines not dispersing fully before being administered.

The type of formulation and hence route of administration may cause some formulations to be seen as difficult to administer, like pessaries, suppositories and enemas. Explaining to the resident what they are doing and why can help with administration:

“Suppositories I think it is a bit difficult to give to them, yeah so, it is difficult, and very rare we are giving suppositories as well.” N1, female, 55 years (CHIN)

“Like enema? Sometimes yeah we do. Umm, but we don’t find any problems at all. Ok they can refuse first but after that we explain and we come back later, as you saw this morning, it’s the same.” N2, female, 26 years (CHIN)

Even with injections, staff have to explain what they are doing and why to reassure the residents. In one case that was observed, the nurse needed a carer to help her hold a resident with dementia while she was giving an insulin injection. This shows that unlike older people, residents with dementia may get scared and not understand why they need an injection. Other formulations, like sublingual ones, were also seen as difficult to administer to residents as they might distress them:

“There was some you got to put underneath their tongue for them to do it, again but for someone who’s got dementia, we mustn’t touch it, you put a glove on your hand, and again the resident will react to the glove” C2, male, 55 years (CHWR)

Inhalers were observed as difficult to administer to residents in all care homes. Different reasons were attributed to this difficulty. One carer said some residents have trouble as they are unable to coordinate their breathing with dose actuation and sometimes cannot understand the complicated instructions. In addition, some find it
difficult to take a deep breath in the morning. Not all care homes used spacer devices to help residents; the residential care homes were not observed using them at all. The reason behind the decision to not use spacer devices is because they were seen as not always appropriate in residents with dementia:

“Yes we have, she has, but whenever you give with that she says ‘no!’ … Yeah, yeah she thinks that, I don’t know, maybe she thinks you will strangle her” N3, male, 48 years (CHIN)

“Umm, inhalers, yes, because due to the level of dementia that the, they don’t understand that you have to actually inhale (inhales) deeply, and so a lot of inhalers, such as the Ventolin, they don’t get the full use, even with a Volumatic” C1, male, 52 years (CHWR)

Even residents who agreed to use a spacer device were still observed using an incorrect technique, and they had difficulties breathing in. Care home staff acknowledged that they did not think residents were getting the clinical effect from inhalers. This emphasises that there is an issue with the respiratory route and its inappropriateness in residents with dementia:

“I think the inhalers don’t work for them at all, that’s my point of view. I think it’s a waste of time and waste of money sometimes to give it to them. Even if you help them, you know, they don’t, they don’t control their breathing sometimes, most of the time really.” N2, female, 26 years (CHIN)

Inability to use inhalers properly may affect the residents’ health. This was observed in one resident at a residential care home. She was unresponsive, had swallowing difficulties, and had little control over her motor abilities. After observing how her inhalers were administered, it was not surprising that she had an asthma exacerbation that morning.

Patches and topical treatments were easy to administer and residents rarely refuse them, and were often easier to administer than oral formulations:

“I find patches are, umm, are more reliable, especially if you, especially if you have someone that, um, has swallowing difficulties, it’s another route to actually, you know, umm, to administer an analgesia, if that’s what the patch is” C3, male, 38 years (CHIM)
6.6.2. Unavailability of appropriate formulations

Sometimes, residents have to continue swallowing certain formulations as an alternative one is not available to be prescribed by the GP. A suitable formulation is either currently unavailable at the pharmacy or unavailable on the market. This means that staff have no choice but to administer medications unsafely and ineffectively. One of the medications, Accrete D3, is a large tablet that many residents are prescribed. It causes a lot of issues with swallowing, and no alternative is prescribed:

“We, yeah, but…sometimes we find difficult, say ‘currently we don’t have this’, if you ask the chemist they say ‘currently we don’t have this’ so we have to keep going with the same medication.” N3, male, 48 years (CHIN)

Unavailability of appropriate formulations may also result in modifying medications. Staff have to sometimes break tablets to get smaller doses or modify capsules for ease of swallowing or addition to food. These modifications may sometimes cause fragmentation of the SODF resulting in loss of medication, and/or the patients refusing them because the medication appears unfamiliar.

Refusal of medication may result in covert administration, as mentioned previously. The medications can be put on a spoon of food to make it easier on the resident to swallow. This can be porridge when it is breakfast time or baked beans when it is lunch time, or sometimes yoghurt. Porridge was seen as the most convenient and easiest to swallow with medications. Efficacy of the medications may be compromised when mixed with food, for example mixing with hot baked beans. The high temperature may alter the medication’s release profile and bioavailability. Another inappropriate modification was cutting a vitamin capsule with a knife and adding it to a resident’s food; the accuracy of the dose may be compromised. The nurse was advised to do this as an interim solution while waiting for a liquid formulation to be available.
Modifying medications may sometimes result in the taste of the SODF changing, as the coating masking the taste is compromised. At one care home, they were advised to add sugar to modified medication to make the crushed medication palatable to the resident:

“They give you a second opinion and then if you can refer to the SALT or we’ll change the medication, crush them or do another, anything for example we give with a, mix up with a juice sometimes, yeah, 2 filled spoons. Another resident on the first floor, if you have seen him, all his medication we crush and put in a liquid then add sugar with a drink” N3, male, 48 years (CHIN)

A switch in formulation may be warranted with challenging behaviour, but it may not always be done appropriately. One resident was known to be agitated when medications are administered, especially SODF; her medications were switched to liquid formulations but the carer was observed mixing all 3 of her liquid formulations together in one medicine cup before administering it to her. This was to ensure all 3 medications were taken.

6.6.3. Individualised preferences

The residents’ preferences for medications need to be taken into account by care home staff. The degree of cognitive decline may not always relate to this as it is rather more related to individualised choice. Overcoming problems swallowing one formulation does not necessarily mean that the resident will be willing to take the alternative formulation. Understanding these preferences may make the medication use process more efficient:

“And we don’t, we don’t find any…there’s no overall prob, really, that you find that, you know, it’s hard with liquids, or we can turn all medications into liquids, it’s easier, or, it just depends on the individual.” C1, male, 52 years (CHWR)

“Yes and no (laughs) I’d say some could do with liquid form to help them if they have that swallowing, but then it depends like on that person, they could throw that at you (laughs) which they do. Or some, really some prefer capsules more than tablets, because I said the coating on the tablets sometimes they find it a bit gritty to swallow.” C5, female, 30 years (CHBR)
Although some residents did not like liquids, as seen in the previous section, others found them preferable due to their sweet taste. Sometimes medications are modified based on the residents’ preferences. One case was a resident who would not open her mouth to eat or take medications. Care home staff have to improvise and modify medications in a way that was acceptable for her:

“Crush them, put in a little bit of water, yeah, or juice, or milk, she likes more sweet drinks. Yes we do, yeah we crush or put in a liquid or juice or, normally juice or milk sometimes.” N3, male, 48 years (CHIN)

6.6.4. Swallowing ability

An observation at all care homes was that residents struggled with swallowing SODF, but were not considered as having swallowing difficulties. This may be linked to care home staff perceptions as to what constitutes as a swallowing difficulty. One carer said that as long as residents are eating their food, that means they have no difficulties swallowing. It may not always be the case as some people can swallow solid foods but still have difficulties with tablets and capsules. One resident was observed having trouble eating yet she was still prescribed SODF. It was evident she was having difficulties swallowing and there is a risk of her choking or aspirating. The carer tried making it easier for her to swallow by spoon-feeding a drink, then switching to yoghurt when the water was not helpful.

Chewing SODF before swallowing was common in all the care homes. Care home staff think some residents find it easier to chew before swallowing and so do not always tell them not to. This practice of chewing may have negative implications on certain medications that are meant to stay intact, such as modified release formulations:

“No, they spit the capsule out and swallow the middle” C4, female, 47 years (CHBR)

“They chew the tablet, if they’re finding it hard they’ll just start chewing on the tablets themselves as well.” C5, female, 30 years (CHBR)
Difficulties swallowing may result in medication modification, a switch to an easier formulation to swallow, or a review of the medication to stop it. In some cases, medication doses are skipped due to inability to swallow and the lengthy process of ordering an alternative formulation:

“Yeah it’s…it’s just like you…you give someone medication and they say she can’t, she find difficult to swallow. Yeah it’s a step back because you need to skip their medications, speak to the GP, yeah, GP says that you need SALT speech and language therapist to review, yes, so some of the days medication we have to skip” N3, male, 48 years (CHIN)

6.6.5. Perceptions on prescribing decisions

Care home staff sometimes request certain medications, but they do not always receive the required formulation. Perceptions from participants demonstrated how cost can dictate which formulation is prescribed. This highlights that sometimes an appropriate formulation is available but is thought too expensive to prescribe, and therefore staff are advised to keep administering the SODF or modifying it:

“Umm, you know because those ones having PEG, we don’t have much PEG feeding. Some of the medications come in liquid form, some is not. I’m not quite sure, in my opinion sometimes liquid form, some of the medications in liquid form is very, very costly so some of the GPs doesn’t (sic) write, so, for example if 1 tablet costs £1 or 50p, that liquid form makes it maybe £50. So sometimes it is not prescribed” N1, female, 55 years (CHIN)

Others found the GP more understanding and would prescribe the more expensive formulation for the residents’ wellbeing. This shows that some GPs put the residents’ preferences above the cost of medications:

“And doctors very good here, if you say, sometimes doctors prescribe a cheaper version and you say well the client doesn’t respond to this, or doesn’t like taking it because the taste is different or the texture, then the doctor would take that into consideration and change, hmm, and give, you know, prescribe the more expensive one.” C1, male, 52 years (CHWR)
The findings identify the factors affecting choice of formulations in care homes and how they may be problematic. Choosing a suitable formulation that meets the residents’ preferences and abilities is imperative to ensure medications are taken as prescribed. Physical barriers, such as swallowing ability, eye sight and manual dexterity may pose problems with medication use and dictate a change to a suitable formulation. Formulations can also be switched according to residents’ preferences and behaviour. Inappropriate formulations have negative implications through unsuitable modifications which may affect the efficacy of the medication. In addition, prescribing decisions seem to reflect medication price rather than optimising medication use.

6.6.6. Staff knowledge

The lack of knowledge concerning certain aspects of medication use and the questionable strategies utilised by some participants highlight areas requiring further education and training. It was observed that not all staff members were up to competent levels, with one carer asking during the round advice about administering an inhaler. Change in medications, such as interchangeability between brand and generic, may cause confusion to some staff when they receive the medications from the pharmacy. This shows a lack of knowledge on medication interchangeability:

“Yes, all we do is phone the chemist up. Sometimes they do change colour in the cassette or whatever and we say, or we send the cassette back to the pharmacy and say ‘it’s the wrong pill’ and they say ‘no it’s not’” C4, female, 47 years (CHBR)

Regarding medication modification, although staff have weighed the benefits with the risks, the questionable methods they employ might affect medication effectiveness and/or cause adverse effects. One carer was observed mixing three different liquid medications to administer. When she was interviewed afterwards and asked about medication modification, she did not mention this. So staff may not be aware that this is a form of modification and the legal and clinical implications involved.
Staff have to monitor residents when giving medications and identify any problems that the residents have. This assists them in recognising issues with certain formulations, such as inability to swallow or disliking taste. They can then request another more suitable formulation from the GP:

“But we, we, in a week, we noticed most of our residents wasn’t able to take it or chew it and find that it was spat out somewhere else, so again, approach the doctor, and now we’re back on the Adecal dissolvable now.” C2, male, 55 years (CHWR)

When care home staff were asked if they thought residents who chewed medications might have swallowing difficulties, they were unsure. This uncertainty may indicate that care home staff need training on how to identify patients with swallowing problems and report them for assessment.

6.7. Suggested recommendations by participants

Care home staff reported their suggestions for improvements to support a better medication use process. Improving the communication triangle between the care home, GP, and pharmacy was seen as crucial to make the medication use process run smoothly:

“I don’t know in which way they can do that, they can improve that but, umm, I feel like sometimes it’s very, umm, weird to deal with them sometimes, you know? But, umm, yeah that’s, I think that it will be better, the communication between surgery, chemist and nursing home.” N2, female, 26 years (CHIN)

Increasing the pharmacist’s role within the care home and involving them in more activities was also seen as beneficial. One residential care home previously had a pharmacist come with every GP visit, which staff valued. Increasing staff levels was encouraged by the majority of participants. Some care homes rely on agency staff to make up for low staff levels. This may not always be a solution as PLWD are not familiar with them and may be less willing to accept medications from them.
Simple measures may be taken to make the round less stressful on staff and to ensure it is efficient. Suggestions included making the management of the round more flexible to enable staff to adapt the round according to residents’ behaviour and preferences. Some care home staff developed a strategy; they start the round with the PLWD that take their medications without issues, and end it with those who need guidance or time. Leaving patients with swallowing difficulties or those who require more time to the end of the round may make the logistics more efficient. In addition, it may cause staff to be less anxious and allow them to take their time with the patients that require attention:

“Yeah so you can spend more time with’em as well and you’re not thinking ‘oh I gotta do that person next’ you know you can sit there and are like ‘it’s ok, that’s done, I can do this now, I can take time with you’.” C5, female, 30 years (CHBR)

More staff, specifically staff trained in medication administration was advocated by participants. Furthermore, the training of more staff may also alleviate some of the burden to ensure the ratio of staff to residents is balanced:

“Yeah, so if you, if someone’s upstairs, and that person is already trained and qualified then that person can say ‘do you know what, you’re dealing with that person who has been challenging, I’ll take that up for you’ you know that, minor very minor things.” C5, female, 30 years (CHBR)

Staff also suggested medication reviews to reassess the need for medications or change to an easily administered and/or acceptable formulation. This is to optimise medication use and make the process easier on staff members administering medications. The availability of essential medications, such as antibiotics and pain relievers, in liquid form was also suggested:

“Sometimes even those who have little bit of memory they will tell that this doesn’t make any sense. So...in that case I should say that we have to have a review of the medications and just minimise the medications, number of medications which they are getting here.” N1, female, 55 years (CHIN)
Some staff would resort to asking another member of staff to administer the medications when they know that the resident would get agitated with them. This was observed in one of the residential care homes and enabled the carer to continue administering other residents’ medications on time. This may also have lowered her stress associated with that specific PLWD:

“But if there is, say myself or another senior on duty, I may ask them to give it because that person might be better with them than they would be with me, just to try to encourage.” C5, female, 30 years (CHBR)

Recommendations by participants all aim to optimise the medication use in care homes through individualised care, effective communication, flexible logistics, and increasing trained staff levels. The findings have enabled the identifications of 6 areas concerning medication use in care homes; these are summarised in Figure 6.1 with their implications on medication use.
**Figure 6.1:** Conceptual model on areas requiring improvement to optimise medication use in care homes

The following chapter (Chapter 7) examines medication use along dementia progression and across care settings. It aims to identify the effects of cognitive decline on medication use, and to inform solutions to address the challenges encountered with progression of dementia.
Chapter 7: Impact of progression of dementia on medication use

7.1. Introduction

The progression of dementia is variable; there is day-to-day variation and no two individuals may go through the same sequence of changes. However, acknowledging these changes and identifying them along the trajectory of dementia may be valuable. This assists in suggesting possible approaches to address these changes and to support caregivers and PLWD accordingly:

“Because one thing doesn’t fit all if you know what I mean?... so there might be somebody that will take them (tablets) and have them with their breakfast with no problem at all, and then you’ll get someone like my husband who if he doesn’t want it at that moment, but I still insist on him taking the tablet”

Caregiver 1, 74 years, Hackney

This chapter reviews all the findings to explore medication use in the context of progression of dementia and implications for caregivers and PLWD. This will assist in informing recommendations to optimise the medication use process along the dementia trajectory in both the community and care home setting, to alleviate caregivers’ burden associated with medication management and administration. Three sources of data were utilised. The interviews with family caregivers and PLWD in the community included discussions about changes they had experienced along the dementia trajectory. The follow-up interviews with family caregivers in the community included questions concerning changes in medication use since the first interview. The third source of data is a comparison of issues between the community and care home settings; this enabled identification of changes to medication use across dementia severities as well as in relation to care setting. The analysis of these findings in this manner fulfils the research objectives by answering the following questions:

- What are the factors contributing to medication use changes as dementia progresses?
- How does family caregiver burden relating to medication use change along dementia progression?
- How does the PLWD’s autonomy impact medication use as dementia progresses?
- What are the factors associated with transition in care from self to caregiver-led?
- How do support needs of family caregivers change?
- Which medication-related issues are care-setting specific?

### 7.2. What are the factors contributing to medication use changes as dementia progresses?

The PLWD’s decline in cognition is a major contributing factor to the challenges associated with the medication use process. The development of dementia not only impacts cognition, but also affects daily activities and communication. A number of medication-related issues occur along dementia progression that affect the medication use process directly. These include an increase in the number and variety of medications, the development of swallowing difficulties, the unsuitability of certain formulations, and how the decline in cognition and capabilities affect the management and administration of medications. Understanding these changes, anticipating them and addressing them with suitable approaches may assist family caregivers in optimising medication use and avoiding future challenges.

#### 7.2.1. Increase in number and variety of medications

The number of medications may increase as the PLWD gets older and dementia progresses. Medication regimens may also become more complex. This was observed with PLWD in care homes who were taking a variety of formulations. The number of medications may influence the medication process, as well as increasing the medication round in care homes and affecting the administration time of other medications. Having a large amount of medications, as well as a variety of formulations to administer throughout the day may be stressful for caregivers and PLWD. Caregivers also worry about the interactions of all these medications:

> “Sometimes you think it's too many tablets or something. It’s just not easy.”

*Caregiver 7, 74 years, Croydon*

The number of medications may also affect the willingness of the PLWD to take them. This was illustrated in one case where the PLWD’s donepezil dose was increased from 5mg to 10mg. He refused taking two 5mg tablets, but accepted the medication once it was supplied as one 10mg tablet. PLWD may have perceptions about the
number of tablets or capsules and may not understand that it is the same medication. This should be taken into consideration when adjusting doses of medications. The number of medications may also cause agitation and refusal of medications:

“So, and I get really lots of the medicine...then the carers are giving me, the carers giving me the medicine regularly, umm...the amount is regular, rather a lot of medicine.” PLWD 1, 74 years, Hackney

Administering multiple medications throughout the day may be seen as restricting for some caregivers. It can also cause worry; having multiple doses to administer and trying to keep sufficient time between each dose may be a struggle:

“What I find most difficult about medications is actually fitting them in, giving, sort of, a reasonable time between the tablets.” Caregiver 1, 74 years, Hackney

As dementia progresses, factors associated with the decline in cognition may make the number of medications more problematic for PLWD. PLWD may have perceptions concerning the amount and need for medications, which may consequently affect their willingness to take medications. Another issue is their inability to swallow a number of medications. The number of medications and dosing intervals should be considered by HCPs prescribing medications to PLWD to optimise administration. For example, ensuring that medications are fewer may also assist caregivers and PLWD in fitting the medications in their daily routine more effectively. Regular reviews to stop medications that are no longer needed may also be helpful to make the PLWD more willing to take their medications, thus maintaining their health.

7.2.2. Development of swallowing difficulties

Memory is not the only aspect affected with progression of dementia. The development of swallowing difficulties may become more common at the moderate to severe stage. This means that certain formulations become more problematic and it may be helpful to switch to more suitable formulations or resort to medication modification. When swallowing difficulties occur, many caregivers tend to resort to modifying medications to make it easier for the PLWD to swallow. This includes opening capsules, breaking tablets in half, and adding medications to food to assist
swallowing. These modifications are conducted without the required information from HCPs.

Another consequence of cognitive decline is that some PLWD may sometimes forget how to swallow and thus can choke on medications or not be able to swallow them at all. Swallowing difficulties may also cause PLWD to fear taking medications:

“Yeah, well we’ve, cuz of their age as well, generally in this sort of age group they might have problems swallowing as well. Even with dementia, you know, you can’t, you can’t remember, you know, they can choke.” C5, female, 30 years (CHBR)

Some PLWD do not have ‘swallowing difficulties’ per se, but have difficulties swallowing a large number of SODF and have to take time to swallow one by one, which was observed in all the care homes. Residents were observed hesitating before swallowing, gagging and coughing after swallowing, and were clearly exhausted in between swallowing, especially with more than four SODF:

“She has a bit, not swallowing problems, the one with a lot of tablets, it’s just sometimes she likes to take them slowly and she’s got a bad chest anyway” C4, female, 47 years (CHBR)

Swallowing ability was found to be variable and may not necessarily be clinical dysphagia. Caregivers had to recognise the factors involved in this process, such as the time of day or requiring more than one gulp when swallowing medications:

“You know if I ask him to take one gulp he can’t quite take that on board so he’ll take several gulps and usually I know if he does, well, 2 or 3 or a few gulps, then I know that usually the pill doesn’t go down with that. Sometimes it does, sometimes it doesn’t, it’s very variable” Caregiver 6, 72 years, Croydon

Ability to swallow large SODF also fluctuates, and may be frustrating to both the PLWD and their caregiver. They can show their frustration to the PLWD, not realising that the PLWD is genuinely unable to swallow. Helping caregivers become aware of the possibility of swallowing difficulties developing and the implications on medication use would be beneficial to alleviating frustration.
Some of the PLWD were chewing their medications before swallowing them, which was observed as well as discussed in interviews. This may be attributed to a number of reasons. It may be an early sign of swallowing difficulties; the PLWD decide to chew the SODF to ensure they can be easily swallowed. Another reason may be that with decline in cognition, PLWD may assume that they need to chew before swallowing:

“But whether she’s decided it would be easier by chewing them up, somewhere in her mind is saying ‘if I chew these up I’ll be able to swallow them’ umm, it may be that she’s reached a point where she’s beginning to find the swallowing a problem, but has decided for herself to chew them. Or it maybe she just just chews them absentmindedly, as an automatic process you put something in your mouth, you chew.” Caregiver, 57 years, Lambeth

Although the PLWD are chewing medications, their caregivers do not believe they are at a stage where they have developed swallowing difficulties. This is because the PLWD are still able to swallow food, so caregivers do not realise that swallowing difficulties can be gradual and may not necessarily translate to difficulties swallowing food. Chewing medications may also have negative implications. Some of the medications may be formulated to specifically degrade in the stomach or intestine, or are modified release. Chewing these formulations may mean that the medication’s efficacy is compromised (for instance treatment failure, affecting half-life of medication). Another concern is that PLWD may be unaware they are actually chewing their medications, which means they are unable to provide this information if asked. Caregivers need to be aware if the PLWD is chewing their medications to be able to relay this information to HCPs as some medications should not be chewed.

Some PLWD in the care homes have developed dysphagia due to progression in dementia. It was observed that even specially made formulations, such as thickened liquids to ease swallowing, were still problematic to administer and were difficult for the PLWD to swallow. This indicates that more suitable formulations are needed for PLWD with swallowing difficulties to ensure the effectiveness of treatment and lower the risk of choking and aspiration.

The findings have shown that PLWD may develop swallowing difficulties with progression of dementia, and these difficulties may progress to clinical dysphagia at the severe stage of dementia. There should be more awareness of the development of
these swallowing difficulties, which may occur at different time points. PLWD should be assessed accordingly by their GPs in the community and speech and language therapist in the care home setting as the findings have shown that better detection of these swallowing difficulties was needed. One possible indicator of swallowing difficulties exhibited by some participants was chewing before swallowing SODF. Caregivers were not aware of the implications of chewing medications on the medications themselves, or that they may indicate the PLWD is developing swallowing difficulties. Helping caregivers and PLWD understand that swallowing ability can fluctuate and may be a reason why some PLWD refuse medication would help in ameliorating any frustration associated with this. Furthermore, appropriate support and formulations tailored for ease of swallowing are also needed along progression of dementia to ensure treatment outcomes are achieved.

7.2.3. Unsuitable formulations

Choice of formulations and route of administration may also be affected by progression of dementia and thus require assessment of suitability. This is to ensure PLWD are receiving their treatment in a safe and effective manner. Some formulations may be considered inappropriate for use in PLWD, especially for those at an advanced stage of dementia where the route of administration may cause distress. One example is pessaries which were causing PLWD and staff distress, and were therefore stopped with no alternative prescribed, even though the PLWD may benefit from them:

"Now that we’re at a stage of her dementia where she may be thinks of herself as being in her childhood a lot of the time...a lot of her mind is like the mind of herself as a child and therefore somebody putting an oestrogen pessary into you is quite distressing, it would be very distressing for a child. ‘What are they doing to me?’ it’s like abuse, it feels like abuse if you don’t understand."

Caregiver, 57 years, Lambeth

Difficulties using inhalers were encountered at both care settings. This indicates the unsuitability of their use in PLWD, with or without help from caregivers. Spacer devices were not used by the community participants, and rarely used in PLWD in care homes due to their degree of cognitive decline. Some PLWD may fear a device covering their face. GPs and pharmacists should ensure that PLWD in both the community and care home settings are effectively using inhalers to be able to achieve
clinical effectiveness. There were other examples of inappropriate formulations that the PLWD in both care settings were unable to use. This indicates the unsuitable prescribing decisions that may not be taking into account the PLWD’s preferences and ability, nor the caregiver’s ability to administer them. To ensure treatment outcomes are achieved, HCPs in both the community and care home setting could assess the appropriateness of these formulations by asking the PLWD and their caregivers about their ease of use.

Some SODF may be seen as too big to swallow and a switch to another formulation is common. It may be easier to spoon liquid formulations, but the quantity and taste should be taken into consideration. Some quantities may be too large for PLWD to tilt their heads to swallow and therefore they may not receive the full dose. Administering medication with a spoon of food was seen as acceptable by both caregivers and PLWD; the appropriateness of this method should be assessed as it may affect medication efficacy.

Route of administration of certain medications cannot be changed, such as inhalers and pessaries. Alternative formulations with different routes are not available, but this means that PLWD are not taking the medication correctly and thereby not receiving the full clinical effect. Modifying medications was done not only for ease of swallowing, but also to achieve the right dose. This points to a lack of appropriate formulations and flexibility of doses. Inappropriate formulations impact the PLWD and the caregiver, as the PLWD may not be able to take the medication and the caregiver becomes stressed about modifying the medication correctly to administer it.

There needs to be more awareness of the impact of dementia progression on formulation type and route of administration to ensure that the most appropriate formulations are prescribed to PLWD along the progression of dementia. Furthermore, the pharmaceutical industry is endeavouring to develop dementia-appropriate medications that are safe and suitable to take as dementia progresses. Assessments during medication reviews can easily incorporate questions to assess the suitability of formulations and whether a switch in formulations is warranted; this assists in optimising medication use and ensures that treatment outcomes are achievable as the PLWD is able to take the medications as prescribed.
7.2.4. Decline in cognition and communication

Progression of dementia and the associated decline in certain capabilities may also affect medication management and administration. This manifests as a decline in language and communication abilities which consequently may result in a decreased ability to verbalise pain and need for medication, and to communicate side effects. This decline poses challenges during medication administration, which in turn may increase caregiver concern as they are unsure when to start or stop a medication:

“All way I started on the tablets yesterday, one a day, but I was reading the leaflet this morning, quite, quite worrying. And what is very worrying is that in cases like (her husband) he wouldn’t be able to say to me ‘oh I’ve got ringing in my ear’ or ‘I’ve got bad stomach ache’ or ‘I’m feeling dizzy’. People with dementia wouldn’t be able to tell you that.” Caregiver 1, 74 years, Hackney

This decline in speech and language also affects how medications are given in care homes as staff may find it confusing not knowing if the PLWD is willing to take the medication:

“Some of them no means yes and when they say yes means they say no, ‘I said I told you no!’ I say ‘no you told me yes, you’re ready to take’ they say ‘no’. So it’s very challenging but we keep going, we try to make them...more comfortable and happy.” N3, male, 48 years (CHIN)

PLWD may also have problems voicing concerns. When administering medications to PLWD at this stage, it may feel like they are being coerced. PLWD may then resort to displaying agitated behaviour or in extreme cases aggression. This may be frustrating for them, and staff need to try and recognise issues and reassure the PLWD:

“It must be terrible, lots of them are not able to voice properly what it is, but, um, someone told me they don’t like it because they felt like choking when you give medicines so they need reassurance” C1, male, 52 years (CHWR)
Observations of PLWD in residential care homes demonstrated that many are either unresponsive or have difficulties communicating. Staff who assume PLWD are able to communicate effectively need to be vigilant when administering medications:

“We’re a residential unit, umm, most of our residents are able to verbally express their needs, umm, but again that can change sometimes” C3, male, 38 years (CHIM)

With decline in cognition, there may also be a decline in understanding and recall. Some PLWD may have difficulties recalling events and rely on their caregivers to provide this information, such as which medications caused them side effects. This indicates the need to obtain the perspectives of both the PLWD and their caregiver to ensure all the necessary information is gathered by HCPs and that any issues are addressed accordingly.

PLWD may reach a stage where they completely forget how to take medications, not just how to swallow them. This may also affect the family caregiver as it also means an increase in their responsibilities. In addition, staff in care homes need to explain and demonstrate how to use medications, such as inhalers. This unfortunately does not always guarantee that medications are used correctly:

“They're not getting any use out of them...because they do not understand the concept that they have to breathe in” C1, male, 52 years (CHWR)

How medications are managed and scheduled may need to change as dementia progresses. Although MCAs may sometimes be seen as a solution for someone with dementia to retain their ability to manage their medications at the early stages, it may not necessarily be beneficial for all PLWD as at a certain point they may become impractical. The assumption that blister packs will be easier for PLWD to distinguish and remember their medications should therefore be made with caution:

“Before you see I don’t have to give her medication, she go buy medication by herself. But now if I tell her that (pointing at blister pack) she couldn’t tell what’s [with] lunch, what’s you know, she can’t! I have to supply her, I have to give her” Caregiver 3, 87 years, Croydon
Reading abilities may also decline with dementia, as seen with some of the participants. This may lead the caregiver to update their method of managing and administering the medications. An example was one caregiver who left her husband notes to take his medications; this method has since changed with his dementia progression and she has to now physically give him his medications.

Some PLWD have difficulties recognising medications, both the formulations and packaging. This was illustrated by one PLWD who was completely confused when her medications were removed from their places and placed in front of her. This is complicated further if the packaging changes. PLWD may also forget medication names. This may occur at any stage of dementia; one PLWD was in the mild stage but was already starting to forget the names of his tablets. This shows the importance of consistency of the shape and colour of medications so that they are familiar to PLWD:

“When I was doing this myself I did have trouble, umm, taking the, umm, the whatever, I forget the name of it, the one I was taking at night.” PLWD 2, 82 years, Hackney

“I don’t know what galantamine is, just a few nice words” PLWD 4, 81 years, Croydon

Approach with medication administration and the language used also changes with dementia progression. A few of the caregivers equated it to how one would talk to a child, without being patronising. This was also observed in the care home setting, in the tone and way staff spoke to PLWD when administering medications.

As dementia progresses, some PLWD may need to be in a familiar or quiet environment to be able to take their medications. This was seen in PLWD who were at the severe stage:

“I mean, sometimes he can manage that, more easily at 10 in the evening but, umm, it’s probably always better to just turn off the television and make sure the radio’s off and try not to do it when there’s lots of people around, I mean we need to be quiet so that he can concentrate.” Caregiver 6, 72 years, Croydon
This shows that environment may be an essential aspect of medication use in some PLWD and should be taken into consideration, which is sometimes difficult if people are not at home and there are distractions around. Caregivers have to plan how and when to give medications when they are out. This may mean medications are sometimes not given on time, or in a place the PLWD is unfamiliar with. This was also voiced by a PLWD, who stated that it was difficult having medications when they go abroad.

Small changes, like going away on holiday, may also cause the PLWD some confusion and it may be difficult for them to return to their normal medication routine. Caregivers need to ensure that the PLWD is comfortable with the routine and are able to take the medications:

“We went to Trinidad for my nephew’s wedding, that’s my mum’s grandson. And when we came back she was a bit, umm, sort of disorientated. So I had to make sure that when she got up in the morning she looked at her note and had her tablet. But after about 2 weeks, she’s back into her normal routine now.”
Caregiver 1, 60 years, Croydon

7.2.5. Behaviour changes

Progression of dementia may also coincide with the development of behavioural changes and willingness to take medications. The PLWD may be affected in terms of behaviour and mood, which in turn may hinder the medication use process when medications are refused or missed completely. Behaviour fluctuations are specific to PLWD and complicate the administration of medications. The impact of behaviour was previously mentioned in Chapters 5 and 6.

The behaviour of some of the residents with dementia may have a negative impact on the logistics of the medication round. This in turn may increase care home staff burden. Care home staff have to then develop coping strategies:

“The client group is very challenging, they’re always calling out, they can argue and start confrontations with each other, and when we are trying to do the medication, that’s very difficult.” C1, male, 52 years (CHWR)
Challenging behaviour may sometimes relate to preferences to medications, and so an alternative formulation may be prescribed. In some cases, medications are not given at all which may impact the PLWDs’ health and wellbeing:

“Well like with Mrs W he’s written a letter saying if we can’t get her medication down, the GP’s aware of it so if we can’t, we can’t, there’s no more, nothing else they can really do” C4, female, 47 years (CHBR)

PLWD may also sometimes be sleeping or can doze off while medications are being given. Agitation and moving about may also make it difficult for the caregiver to administer the medications to the PLWD. This was observed when one caregiver was trying to administer her husband’s lactulose during the interview, and he kept dozing off. So a medication that should be given in less than a minute took around 5 minutes to administer. PLWD may sometimes refuse medications and spit them out if they do not like them, or hide them in their mouth.

“And I know, as I said, that I’ve had problems with her giving her tablets which she then put down the sides of her mouth and kept them there until tooth brushing time and then spat them out.” Caregiver, 57 years, Lambeth

Another reason for refusing medications may relate to the trust between the PLWD and the person administering the medications and their approach:

“Umm, I don’t refuse, but I check and I…I don’t take it by chance, I don’t take it by chance” PLWD 1, 74 years, Hackney

Behaviour may fluctuate from day to day, which may affect the PLWD’s ability or willingness to take medications. This unpredictability may be challenging for the caregiver:

“And it just depends on his mood really, because sometimes I’ll get him to put the pill on his tongue and then take one gulp. And somehow or another, sometimes he spits the pills out, or he shoves it into a part of his mouth where when he takes a drink it doesn’t go down. And then it has to come out.” Caregiver 6, 72 years, Croydon
The previous sections have shown what changes occur to the medication use process as dementia progresses. These changes may also affect the caregiver by increasing their responsibilities and their associated burden, and may cause them to compromise the PLWD’s autonomy. Decline in cognition and its consequence of inability to manage medications should not be universally assumed, as some PLWD may still retain this ability and therefore may be included in the medication use process. Some aspects cannot be modified, such as decline in recall and understanding and swallowing abilities. However, measures may be taken to alleviate their impact on medication use, such as prescribing suitable formulations for ease of swallowing and assessing suitability as dementia progresses. Strategies may be developed to help with behaviour issues. Identifying the root of this issue, such as preferences for medications or time of day, may assist in optimising medication use.

7.3. How does family caregiver burden relating to medication use change with dementia progression?

As the PLWD’s cognition and capabilities decline, more responsibilities are gradually assumed by the family caregiver, which may in turn increase their burden. Their burden is intensified through an increase in their medication-related responsibilities, such as managing and physically administering medications. Their burden is also affected by their expectations for the future regarding the PLWD’s decline in cognition and concern about meeting future medication needs.

Caregivers who work may reach a point along the progression of dementia where they decide to retire to be able to fully take on the caring role:

“I mean it’s much easier now because I’ve just retired but when I was at work I would have that anxiety, has the medication been taken.” Caregiver 1, 60 years, Croydon

Caregivers may also have expectations about the PLWD’s health state and decline in cognition and what it will mean, such as inability to swallow food and medications, or changes in their behaviour affecting medication use. Caregivers also worry about any new medications in the future that might be added and how the PLWD will respond to the increase in their therapy:
“Yeah, at the moment he’s not at that stage, you know, at the moment he just happily just takes them when I give them to him. But I should think further down the line that could be a problem if he needs to swallow them.” Caregiver 8, 70 years, Croydon

For some caregivers and PLWD, minimal changes may occur to medications and the caregiver’s role within the medication use process along the progression of dementia. Nevertheless, both the PLWD and their family caregiver are getting older, which may make their role more difficult to manage. This should be taken into account by HCPs who may assume caregivers are able to cope based on their previous ability, to be able to provide appropriate support:

“I think whether it’s just me getting older and more crotchety (laughs) or whether illness is developing and I think things are, it’s not medication that’s becoming more difficult but I think life generally is.” Caregiver 5, 89 years, Croydon

Expectations of the future and what it may bring may make some caregivers anxious. This was expressed by all caregivers in one way or another. This is more so for spouses who are elderly themselves. They become aware of what their caregiving role entails, and fear for the future:

“I’m happy with that to supply as I’m here. But my concern is if I can’t, who’s going to do that? That is worries for me you see? If I can’t, I can’t predict my situation you see?” Caregiver 3, 87 years, Croydon

As a consequence of that fear, some caregivers may take extra time to make sure charts or notes are prepared and medications are easily found, to make it easier for whoever takes over their caregiving role. Caregivers have to also think about evolving their ways of managing medications as they themselves are getting older and require assistance.

Anxiety about future changes in medication use due to progression of dementia may cause caregivers stress and decline of health, as seen in some participants. Deterioration in the caregiver’s health may mean they cannot effectively take care of the PLWD, and may decide to hire a paid carer or move the PLWD to a care home. HCPs should endeavour to take care of the caregiver’s health alongside the PLWD’s.
Furthermore, alleviating caregiver burden may have a positive effect on the caregiver’s health and they may be able to take care of the PLWD for longer at home.

Acknowledging that caregiver burden may change along dementia progression is the first step to understanding how to alleviate this burden. Furthermore, understanding what caregivers’ experience assists in providing them with tailored support. Suggested solutions are provided at the end of this chapter that may help support caregivers along the progression of dementia to alleviate their burden and prepare them for future changes.

7.4. How does the PLWD’s autonomy impact medication use as dementia progresses?

The previous chapters (chapters 5 and 6) have recognised the importance of the PLWD’s autonomy within the medication use process in both the community and care home setting. With decline in cognition, some PLWD also experience deterioration in their capabilities, such as language and understanding as mentioned previously. This decline may have a negative effect on the PLWD’s autonomy, as in many cases there is a decrease in independence and a subsequent increase in reliance on the caregiver. This compromise in the PLWD’s autonomy affects how medications are managed and administered.

With progression of dementia, the medication-related activities and decision-making are gradually assumed by the caregiver. This places more pressure on the caregiver and may increase their burden, particularly when there is a decline in the PLWD’s ability to participate in decision-making. Decision-making is a complex process linked with the PLWD’s autonomy and wellbeing, and the caregivers’ knowledge and health literacy. Health literacy is defined in this context as knowledge and perceptions about medications and how that affects the decisions they make about medications. New medications or a change in medications may also complicate decision-making. The PLWD’s decline in cognition, communication and development of challenging behaviour also affect decision-making. Caregivers were seen struggling to balance between their knowledge and the decisions they have to make. Furthermore, caregivers think about optimal use of medications versus respecting the PLWD’s choice. Meeting information needs may mean decision-making becomes relatively easier on the caregiver and less burdensome.
Along the progression of dementia, some PLWD may gradually lose their ability to communicate effectively, as mentioned earlier. There needs to be better understanding of the PLWD’s preferences for medications to ensure that even when they reach a stage where they cannot voice their needs or issues, the caregiver is well aware of them to respect their autonomy. A suggestion would be to have an approved medication plan between the PLWD and their family caregiver before dementia progression. This information could be transferred from the community to the care home setting once the PLWD has transitioned to ensure their autonomy and preferences are maintained. Also with cognitive decline, some PLWD may also forget whether they have taken their medication and may wrongly believe they have taken it, which frustrates the caregiver.

PLWD who were at the moderate to severe stage required supervision when they were given their medication which compromises their autonomy in this context:

“And I always have to get him to put the pill on his tongue, hold it on the front of his tongue, take one gulp of liquid only, put his head back and encourage him to swallow it. Once or twice he’s spat the whole lot out.” Caregiver 6, 72 years, Croydon

The PLWD may accept the supervision, and this depends on the relationship between the PLWD and the caregiver which was elaborated on in previous chapters. Sometimes the supervision is not to make sure the PLWD takes the medication, but that they follow the complicated instructions, such as with inhalers or nasal sprays:

“Just an extra nuisance remembering and getting them and bringing them in here to have them. So I can watch you take them and tell you how to take them when I’ve read the instructions.” Caregiver 5, 89 years, Croydon

Practical problems with medication use and behaviour issues as seen in previous chapters may also evolve, which raise ethical concerns for caregivers. Some caregivers may have to adopt strategies to manage and administer medications in a way that still respects the PLWD’s autonomy. This can be through involving them in the organisation and scheduling of medications however minimally, and providing some control over the administration of medications.
PLWD in care homes also progress in their decline of cognition which may affect the medication use process. Decline in cognition may also mean the possible loss of their autonomy and their exclusion from decision-making. This was seen when PLWD were sectioned or were covertly administered their medications. In care homes, staff may take control of the medication use process, largely excluding the PLWD. The issue of autonomy in care homes is the control of medication use by staff versus the choice of PLWD. Caring for PLWD in the community setting for longer may mean their autonomy is respected. Supporting the caregiver effectively may assist in achieving this; this may be through meeting their informational needs and optimising medication use.

7.5. What are the factors associated with transition in care from self to caregiver-led?

Caregivers discussed situations and events that led them to decide a transition in care was needed. Examples include medications left in MCAs by PLWD and mixing their medications together. MCAs may be effective at the beginning when PLWD are still at the mild stage and this method enables them to maintain their autonomy while still taking their medications in a safe and effective manner. This stage in the transition raises a few issues in relation to medication use and safety. When PLWD transition from using OP to using MCAs, they may have residual medications which may lead to confusion and overdosing. In addition, in the transition from self to caregiver-led care, the caregivers have to be vigilant and notice the signs (such as loose tablets) because PLWD may not admit they are encountering problems.

Identifying what helps or hinders this transition in care may assist in optimally managing this transition for caregivers and PLWD in the community. A major contributing factor to this is when the caregiver has already taken on the medication role long before the development of dementia:

“I’m not sure there was a transition, I think I’ve always done tablets”

Caregiver 4, 74 years, Croydon

A shift where the spouse or daughter/son becomes the caregiver may not be taken well by all PLWD. This may be more so when the caregiver has not been taking care of medications before the PLWD developed dementia. Those dyads where the PLWD was used to having someone manage the medication process seemed to be more
adaptive and happy with the transition. Some PLWD may also require validation or confirmation from a HCP that they need assistance with their medications. Hence, including HCP in the process of transition may be helpful.

The family caregiver’s previous experience may also be a factor in the PLWD accepting assistance with medications. This was demonstrated with one caregiver who was a retired GP, as was her husband. This had an effect on her role as she was more knowledgeable about medications and knows where to go for information. This also made her mother trust her more as a caregiver:

“I don’t know the names of the medicines and I don’t know anything. it’s just given to me and I take them since I have the advantage that she’s a doctor and her husband’s a doctor and their daughter is now becoming a doctor so (laughs) I just, I say my god (laughs) whatever I have to take give it to me I’ll just take it (we both laugh).” PLWD 1, 89 years, Croydon

The PLWD’s autonomy is also a factor to be acknowledged in this transition. One way is involving the PLWD in the medication use process, or making them feel like they are involved even though in reality the caregiver is performing all the medication-related activities. When PLWD feel they have not been completely removed from the process, it may satisfy them hence make the transition much easier, even though there is only the appearance of their autonomy and involvement.

The PLWD’s acceptance of their cognitive decline and hence their need for help with their medications also assists in creating an easy transition in care. Family caregivers may be able to take advantage of the PLWD’s acceptance in managing the transition well:

“I think I started getting a bit forgetful, you know, sometimes I used to forget to take, say the afternoon one or something, occasionally. So then she thought best that she take over the responsibility of making sure that I take the medicines every day.” PLWD 1, 89 years, Croydon

For some caregivers and PLWD, though their transition seemed smooth, they nevertheless experienced a few challenges to begin with. Transition in care was difficult to adjust to, and evolved in order to establish the right routine and system with medications:
“Well, it was a bit difficult at first until I worked out a system because I just didn’t see how I could go to work and oversee everything but we just, sort of, just evolved to help us to cope, you know, making the sandwich in the morning, keeping it ready with the medication, keeping all the breakfast things laid out. So we just gradually evolved as a coping mechanism (she laughs)” Caregiver 1, 60 years, Croydon

Some caregivers had to develop strategies to help them with the transition through trial and error. One caregiver said she would have liked someone to have suggested useful strategies. This discussion may be helpful for future caregivers as it provides examples of strategies so that they can make informed decisions about managing the transition in care.

Providing a gradual transition in care where both the caregiver and PLWD share responsibilities according to their abilities may be beneficial for both, and may decrease burden and increase satisfaction. However, it is not possible in all cases as dyads may have unique circumstances, and dementia type and progression differs between PLWD.

7.6. How do support needs of family caregivers change?

Progression of dementia may indicate a change in support needs; identifying these changes and when they occur may assist in informing recommendations for interventions and support. Even though the initial diagnosis of dementia is challenging to adjust to, many of the participants did not express need for support. With the progression of dementia and worsening of symptoms, such as inability to communicate well and development of challenging behavior, caregivers felt overwhelmed and required more support:

“In the beginning I suppose I required less, sort of, support because my husband wasn’t, I mean it’s worsened plus the fact he’s been now diagnosed with cancer, umm, so yes it’s becoming more” Caregiver 1, 74 years, Hackney
Some caregivers were aware of support outlets, but felt they were not at the stage where they require it yet. This still means that caregivers need to be made aware of all medication-related support to anticipate their needs:

“Well, I mean at the moment I’m, I’ve been pretty good over the years and I haven’t actually as I say I know of these things which will set off an alarm at various points of the day, and I’m aware of that sort of stuff which is available from Alzheimer’s and diabetes UK. And there are things to help.” Caregiver 2, 73 years, Croydon

Progression of dementia may indicate a need for more support for some caregivers as their health deteriorates as they age:

“No, while my memory holds out, all’s well. But of course if that starts to go then we would need a lot more support.” Caregiver 6, 72 years, Croydon

It was evident from participants that no two people had similar experiences or used the same strategies to ease transition, medications management and administration. The same can be said about providing patient-centric care; it should be specific and tailored to each PLWD and caregiver to meet their needs. Interventions and support should acknowledge potential issues and respond flexibly:

“That’s life, no two people are the same, are they? We’re all different” Caregiver 5, 89 years, Croydon

7.7. Which medication-related issues are care-setting specific?

The previous results chapters have demonstrated the similarity of some of the factors affecting medication use at both care settings. These include the appropriateness of formulations and the difficulties encountered with the administration of medications. However, there were also medication-related needs and problems specific to either the community or care home setting.

PLWD in the care home setting were more likely to have developed swallowing difficulties due to their severity of dementia and higher pill burden. PLWD in the community had less swallowing difficulties and their ability to swallow was seen as fluctuating. Care homes have PLWD at a more severe stage than those in the
community, and less able to take their medications without difficulties. Furthermore, care homes may have speech and language therapists so it may be relatively easier to recognise and manage swallowing difficulties, whereas this awareness and support may be less accessible in the community setting. In addition, the prevalence of dysphagia and behaviour issues in care homes may mean that more medications are modified or switched to a liquid formulation for ease of swallowing, as opposed to the community setting. This may also be attributed to the availability of HCPs to make the process of prescribing easier, as well as the availability of knowledge about modifying medications. This may not be the case in the community setting where caregivers may not be aware of other formulations available or the correct way to modify medications.

In this sample, modifying medications was rarely reported by family caregivers, whereas it may be more common in care homes to mix medications or add them to food. In the community, the decision to modify medications may be done with little to no information; the decision is based on the PLWD’s wellbeing rather than their autonomy and the caregiver’s own knowledge. Although staff may receive information from the GP or pharmacist, the process of medication modification may still be conducted with only the need to administer the medications in mind, rather than the implications of the modification or the PLWD’s autonomy.

In care homes, food was sometimes used with medications to make them easier to swallow. This was done by placing the tablet or capsule on a spoon and fed to the PLWD, followed by a spoon of food. The food, such as yoghurt or porridge, would act as a vehicle to ensure the PLWD is able to swallow without difficulties. This could be used in the community setting for PLWD who have reached a stage where they have begun to develop some swallowing difficulties and are happy to be spoon-fed by their family caregiver.
In the care home setting, PLWD may sometimes be at a disadvantage as they may not always get individualised time. This was observed when they ask about their medications and they are not given explanations due to confidentiality issues. Staff tell them they will talk to them privately at the end of the round, by which time they could have forgotten:

“Yeah, and like sometimes if they do ask that I’ll say to ’em ‘I’ll talk to you afterwards’ cuz it’s not private in the dining room is it? Cuz everyone doesn’t wanna know what they taking.” C4, female, 47 years (CHBR)

The decision-making process regarding medications and their administration also differed between care settings. In the community setting, caregivers may have to balance their knowledge against the PLWD’s wellbeing and autonomy. Whereas in the care home setting, staff have a support system (other staff, GP and pharmacist) that they can rely on for decision-making; they only have to ensure that they give the medication but not force the patient, hence ensuring their autonomy. In addition, the partnership between the family caregiver and PLWD contributes to the involvement of the PLWD within the decision-making process, however minimal their capacity is. This provides the PLWD with some semblance of autonomy. The same cannot be said of the care home setting where prescribing decisions and changes in medications are undertaken without the PLWD; the PLWD’s autonomy is sometimes respected by giving them a choice of PRN medications and scheduling of doses. This shows how maintaining the PLWD’s autonomy may be more valued in the community through involvement in the medication use process and decision-making.
7.8. Summary of main findings

The findings have identified the variability in the progression of dementia and the changes to the medication use process that occur with decline in cognition. In some cases minimal to no changes occurred. Nevertheless, this still indicates that changes are not uniform and there is variability in dementia progression. Identification of the key changes to medication use that happen along the trajectory of dementia, and how and when they arise assists in informing recommendations to optimise medication use by anticipating these changes and targeting them accordingly. The key changes include the PLWD’s gradual decrease in independence and its implications on caregiver burden; the transition in care; the development of swallowing difficulties; the administration of medications; and the appropriateness of formulations. Along dementia progression and the resultant changes to the medication use process, the findings have shown various similarities and differences between care settings. In many cases, what seems to be a difference may in reality be attributed to the care setting and environment, such as the availability of information and support from HCPs.

It is difficult to allocate challenges to medication use to specific points along the trajectory of cognitive decline; every PLWD has an individual progression based on the type of dementia and other comorbidities. Nevertheless, the findings from the participants have assisted in identifying challenges that are linked with the progression of dementia that may be applicable to other PLWD in similar situations. The findings also illustrate how these changes to medication use due to decline in cognition impact negatively on caregiver burden by affecting their health and thus their ability to effectively manage the PLWD’s medications.

Identifying and understanding the factors associated with the development of dementia and anticipating how they may affect the medication use process may inform recommendations to support the optimisation of medication use and assist future caregivers, thereby reducing their burden associated with the medication use process. Supporting the caregiver accordingly may lower their burden and help them take care of the PLWD in the home setting for longer. Figure 7.1 displays a model highlighting the key changes affecting medication use along the progression of dementia and suggested solutions.
The next chapter discusses the contribution to knowledge in the context of previous literature. Recommendations based on the findings are also provided to optimise medication use and reduce caregiver burden. The implications on dementia care and future research are also detailed.
Figure 7.1: Conceptual model of changes affecting medication use along dementia progression and suggested solutions

- Review medications to decrease number and multiple dosing
- Inclusion of PLWD and their caregivers in consultations
- Assess swallowing ability
- Gradual transition in care
- Maintain autonomy and preferences for medications
- Assessment of formulation and route of administration appropriateness
- Involvement of caregiver in care home
- Ongoing input along dementia progression about changes to anticipate how to manage them
- Provide support strategies in transition of care
- Provide contingency plan if caregiver is unable to take care of medications

Some recommended solutions

- Development of swallowing difficulties
  - Chewing SODF
  - Increase in swallowing difficulties
  - Modification of medications or switch in formulations (SODF to liquids)
- Increase in number and variety of medications and complexity of regimen
- Appropriate formulations
  - Difficulties with inhalers, pessaries, eye drops
  - Formulations and route of administration may become unsuitable and require change
- Decline in cognition and communication
  - Decline in understanding and recall
  - Unable to recognise and take medications
  - When and how medications given is affected
  - Concerns about side effects may not be voiced
- Behaviour changes
  - Need individualised approach with medication administration
  - Quiet and familiar environment may become important for medication administration
- Caregiver expectations for the future
  - Deterioration in caregiver health and getting older may affect ability to manage medications
  - Fear for how to cope when decline in cognition affects medication use
- PLWD’s autonomy
  - At beginning PLWD may still able to be involved in medication use process, maintain autonomy
  - Desire to respect autonomy by involving in decisions and medication management
  - More difficult to respect autonomy as dementia progresses (ethical dilemma Vs. optimal medication use)
  - Supervision of medication taking may become necessary
- Transition from self to caregiver-led care
  - Gradual assumption of medication-related activities by family caregiver
  - Endeavour to respect PLWD autonomy with transition
- Changes in support needs
Chapter 8: Discussion and conclusion

8.1. Introduction

This chapter provides a discussion of the main findings and their implications on public health policies and recommendations, and is divided into four sections. Section 8.2 details how the findings contribute to existing knowledge and take it forward. The strengths and limitations of the present research are outlined in section 8.3. Section 8.4 describes the recommendations for healthcare policies, primary care, and the pharmaceutical industry in light of the research findings. The direction of future research is outlined in section 8.5. The conclusion ends the chapter in section 8.6.

8.2. Contribution to knowledge

The present study findings corroborate many from previous research discussed in the literature review (Alsaeed et al., 2016b). However, the following sections detail how the current findings contribute to existing knowledge and take it forward.

8.2.1. Family caregiver’s burden in relation to medication use

Caregivers of PLWD are known to have more burden in comparison with other caregivers due to the symptoms of decline in cognition which may include decline in communication and a change in behaviour in the PLWD (Smith et al., 2001; Brodaty et al., 2005). Administration of medication can be a hassle experienced by caregivers within the medication use process and contributes to their burden (Travis et al., 2005), and this was true in the present study as well. The factors that made the administration of medications more difficult relate to the fact that the care recipient has dementia; these include the caregiver monitoring for side effects when the PLWD is unable to communicate and negotiating with the PLWD to take their medications when they refuse. This indicates that caregiver burden in relation to medication administration to PLWD may be greater than other caregivers due to the complexity of duties.

Currently the FCMAHS is the only tool available to measure caregiver burden relating to medication-related activities. This tool was recently used to measure medication administration hassles in family caregivers of PLWD (George and Steffen, 2017). Hassles were found to be linked with the number of medications managed, the functional and cognitive impairment of the PLWD, education, caregiver preparedness with their role and depressive symptoms. This study did not recruit spousal caregivers
and this may have affected their findings. The majority of participants in the present study were spouses and their perceived hassles may differ from caregivers who are adult children.

Findings from the FCMAHS in the present study indicate that it may not provide a full scope on the hassles faced by caregivers, as some caregivers provided contradicting information in their interviews. Furthermore, it lacks clarification and context, which the data from the interviews provided. In addition, the interviews identified areas that contribute to caregiver burden that are not included in the FCMAHS. The results of the present study have shown how medication-related activities may increase caregiver burden, and therefore a reliable tool tailored to caregivers of PLWD is needed to measure this to ensure any interventions to decrease this specific burden are effective. Findings have also identified how family caregivers’ burden related to medication use may change as dementia progresses; this is also not measured by the current tool. Areas identified from the findings that would be useful to include are expectations about future medication use, swallowing difficulties, challenging behaviour and the PLWD’s autonomy. Furthermore, changes in medications or addition of temporary ones, such as antibiotics, were identified as contributing to medication scheduling difficulties; this is also missing from the tool. Tailoring this tool for caregivers of PLWD can assist in identifying which areas pose the most difficulties and hence provide an indication of the support required to alleviate caregiver burden. Developing a framework with these new domains based on the findings and adapting the FCMAHS to add these new sub-domains would be the first step in tailoring the tool for caregivers of PLWD.

Some caregivers found making decisions difficult regarding scheduling and administering medications. This difficulty was related to two factors; lack of information and respecting the PLWD’s autonomy. Lack of information may cause anxiety in the caregiver as they are responsible for the care recipient’s medications (Goldstein and Rivers, 1996), and was evident in the current sample. Furthermore, their increasing role with medication use, decision-making and maintaining the PLWD’s autonomy may also add to their burden. These were previously explored, but not in the context of medication use (Fetherstonhaugh et al., 2017). Managing challenging behaviour when administering medications was also found to be stressful for caregivers. Previous research has shown challenges associated with the caregivers’ transition into their role which include their lack of preparation for the role, being
unaware of informal and formal support and services, and the inability to prepare for the future with the PLWD (Ducharme et al., 2011). The current findings support this in the context of medication-related activities.

Family caregivers of PLWD may have general fear of expectations of the future (Butcher et al., 2001). The decline in the cognition and worsening of behavioural symptoms are known to increase caregivers’ burden (McCabe et al., 2016), but the focus was not on medication use issues. Previous studies discussed in the literature review identified that family caregivers’ concerns change as dementia progresses and burden increases. The present study has expanded on the expectations for the future topic by identifying which changes to medication use contribute to caregivers’ burden. Expectations of progression of dementia and its implication on the medication use process affected caregiver burden and were experienced by all the family caregivers. These include the addition or change in medications, coping with the development of swallowing difficulties, the impact of decline in communication and cognition on medication administration, coping with the development of challenging behaviour, and fearing for the management of the PLWD’s medications if they are unwell. This unpredictability in the caregiving trajectory of caregivers of PLWD needs to be taken into account by HCPs, as caregivers appreciated timely support and services along this trajectory, rather than waiting till they could not cope, as expressed by current participants and previously (Singh et al., 2014). The findings have shown that although the caregiver role may not change drastically with time, support needs change alongside the PLWD’s decline in cognition and therefore regular follow-ups are helpful in supporting family caregivers and PLWD, as seen previously in other caring activities (Andrieu et al., 2005).

Part of the caregiver burden expressed by participants in relation to medication use was its impact on their daily life and health where they may sometimes disregard their own health for the sake of the PLWD’s wellbeing. This compromise in their own health needs may stem from a sense of guilt as they feel responsible (Hughes et al., 2002). Furthermore, caregiving has been shown to affect caregivers’ adherence to medications and GP appointments (Wang et al., 2015). The impact of medication use on the caregivers’ daily life was great and could result in a disruption of their daily activities and plans and ultimately retirement to be able to assume their role more effectively as dementia progressed. Some caregivers of PLWD are known to become isolated due to their role, and as dementia progresses they may become less involved
in their usual hobbies, and they may resort to retirement (Brodaty and Green, 2002), which was also evident in the current sample. Furthermore, it has been acknowledged 20 years ago that many caregivers are getting older themselves and may have comorbidities or decline in their cognition, which may make it more problematic for them to cope with the increasing responsibilities (Goldstein and Rivers, 1996). There is a need for support to cope with this to assist caregivers and ensure that the PLWD will be taken care of.

Focusing on the caregivers’ accounts and understanding caregiver burden in relation to their medication role, as well as their relationship with the PLWD and transition in their role, has identified where challenges are experienced. Addressing their needs is pivotal to decreasing their burden and improving the quality of care of the PLWD. Below are areas identified from the current findings that may assist in alleviating caregiver burden associated with medication use:

- Preparing caregivers for the medication-related activities with their role and how their responsibilities may change as dementia progresses, and what to anticipate (section 8.2.6.)
- Discussing with caregivers the position of the PLWD’s autonomy within the medication use process, and recommending medication management strategies that respect the PLWD’s autonomy.
- Including caregivers in consultations and decisions about the PLWD’s medications.
- Meeting the caregivers’ informational needs relating to medications (section 8.2.4.).
- Supporting caregivers with the decision-making process at home by meeting their medication informational needs and providing support as their needs change along dementia progression.
- Meeting caregivers’ health needs and support their own medication use alongside the PLWDs’.
- Ensuring caregivers are coping well with the PLWD’s regimen, such as fitting it in their daily routine.
8.2.2. The PLWD’s autonomy in the context of the partnership between the caregiver and PLWD

Previous research discussed in the literature review has highlighted the PLWD’s autonomy and its importance (Alsaeed et al., 2016b). The current findings have expanded on this topic by examining the PLWD’s autonomy within the medication use process in the context of the partnership between the caregiver and PLWD. This has enabled the identification of the impact of the PLWD’s autonomy on the relationship between the caregiver and PLWD and the decision-making process, as well as how it contributes to caregiver burden.

The importance of the PLWD’s autonomy within the medication use process and endeavouring to respect it as cognition declines was identified. Overriding their autonomy may result in challenging behaviour and place more pressure on the caregiver. Respecting older people’s autonomy and providing them with dignity have been recognised as crucial in healthcare in the UK (Coulter, 1999; Lothian and Philp, 2001) and is imperative in person-centred care (Edvardsson et al., 2008). PLWD’s autonomy was closely linked with the challenges associated with medication use; allowing them to be part of the process of organising and scheduling medications was advocated by participants. This is beneficial for strengthening the partnership between the caregiver and PLWD and sharing these responsibilities may alleviate caregiver burden. Involving PLWD in their medication decisions and providing them with choices increase their feelings of worth, and caregivers are central in enabling this. This was advocated previously in the general caring context (Fetherstonhaugh et al., 2013).

The partnership may enable the sharing of medication-related activities and therefore preserve the care-recipients’ autonomy, seen in the current findings and previously (Francis et al., 2006). Caregivers that developed strategies for managing medications that respected the PLWD’s autonomy by involving them (such as through placing medications in areas in the house the PLWD is able to remember and take on their own) expressed fewer problems with medication use. Strategies worked best when they are tailored to their cognitive decline and abilities, and respect the PLWD’s autonomy. Even though previous research has shown that the involvement of a caregiver may disempower the PLWD as there is a shift in the relationship from spouse or child to caregiver (Martin et al., 2012), caregivers in the present study have
provided ways where the PLWD is able to self-manage some aspects of the medication use process and thereby feel independent and empowered. Nevertheless, participants sometimes went against the PLWD’s autonomy within medication use to ensure their health and wellbeing; this principle is based on beneficence (Smebye et al., 2016). This can create ethical dilemmas for both family and formal caregivers.

There should not be an assumption that PLWD are unable to self-manage, and they should be given the chance to be involved according to their abilities and be supported accordingly. That being said, some caregivers allowed the PLWD to administer certain formulations on their own, such as inhalers, without the need to check if they have. This can relate to the caregiver’s need to maintain the PLWD’s autonomy, but it can also be associated with their overestimation of the PLWD’s ability (Brady and Weinman, 2013). This has to be corrected as it impacts on the PLWD’s adherence to their medications.

Previous research concerning decision-making and autonomy focused on general everyday decisions or end of life care (Livingston et al., 2010; Miller et al., 2016; Dening et al., 2017; Hinsliff-Smith et al., 2017). Caregivers become involved in the decision-making process for PLWD from diagnosis onwards, with their involvement increasing with the PLWD’s decline in cognition, seen here and previously (Hirschman et al., 2004; Samsi and Manthorpe, 2013). The decision-making process has been found to be either done collaboratively with the PLWD, or be done completely by the caregiver (Hirschman et al., 2004; Samsi and Manthorpe, 2013), with the PLWD’s involvement corresponding directly to their degree of cognitive decline and therefore their mental capacity. This was similarly found in the present study, although even caregivers of PLWD in the moderate to severe stage still endeavoured to include the PLWD in decisions however minimal their input is.

Studies have shown PLWD wanted more information (continually along disease progression) about their disease and want to preserve their autonomy for as long as possible (de Boer et al., 2007; Lauriks et al., 2007; von Kutzleben et al., 2012). Furthermore, PLWD have previously expressed their need to be involved in their own decisions, although in reality the extent to which they are involved is limited, even those with mild dementia (Miller et al., 2016). PLWD in the present study were in most instances happily reliant on their caregiver to make medication decisions on their behalf, although they still wanted their preferences to be taken into account.
Resident autonomy within the care home setting has been discussed in previous literature in the context of involvement in care and medical decisions, HCPs requiring control of prescribing and administration processes, and person-centred care (Hughes and Goldie, 2009; Rodgers et al., 2012; Garcia et al., 2016). The findings from the present study provide insight into how care home staff endeavour to respect residents’ autonomy with medication administration by providing choices and subtle supervision. In addition, staff that adopted an individualised approach by understanding the residents’ preferences with how medications are administered and which formulations they preferred reported less issues with behaviour.

The PLWD’s autonomy may be maintained by including the PLWD within the medication use process according to their abilities, by explaining the process better, by sharing responsibilities, and by shared decision-making. Understanding these changes to the decision-making process and how it affects the caregiver and PLWD is important to ensure that the PLWD’s autonomy is maintained, their preferences for medications upheld, and the caregiver is supported in this process. Section 8.4 details how GPs during consultations may be able to identify changes to decision-making, and support maintaining the PLWD’s autonomy.

8.2.3. The choice of formulation and swallowing difficulties

Medication characteristics, (such complexity of regimen, size and shape of SODF, inconvenient formulations and packaging) have been shown to contribute to medication burden for patients in general (Mohammed et al., 2016). These issues were similarly expressed by participants, and the specific characteristics posing the most difficulty were discussed in the results chapters (Chapters 5-7).

Previous research discussed in the literature review has highlighted the issues associated with formulations generally. The present study focused on the use of appropriate formulations and preferences to identify PLWD and caregiver needs in this regard and optimise medication use. The choice of formulation for the PLWD has to take into account a variety of factors which are the ease of use of formulation by the caregiver (including the packaging), the PLWD’s preferences (such as regarding taste, colour and size), the PLWD’s swallowing ability, frequency of dosing and route of administration.
Older people have been documented as having difficulties handling packaging, administering medication and swallowing medications, and may resort to modifying medications to make them easier to administer (Beckman et al., 2005; Tordoff et al., 2010; Messina et al., 2015). This should be taken as an indication that the formulation is not suitable for the patient and/or not meeting their needs. All participants discussed difficulties that indicate that the choice of formulation was not appropriate for the PLWD and/or their caregiver.

Participants faced some difficulties with packaging, especially those with poor manual dexterity. This is prevalent in older people, but regulatory bodies have yet to include testing of packaging user-friendliness in requirements (van Riet-Nales et al., 2016). A previous study has shown how the visibility of the medication within the blister and its perfect fit within it were seen as encouraging patient satisfaction with packaging (Braun-Münker and Ecker, 2016). Suggestions from the present study participants show that packaging can be made user-friendly by having easy to manipulate foil backing and tear-away blisters.

Participants, both caregivers and PLWD, sometimes had individual preferences towards medications and formulations, and this feeds directly into the acceptability of formulations. Acceptability of formulations is important to enhance adherence to medications and achieve therapy outcomes (Liu et al., 2014, 2016). Certain characteristics, such as size, shape and texture, may all affect how easily a medication can be swallowed (Liu et al., 2016). Ability of caregivers to administer formulations can determine their acceptability (Liu et al., 2014), and this was similarly expressed by participants.

Inhalers were found to be unsuitable, as are the methods used to administer them such as spacer devices, in both settings. They were also found to be difficult to schedule and were easily forgotten, as were eye drops and other formulations that were not SODF or liquids. Difficulties with inhaler use in care homes have been previously reported (Alldred et al., 2011). Previous findings indicate the PLWD may be unable to use inhalers correctly (Allen, 1997). They may also have difficulties learning new techniques, as was seen in some participants. Patient education may help, as shown in one study where residents with dementia from one care home who were counselled and supervised were able to use a dry powder inhaler (Fraser et al., 2012). Unfortunately, this type of supervision is not always feasible and therefore inhaler use
may be suboptimal in PLWD (Quinn et al., 2016). Inhaler use should be assessed by HCPs and an appropriate formulation (such as dry powder inhaler or metered-dose inhaler) prescribed according to the PLWD’s ability. A spacer device may be added if it is acceptable for the PLWD to use. If inhaler use is still suboptimal, the use of a nebulised formulation may be indicated.

The EMA has recognised the unsuitability of certain formulations in people with cognitive impairment, such as pessaries (European Medicines Agency, 2017). Inappropriate formulations that were difficult to administer led caregivers to sometimes modify medications without appropriate advice, which may compromise the formulation and may affect the PLWD’s health, as well as increase the caregiver’s burden as they make these decisions with little to no knowledge. Modifying medication without seeking advice was also seen previously in older patients (Lau et al., 2015). In addition, the use of unsuitable formulations can lead to incorrect use and thus negatively affect the PLWD’s health. Swallowing difficulties and dysphagia and/or challenging behaviour resulted in staff modifying medications, either through opening capsules, adding medication with food, or combining liquids. Manipulating a medication renders it unlicensed, therefore the HCP administering the medication is liable for any adverse effect caused by the modified medications (Schiele et al., 2013; White and Bradnam, 2015). HCPs need to assess the appropriateness of formulations to overcome this issue. The availability of suitable alternative formulations or the provision of information concerning modifying medications appropriately is advocated.

The number of SODF medications may also contribute to swallowing difficulties (Liu et al., 2016), which was similarly seen in the present study. Swallowing difficulties and dysphagia, and thus inability to take medications should be recognised as a major factor that can contribute to unintentional nonadherence and under-dosing (Brady and Weinman, 2013; Schiele et al., 2013; Stegemann et al., 2014; European Medicines Agency, 2015). The study findings support this as PLWD in both care settings would sometimes miss doses due to swallowing difficulties. In a recent study, observation of nurses in care homes administering medication to patients with dysphagia highlighted that staff need training in recognising and reporting difficulties swallowing medications to HCPs (Serrano Santos et al., 2016). This was similar to the sample observed in the present study. Furthermore, some PLWD instinctively chew medications and may not understand instructions, thus certain formulations may be
ineffective or unsafe. Although some participants were chewing SODF before swallowing, the availability of chewable formulations may not be a solution. Some PLWD’s ability to chew may be reduced and/or have dentures (Liu et al., 2014, 2016).

Modifying medications and mixing them with food and drinks were found in both care settings. Mixing medications with food may affect the bioavailability of the drug (Hanning et al., 2016). The EMA has recently indicated that instructions should be part of the summary of product characteristics (SmPC) to ensure any modification is undertaken in a safe and effective manner (European Medicines Agency, 2017). Furthermore, it has stated that pharmaceutical companies should endeavour to conduct studies to ensure the stability, bioavailability and acceptability when such modifications are made. The study findings support this recommendation, especially in care homes where modifications are more common due to decline in cognition, swallowing difficulties and challenging behaviour.

Changes to medications on follow-up of the community participants indicate that more regular reviews are beneficial, not only to stop unneeded medications or change them, but to also explain to caregivers and PLWD why. Furthermore, caregivers and PLWD were unaware of alternative formulations, therefore there was rarely a change in formulations in the community setting as opposed to care homes. The National Service Framework for older people states that annual reviews are required for people aged 75 years and older, with this review being 6-monthly if they are on 4 or more medications (Department of Health, 2001). Findings show that PLWD may not have regular reviews, and this needs to be enforced. Furthermore, the age may need to be lowered to include all people with cognitive decline.

Interchangeability of medications between manufacturers and brands was also an issue in the community setting. This is an acknowledged problem that affects medication recognition in patients (van Riet-Nales et al., 2016). In addition, substituting branded medications with generic ones may also affect patient adherence (Håkonsen and Toverud, 2012). The current findings indicate that the interchangeability of medications issue can be avoided if it is explained to caregivers and PLWD when obtaining medications that the medication is the same. Only one caregiver and PLWD expressed the need to obtain the named brand of a specific medication due to side effects experienced with the generic medication.
There has been a rising interest in the development of age-appropriate formulations. Research has been focused on developing these formulations for anti-dementia medications, such as rivastigmine patches and extended-release formulations of galantamine and donepezil (Blesa et al., 2007; Winblad and Machado, 2008; Molinuevo and Arranz, 2012a, 2012b; Brady and Weinman, 2013; López-Pousa and Arranz, 2013). There has been the development of formulations that overcome swallowing difficulties. These are orally disintegrating tablets (ODTs), multiparticulates, dispersible tablets and mini tablets (Carnaby-Mann and Crary, 2005; Gandhi and Baheti, 2013; Liu et al., 2016; Lopez et al., 2016; Quinn et al., 2016; Walsh et al., 2017). Mini tablets may be too small to see by older people or be difficult to handle. This was seen with some of the current participants who complained about the small size of some tablets. Caregivers of PLWD preferred ODT donepezil over the film-coated formulation due to its ease of administration (Sevilla et al., 2009). Although all these alternative formulations have their advantages, they are not perfect and further research is needed to overcome some of the disadvantages, such as unpalatable taste (Slavkova and Breitkreutz, 2015; Liu et al., 2016; Lopez et al., 2016).

A relatively newer formulation is the oral disintegrating film (ODF) which is a thin film containing the medication and is placed on the tongue or in the buccal cavity to dissolve (Liew et al., 2011; Kathpalia and Gupte, 2013). It has various advantages such as no need for water, it is suitable for people with swallowing difficulties, and it is more stable than liquid formulations (Liew et al., 2011; Slavkova and Breitkreutz, 2015; Walsh et al., 2017). Furthermore, future directions indicate the feasibility of creating patient-tailored ODFs in community and hospital pharmacies (Visser et al., 2015). Donepezil has been formulated as both ODT and ODF to increase compliance to medications in PLWD (Di Stefano et al., 2011; Liew et al., 2011, 2015). Donepezil as the ODF formulation has received a marketing authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) (Medicines and Healthcare products Regulatory Agency, 2011). The intra-nasal route has also been of interest in the design and development of patient-friendly galantamine and donepezil formulations (Di Stefano et al., 2011; Bhavna et al., 2014). The current findings show that PLWD and their caregivers face challenges with a variety of medications, thus similar attention should be placed on developing dementia-friendly formulations of common medications.
There has been rising attention towards the design and development of geriatric medications by medication regulatory agencies. This has been recently the focus of the European Medicines Agency which has published a reflection paper on issues to be considered by the pharmaceutical industry (European Medicines Agency, 2017). The pharmaceutical industry is gradually understanding the need to not classify the older population in one category as they are a heterogeneous population with various co-morbidities and needs and that there is a need to adopt a patient-centric approach to drug design (S. Page et al., 2016). The term ‘patient-centric’ has been recently defined in the context of pharmaceutical drug design and development (Stegemann et al., 2016). The proposed definition states ‘The process of identifying the comprehensive needs of individuals or the target patient population and utilising the identified needs to design pharmaceutical drug products that provide the best overall benefit to risk profile for that target patient population over the intended duration of treatment’. The findings demonstrated the characteristics of medications prioritised by participants that require improvement, which include dose flexibility, route of administration (ease of administration), swallowability, instructions and formulation characteristics.

There is limited research concerning acceptability of formulations in older people in comparison with other age groups, especially PLWD (Walsh et al., 2017). It is imperative to achieve optimal medication use in PLWD by asking about how they feel about their medication and/or formulation (European Medicines Agency, 2015). Although the current findings did not test the acceptability of specific formulations, nevertheless it still contributes to knowledge by identifying the importance of the choice of formulation in this patient population and their caregivers and what factors to consider. Section 8.4.2 details the specific recommendations to the EMA and the pharmaceutical industry.
8.2.4. Informational needs of caregivers and PLWD

Studies discussed in the literature review have highlighted that caregivers and PLWD lack medication information. The current findings have identified the informational needs of caregivers and PLWD that are required to optimise medication use and alleviate caregiver burden.

Participants have shown a lack in medication-related information, which affects medication use, decision-making and caregiver burden. Other caregivers have shown how they have limited information when administering multiple medications, which may give rise to errors (Donelan et al., 2002). Caregivers of PLWD are often making most of the decisions regarding medications on their own (Brodaty and Green, 2002) and therefore require all the needed information to make these informed decisions.

Caregivers and PLWD were not always aware of services or support, even though they needed them. Reasons include no signposting by HCPs or that they felt they were not at the stage where they require it yet. Caregivers of PLWD are known to show low uptake of services and support in comparison with other caregivers, even though they also show a high need for them (Donelan et al., 2002; Toseland et al., 2002; Brodaty et al., 2005; Ducharme et al., 2011; Singh et al., 2014).

Health literacy is known to decline with age, and HCPs should acknowledge this when providing information to caregivers and PLWD (Kobayashi et al., 2015; Peterson et al., 2016). HCPs should be able to meet these informational needs and be able to signpost caregivers and PLWD and/or refer them to the appropriate source of information. In addition, the findings have indicated how medication use and issues change with dementia progression, hence information and support needs of family caregivers change over time and this should also be acknowledged and met accordingly. Changes in information needs of caregivers of older people and PLWD have been identified before, but not in relation to medication use (Washington et al., 2011; DiZazzo-Miller et al., 2013). The findings have identified what information is needed by caregivers and PLWD:

- Information concerning the addition of and/or change in medications and why
- Information about alternative formulations in case a switch is required
- Information about the correct modification of medication if required
- Information about interactions with medications and food
- Information about side effects and how to identify them if the PLWD is unable to communicate effectively
- Information about the effectiveness and need for medications

The findings show the importance of including both the PLWD and the caregiver in consultations to be able to gain both perspectives about medication use and any issues encountered to be able to address them accordingly. It should be acknowledged during the interface with formal care that dementia means the usual dyadic relationship between the GP and patient changes to a triadic one between the GP, patient and their caregiver (Beisecker et al., 1997). This not only means the importance of including the caregiver in consultation, but also that HCPs should be aware of the quality of partnership and relationship dynamics between the PLWD and their caregiver and its implications on medication use. Issues concerning confidentiality should be addressed to ensure communication is effective.

Most caregivers and PLWD were satisfied with their GPs and pharmacists, but findings have shown a need for a more active partnership where information is provided clearly and communication is a two-way process. When this is not the case, it can result in breakdown of trust and thus can negatively affect medication use. Previous research has shown that shared-decisions in consultations were deemed important to caregivers (Hughes et al., 2002). PLWD also felt that HCPs do not involve them in decisions about their care (Lakey et al., 2012). Caregivers may also need to have informal chats with HCPs, but do not know who to approach (Goldstein and Rivers, 1996). Recommendations to improve interactions with formal care, such as with GP consultations and MURs with pharmacists are needed to be able to meet PLWD and their caregivers’ informational needs, hence optimising medication use. These are detailed in section 8.4.1.

It has been previously advocated to provide patients with information and enhance their health literacy, as well as involve them in their care to improve medication use (Coulter and Ellins, 2007). Patient leaflets are usually written in scientific terms that users, especially older people, may not be able to understand due to low health literacy (Stegemann, 2016). This is further complicated with visual and/or cognitive impairment when the writing is small and patients may not be able to remember oral information from HCPs (Hanning et al., 2015). The findings show that information should be improved and tailored to meet the PLWD and their caregivers’ needs.
Section 8.4.2 details recommendations for the pharmaceutical industry concerning relevant information to be added to leaflets.

### 8.2.5. The PLWD’s behaviour

One of the challenges to medication use in both settings is the PLWD’s behaviour and how to manage it, as it affects the PLWD’s willingness to take medications. Studies discussed in the literature review acknowledged the PLWD’s behaviour as a challenge, and the current findings have identified how behaviour affects medication use and how the partnership and the PLWD’s autonomy are connected. The relationship with the PLWD and understanding their individual needs, such as how they like to be approached, may overcome issues with behaviour. Furthermore, there is a possible link between developing challenging behaviour and the PLWD’s autonomy.

One of the important interactions within the care home is the relationship between care home staff and the PLWD, as approach and familiarity are both important when administering medications. Staff should be encouraged to establish rapport with PLWD to make administering medications easier. Furthermore, ensuring that staff turnover is minimal so that PLWD are familiar with staff members may lessen their agitation and make them more willing to take medications.

In the community, it is the family caregiver’s sole responsibility to administer the medications and try to develop strategies with approach. This differs in the care home setting where staff have the ability to rely on another member of staff whom the PLWD is more familiar with and therefore more agreeable to receive medications from with relative ease. In addition, sometimes it was not the medications that the PLWD found difficult in the community, it was the time of day and the PLWD’s mood and behaviour. Medication timings can be individualised according to each PLWD in the care home as many residents refused their medications because it was not a suitable time for them. This can make the medication round longer, but with the correct organisation, it may also make the medication round more efficient, waste fewer medications, and ensure residents agree to receive their medications to get the clinical benefit.
Challenging behaviour affected care home staff negatively, and this was seen in previous research (Brodaty et al., 2003; Holst and Skär, 2017). Identifying triggers and adopting an individualised approach may be beneficial in managing behaviour and can assist in alleviating the stress associating with administration of medications. Challenging behaviour may sometimes be attributed to caregiver factors, such as how they react to and manage these behaviour changes (Feast et al., 2016). This was similarly seen in the sample in both care settings where how caregivers approach the PLWD may trigger and/or aggravate behaviour further. In the care home setting, familiarity with staff administering medications, gender of staff, how staff approach the resident (such as language and tone used) and time of day were all identified from the present study as affecting the residents’ cooperation with medication administration. Educating staff members about these may assist them when administering medications.

Some participants expressed how the PLWD would refuse food or be unable to eat due to dysphagia and/or cognitive decline. This affects the administration of medications that need to be taken with food. Studies investigating the effectiveness of interventions to support food and drink intake are limited and/or lack high quality (Abdelhamid et al., 2016). Interventions include the use of finger foods, modified food to suit people with dysphagia (thickened liquids and pureed food), and eating with caregivers. Suggestions for improving feeding can be provided to family caregivers and staff at care homes to assist with medication administration.
### 8.2.6. Impact of progression of dementia on medication use

A previous study interviewed a sample of PLWD, their family caregivers and their HCPs to identify the barriers and facilitators to medication management in early and severe dementia (Kaasalainen et al., 2011). Figure 8.1 illustrates the medication management process proposed by the authors. It shows that medication management may change according to the level of severity of cognitive decline, but that facilitators, challenges and strategies overlapped across dementia severity.

**Figure 8.1:** Conceptual model of the medication management process for PLWD (adapted from Kaasalainen et al., 2011)

The present study proposed a conceptual model in Chapter 7. Medication and patient care is not always linked to dementia severity; the findings have indicated that changes to medication use are not uniform and may occur at any stage along dementia progression. Furthermore, PLWD with mild dementia may refuse medications due to needing their independence, as seen in the model above. However, this is not always the case and the current findings have shown that it is far more complex and relates to the PLWD’s partnership with the caregiver and the transition from self to caregiver-led management. Furthermore, the literature review highlighted that challenges with medications are either associated with cognitive decline or regimen complexity. The
current findings have demonstrated that challenges with medication use can be attributed to both factors and thus should be taken into consideration by HCPs.

Issues changing with dementia progression have been discussed in previous sections, such as caregiver burden, PLWD’s autonomy, the partnership between the caregiver and PLWD, and appropriateness of formulations. Ensuring that HCPs and caregivers and PLWD are aware of these changes so that they may anticipate them would be beneficial in optimising medication use and alleviating caregiver burden.

The study has also identified the factors associated with the transition in care from self to caregiver-led. Understanding this transition and the challenges associated with it can help caregivers and PLWD and their HCPs anticipate any issues before they occur and deal with them accordingly. The transition from self to caregiver-led management was an area that posed challenges for some participants. Receiving a diagnosis of dementia was significant and contributes greatly to the challenge of transition in care (Martin et al., 2012). This was similarly seen in some of the participants who could not accept this diagnosis and what it represented in terms of compromising their independence. Progression of dementia may also mean the responsibility and decision-making shifts increasingly to the caregiver. This transition in care should be managed to optimise the medication use process and ensure caregiver burden is not affected negatively. For caregivers that take on new medication-related responsibilities, sharing activities within the partnership and respecting the PLWD’s autonomy is advised. This may not be possible in all cases as they may have unique circumstances and the dementia type and progression differs between PLWD. The caregiver or pharmacist may be able to see signs that indicate the PLWD requires assistance and has to transition from self to caregiver-led care. Involving HCPs in the process of these transitions can help make the transition process and the decisions relating to them easier on caregivers and PLWD, as well as alleviate caregiver burden as they feel supported.

Progression of dementia can also be seen as a trajectory of when swallowing difficulties occur. This relates directly to the findings that illustrated that sometimes prescribing decisions do not take into account PLWD and their preferences, especially their ability to swallow. Just as the progression of dementia is variable, so are the PLWDs’ preferences for medications; HCPs should not assume that a switch from a SODF to liquids is the solution that is appropriate for all PLWD. Furthermore,
swallowing difficulties may not be recognised well in the community setting. This has negative implications on medication use through unsuitable formulations being chewed or modified which may affect the PLWD’s health and may increase caregiver burden. This highlights the issues of safety and appropriateness of these prescribing decisions regarding formulations. Additionally, there is a need to consider other routes for formulations inappropriate in PLWD, such as pessaries, suppositories, and inhalers. Administration of medications may also become problematic with dementia progression as changes occur in the PLWD’s behaviour and willingness to take medications. This was difficult on both family caregivers in the community and formal care in the care home setting. Identifying why these behaviour changes are manifesting (time of day, mood, approach with medication administration, PLWD preferences for medications) and resolving them accordingly will help optimise medication use and lower caregiver burden.

8.3. Strengths and limitations of the present research

This literature review does not include many studies, but this may be attributed to the specificity of the research question (Alsaeed et al., 2016b). Furthermore, this highlights that this topic may be relatively new. Some of the findings included were from conference abstracts; although the findings may not always be as comprehensively peer-reviewed as journal articles, they widen the scope of the issues. Many of the studies had small sample sizes; this can be due to the qualitative methods used and the difficulty in recruiting PLWD and their caregivers (Hutchings et al., 2010; Goodman et al., 2011). Nevertheless, the literature review has enabled the synthesis and analysis of available data on the subject to inform future research.

To create trust between the participant and researcher for them to feel comfortable to talk freely, the researcher talked about general topics before commencing the interview to establish rapport. This also enabled the researcher to discern the PLWD’s level of cognitive function and their ability to communicate.

The community sample may not be representative as people from organisations, such as the Alzheimer’s Society in this case, may be motivated to be included in research. They are also from specific areas in London and may not be generalizable to other populations. Furthermore, there is no knowledge of how the dementia advisors approached participants. However, the participants were from diverse socio-economic and ethnic backgrounds and therefore can be representative of a London population.
Within the community setting, a total of 21 participants were included. Of those 21, 11 were family caregivers and 10 were PLWD. There were 9 dyads interviewed together. The caregivers were predominantly spouses, with 4 wives and 5 husbands and 2 daughters. These numbers are similar to previous studies as seen in the literature review (Alsaeed et al., 2016b). Furthermore, the sample is similar to caregiver literature that shows family caregivers were more commonly spouses with wives being predominant, and female adult children were more likely to act as caregivers as opposed to male adult children (Smith et al., 2001).

Although only four care homes participated, they were from different areas and providing a variety of care and can be representative of a sample of similar care homes. The participants interviewed from all the care homes were diverse in their age, ethnic background, and years working in caring. Challenges were encountered with recruitment of care homes, and this has been acknowledged in previous research (Alldred et al., 2009).

The sample size in the present study may be considered small, but recruitment and data collection continued until no new topics emerged from initial analysis, so data saturation was achieved (Fusch and Ness, 2015). Furthermore, unlike quantitative research, qualitative research yields a large amount of textual data to be analysed and thus small samples are sufficient to achieve the research aim and objectives (Smith, 2010).

The present study did not utilise a scale to directly measure disease severity, as these scales, such as the MMSE, may be seen as distressing by some PLWD and their caregivers (Hughes et al., 2002). Furthermore, recruiting from the Alzheimer’s Society guaranteed that participants had a form of cognitive impairment. Instead, a triangulation of methods based on time spent caregiving (the CAS), time the PLWD can be left alone, and the caregiver’s own opinion on disease severity were used to estimate disease severity. Studies have shown that the time spent caregiving increases with cognitive and physical decline of the PLWD (Caro et al., 2002; Neubauer et al., 2008; Dumont et al., 2010; Spackman et al., 2013). The CAS was found to be inaccurate due to caregivers overestimating time spent for each category and overlapping of categories causing confusion. This was found previously and the findings from these methods highlight the need for a simple and indirect way to estimate dementia severity (Dumont et al., 2010). The average time spent caring per
week was 147 hours; this is much more than the reported average spent by caregivers of PLWD of approximately 90 hours (Smith et al., 2001; Sink et al., 2006). Nevertheless, triangulating methods to report approximate severity of dementia was sufficient to illustrate the diversity of the sample.

### 8.4. Recommendations

The findings have identified areas that require improvement to optimise medication use. These were previously suggested in Chapters 5-7. Caregivers and PLWD also provided suggestions for improvements for care, and their perspectives are taken into account within the recommendations. The perspectives of caregivers are essential in the development or redesign of services to meet their needs (Royal College of General Practitioners, 2013). The implications of these findings for HCPs, services and support are wide-ranging. Recommendations are for practice and policy, as well as the pharmaceutical industry to optimise medication use in both the community and care home settings.

#### 8.4.1. Practice and policy implications

There is a high prevalence of potentially inappropriate medication use in care homes, with about one third to one half of residents exposed to these (Somers et al., 2010; Morin et al., 2016). PLWD in the community are also at risk of polypharmacy and inappropriate medication use, with 64.4% (n=4393) being prescribed potentially inappropriate medications (Barry et al., 2016; Parsons, 2017). This highlights the need for better prescribing patterns and medication reviews. Figure 8.2 proposes a model to optimise medication use in PLWD, based on the current findings and adapted from the Royal Pharmaceutical Society (Royal Pharmaceutical Society, 2013). To optimise medication use and achieve optimal patient outcomes, there is a need to engage the PLWD and their caregivers’ attitude and behaviour in the context of medication use. The original model was presented in the introduction chapter (Chapter 1), but it failed to take into account caregivers. The proposed model includes both PLWD and their caregivers as the findings show that optimising medication use requires addressing both their medication needs. The four principles that form the original model are the same except they specify both the PLWD and their caregiver in the new model. Furthermore, specific processes to optimise medication use identified from the findings are attached to each principle of the proposed model to clarify how the principle can be implemented.
The findings identify a need for a more individualised approach towards medication use for PLWD, which involves prescribing appropriate formulations and addressing barriers to effective use. There is a need for ongoing input as dementia progresses in the community and care home settings to identify changes as they occur.
Figure 8.2: Medicines optimisation for PLWD and their caregivers when prescribing, dispensing, administering and taking medication (adapted from (Royal Pharmaceutical Society, 2013))
Consultations with GPs

The consultation with the GP is an important setting where medication use can be optimised for PLWD and their caregivers. The findings have identified how consultations can be improved to meet PLWD and their caregivers’ needs, and these are detailed below concerning the operational aspects (frequency and triggers) and the content (questions to be asked and factors to consider).

As ongoing input is necessary to recognise changes and issues in the medication use process, continual contact with the PLWD and their caregiver along the progression of dementia is beneficial. Different approaches can be taken to maintain this continual contact. Reviews/consultations with the GP should be requested by either the caregiver or the pharmacist when concerns about medication use arise. Caregivers should be encouraged to be proactive and ask for a consultation as per their and the PLWD’s needs. This is because the progression of dementia is variable and so are the issues that arise along this progression; some caregivers and PLWD may require bi-weekly consultations while others may need a consultation every 3-6 months. Furthermore, participants valued continuity in care when they see the same GP over the years who are familiar with their medication experiences. Having a named GP for caregivers and PLWD may assist in achieving this continuity in care and ensure their familiarisation with their needs. This has been advocated previously (Oliver et al., 2014).

The consultation should include both the caregiver and PLWD to be able to gather a full scope of issues from both parties as their views and needs may differ, as demonstrated by the findings. Caregivers usually encountered issues with medication packaging, administration of medications, and concerns regarding the medications. PLWD were more concerned with the number of medications, frequency of dosing, and formulation characteristics (such as taste, size and colour). Gaining both their input would enable appropriate assessment of medications, formulations and addressing their needs. Furthermore, the role of the caregiver as an expert should also be acknowledged as they may encounter potential difficulties with the regimen, handling packaging, and have concerns with administration. There may be confidentiality issues and these should be addressed at the start between the PLWD and their caregiver with an agreement to allow them both to be in all consultations. This also ensures that the PLWD’s autonomy is respected. This may not always be
appropriate, and GPs are professionally accountable to ensure rights are respected and needs met in the best possible way (Royal College of General Practitioners, 2014). Some caregivers feel they cannot voice their concerns in front of the PLWD as they fear harming their feelings; it can be suggested that the GP meet with the caregiver alone so that they are able to talk freely.

Effective communication to create trust between the GP and caregivers and PLWD assists in allowing them to voice their concerns about medications and consider the HCP as a source for medication-related support. There is the issue of PLWD who rely on their caregivers when they are with the GP; it is not known how their concerns are being voiced and whether HCPs ask them directly. That means some issues may not be resolved. Recognising both the caregiver and the PLWD in consultations and sharing decisions with them about medications and information about risks and benefits can assist them in making informed decisions at home and have the right information for them (Department of Health, 2001).

The content of the consultations would need to change along dementia progression to adapt to changes to medication use and the PLWD and caregivers’ needs. The findings demonstrated these changes and assist in recommending topics and questions to address these changes. Once dementia diagnosis has been confirmed, the GP could enquire about how the caregiver and PLWD are managing the transition in care and provide suggestions to facilitate this process, such as involving the PLWD as much as possible without impairing medication use. They can also try to establish an informal arrangement between the caregiver and PLWD about the PLWD’s preferences for medications and formulations to anticipate future changes in treatment. This would also assist the caregiver in making medication decisions without fear of compromising the PLWD’s autonomy or go against their preferences. Research has illustrated that even caregivers that have a good relationship with the PLWD may still no be in agreement with their treatment preferences (Dening et al., 2016, 2017), and this was also seen in the current findings. Other research has advocated a similar approach with goals of care along dementia progression (Lindauer et al., 2017). These plans can be made and updated along dementia progression with the caregiver and PLWD to optimise medication use and respect the PLWD’s autonomy and preferences. An example of a successful intervention is when the PLWD and their family caregivers are involved in one-on-one counselling at the beginning of dementia diagnosis regarding future care (Whitlatch et al., 2006). This shows it is feasible to
adopt a similar intervention once dementia has been diagnosed to identify PLWD’s preferences for medications and formulations to be carried all the way through care transitions to uphold their autonomy. This agreed medication plan should include:

- Medications desired by the PLWD, such as prescribed or PRN (pain relief)
- Preferences when taking medications, such as with/without food to assist administration if required
- Preferences and acceptability of certain formulations (tablets, capsules, liquids, patches, creams, etc.)

In later consultations with further cognitive decline, the GP may ask about swallowing difficulties and assessing these if there are any concerns, or referring the PLWD to a specialist. There could also be an assessment of formulations and route of administration of medications for their suitability. Screening tools could also be used to assess the need for medications and allow de-prescribing; some examples are the Beers’ criteria and STOPP/START (Hughes et al., 2016). A recent update of the criteria of the STOPP/START was published (O’Mahony et al., 2015). This tool has been shown to optimise prescribing and has also been used successfully as part of a pharmacy service intervention targeting people over the age of 65 on four or more medications (Twigg et al., 2015; Hill-Taylor et al., 2016). GPs should also provide information that the caregiver and PLWD lack regarding medications, or refer them to the pharmacist for this information. As cognition declines, GPs may inquire about difficulties with administration of medications and the PLWD’s cooperation and behaviour, and ways to alleviate this barrier discussed. GPs could also be targeting the caregiver as they are a vital part of the medication use process; consultations should include assessment and identification of areas causing caregiver burden, and should provide tailored support to alleviate this burden effectively.

Fulfilling the caregivers’ and PLWD informational needs helps them make informed decisions within the medication use process. If HCPs anticipate issues as they come along the progression of dementia, then they can effectively support and improve the medication use process and ultimately lower the burden on the caregiver. Information needs identified from the findings were discussed in section 8.2.4.
HCPs may not be recognising and assessing swallowing difficulties in older people (Rothenberg et al., 2007; Stegemann et al., 2012; Schiele et al., 2013). This may also be the case in PLWD living in their own homes, as caregivers of PLWD in the present study who demonstrated swallowing difficulties were not aware. It may not be enough for HCPs to just ask ‘do you have swallowing difficulties?’ as some PLWD and their caregivers may not be aware and therefore they would not be able to give an accurate answer (Miller and Patterson, 2014). Asking about behaviour when administering medications or issues with certain formulations may indicate the presence of swallowing difficulties and therefore require an assessment. GPs should also be aware about the development of swallowing difficulties; better recognition and assessment are needed. Tests are available that are valid and have been tested in dysphagic patients, but may not be applicable in PLWD who may have difficulties remembering any changes in swallowing or even communicating this (Wallace et al., 2000; Dwivedi et al., 2010; Liu et al., 2016).

Guidelines and tools can assist in optimising medication use. A consensus guideline is available to assist HCPs in managing medications for people with swallowing difficulties (Wright et al., 2015a). Advice is provided concerning route of administration, alternative formulations and modifying medications. The use of this guide by HCPs in both the community and care home setting may assist in managing PLWD who have swallowing difficulties to ensure they receive safe and effective treatment.

A new set of criteria aimed to optimise medication prescribing in PLWD has recently been published. The Medication Appropriateness Tool for Co-morbid Health conditions in Dementia (MATCH-D) is a consensus criteria that was developed using the Delphi technique and involved pharmacists, doctors, nurses, a psychologist and a patient advocate (Page et al., 2016). It includes details concerning treatment goals, principles of medication use, medication reviews and preventative medication for each stage of dementia.
A similar tool can be developed for GPs to help assess medication use in PLWD and their caregivers to be able to optimise medication use. This tool can assist GPs in asking the right questions. The findings have assisted in providing the points below, which may be used as an initial framework for questions for GPs during consultations with PLWD and their caregivers:

- How the PLWD and their caregiver are managing with the number of medications and dosing schedule, especially alongside the caregiver’s medications and daily routine?
- Are there issues encountered with swallowing certain formulations (tablets, capsules, liquids) or the PLWD chewing medications before swallowing?
- Acceptability of the taste, size and shape of formulations?
- If the caregiver has ever broken a tablet or opened a capsule and why?
- Explain the occurrence of swallowing difficulties and the need to alert the GP if they occur.
- How the PLWD and caregiver are using/administering the inhaler and how they are fitting it in their schedule (assess inhaler technique).
- Assessing the PLWD’s autonomy:
  - How involved the PLWD is with medication use?
  - Does the caregiver explain what the medications are for?
  - Do the caregiver and PLWD share responsibilities?
  - How are decisions regarding medications made (such as giving PRN medications or when the PLWD refuses a dose?)

The role of the pharmacist

The involvement of both the GP and pharmacist is recommended to identify the scope of issues that may arise. PLWD and their caregivers may present different concerns in consultations with GPs and conversations with pharmacists, as some participants expressed they voice their concerns to their pharmacist rather than their GP. It was recommended earlier of having a named GP for continuity in care. This may be also recommended for pharmacists, and there could also be a dementia register that is shared by the GP and pharmacist to enable the pharmacist in sharing medical information. There may be confidentiality issues associated with this, and this can be discussed with PLWD and their caregivers in early consultations to gain their consent.
Having a named pharmacist may enable continuity in care and allow pharmacists to identify PLWD and their caregivers to be able to ask them questions and identify their need for a medication use review (MUR). Participants valued informal conversations with their pharmacist and the pharmacist’s familiarity with their medications. If PLWD and their caregivers do not want their information shared with the pharmacist, the pharmacist may still be able to identify them through the prescription of ant-dementia medications.

The role of the pharmacist, their skills and their medication knowledge should be utilised in optimising medication use through identifying medication use concerns, advice on medication management, medication administration, and reviewing medications. The findings identified the medication information that caregivers needed, such as alternative formulations and modifying medications, can be provided by the pharmacist. Pharmacists are also able to conduct MURs; MURs are intended to optimise medication use by identifying and reducing medication issues. MURs are one of the advanced services within the National Health Service (NHS) (Pharmaceutical Services Negotiating Committee, n.d.). Below are recommendations for tailoring MURs for PLWD and their caregivers to identify and address their concerns appropriately. The operational aspects and suggested content are also considered.

MURs could be prompted by the pharmacist identifying the need through casual talk with the caregiver and/or the PLWD when obtaining medications. Pharmacists should be encouraged to ask the caregiver and/or the PLWD general questions about medication use (such as how are they finding managing the medications) that can establish rapport and open communication so that the caregiver and/or PLWD feel able to voice their concerns. The pharmacist would then establish the need for a MUR that includes both the PLWD and their caregiver to ascertain the full scope of issues relating to medication use. MURs could also be initiated when new medications are added or changed to ensure both the caregiver and PLWD understand how this affects medication use, and to enable them to voice their concerns. Caregivers and PLWD should also be given the option to ask for an MUR when they deem it necessary to tailor the review frequency based on the PLWD and caregiver needs.
Standard MURs are usually between the patient and pharmacist. The current findings indicate the need to include both the PLWD and their caregiver to gain both their perspectives and concerns to enable identification of the scope of issues. Confidentiality issues will need to be addressed by an informal agreement between the pharmacist and PLWD and their caregiver. This informal arrangement could also include future concerns, such as when the PLWD’s decline in cognition results in inability to communicate or provide informed consent and whether they agree for their caregiver to be involved in an MUR when they are unable to. This respects the PLWD’s autonomy, and can be discussed before the first MUR. Participants showed that they relied on their caregiver with regards to medications, so it can be anticipated that PLWD would often agree for the caregiver to be involved. Once the pharmacist has identified the need for an MUR, they can set a date and time convenient for the caregiver and PLWD. The MUR can take place in a designated consultation room in the pharmacy. If it is not feasible for the PLWD to attend the MUR at the pharmacy, a home MUR could be suggested to accommodate the PLWD and their caregiver’s needs. It should be anticipated that pharmacists may be unable to undertake this responsibility due to a variety of factors, such as workload and remuneration of services (Harris et al., 1998). Therefore, there should be incentives to encourage pharmacists to undertake these MURs. Furthermore, it was recommended earlier to have a named pharmacist; the named pharmacist may not always be available to conduct MURs or speak to the PLWD and their caregiver due to work shifts. This should be anticipated and a schedule arranged to allow streamlining this service.

MURs usually contain standard topics to be asked by the pharmacist. The current findings have identified new topics to be included to tailor MURs for PLWD and their caregivers. MURs conducted by pharmacists should follow a guideline which includes specific questions that help identify medication-related problems from the PLWD and caregiver perspectives. The guideline for the MUR should include questions about swallowing ability, the ease of use of formulations, inhaler technique (which should be demonstrated), and suitability of route of administration. The issue of medication modification could also be discussed. Counselling on the use of medications and how to incorporate them in the daily schedule could also be provided. Findings have indicated areas that could be added to MURs to tailor them for caregivers and PLWD.
Below are some proposed points to be included:

- Ask about issues with certain formulations (such as tablets, capsules, liquids, inhalers) to assess suitability of formulation and route of administration, and ease of use from both perspectives.
- Ask about ease of use of packaging from both perspectives.
- Assess whether there are swallowing difficulties by asking the caregiver about behaviour with medication-taking (such as chewing medications), and asking the PLWD if they encounter issues with the size of tablets/capsules.
- Ask caregivers and PLWD about dosing and scheduling to assess if a switch to a less frequent formulation is needed.
- Ask caregivers and PLWD understanding of scheduling, and need and purpose of medications.
- Explain side effects of medications and interactions, especially with food, and what to do.
- Discuss with caregivers how to decide to give PRN medications, such as for pain relief or constipation.
- Ask the caregiver about modifying medications (such as adding with food) and reasons why.

The report following the review is then sent to the GP to highlight medication-related problems identified, to be reviewed and assessed by the GP. Supporting a shared register between GPs and pharmacists can streamline this process and enhance communication between HCPs.

The role of the pharmacist can also be improved by endeavouring to create dementia-friendly pharmacies where pharmacists are knowledgeable about dementia and PLWD and their caregivers, have improved communication skills, and provide a dementia-friendly environment as advocated by current participants and previously (Stafford, 2015; Gilmartin-Thomas et al., 2017).
Improvements in care homes

As dementia progresses and PLWD may transition into the care home setting, family caregivers should be involved as it may assist in optimising medication use in care homes. This was advocated by one of the participants as her mother has transitioned to a care home, but still stays with her once a month. Other PLWD and their caregiver may be in similar situations, and involving the family caregivers can be beneficial for medication use in care homes. There should be open channels of communication between family caregivers and care home staff regarding medication use as family caregivers may provide insight that can help with approach, behaviour changes, and medication preferences.

The study findings have indicated that a person-centred approach to care would be beneficial to the medication use process in the care home. This is especially so when choosing formulations and in the design and development of newer formulations acceptable for use by PLWD and their caregivers. The concept of person-centred care in dementia was recognised by Tom Kitwood in 1988 (Brooker, 2003) and has been encouraged by the National Service Framework in the UK (Department of Health, 2001). Many studies have been conducted that use interventions based on person-centred care to improve care for PLWD by reducing agitated behaviour, antipsychotic prescribing and staff burnout (Buron, 2008; Chenoweth et al., 2009; Røsvik et al., 2011; Jeon et al., 2012; van de Ven et al., 2012; Fossey et al., 2014; Roberts et al., 2015).

Encouraging care home managers and staff to adopt a person-centred approach that moves away from paternalistic tendencies can assist in respecting the PLWD’s autonomy, improving the relationship between PLWD and staff, and may improve medication administration, as observed in the present study. Involving PLWD with decisions about medications can assist in this approach to respect their autonomy, as demonstrated by some staff observed. PLWD are more likely to not be included in decisions about their health, instead family members and staff undertake this on their behalf (Orrell et al., 2008). Empowerment of PLWD should not be restricted in the community setting, and should be encouraged in the care home setting. Suggested recommendations from the findings are through educating care home managers and staff administering medications about respecting the PLWD’s autonomy.
Some suggestions or observed practices include:

- Involving them in decisions about changes or additions to their medication regimen and explaining why
- Respecting their need for independence by providing subtle supervision of medication taking and following their preferences for how medications are administered (such as placing all the tablets in their hands or on the table for them to take one at a time)
- Providing them with choices of drinks to take with the medications
- Respecting their decision to take their medications at another time, but still endeavouring to approach using friendly language when they refuse medications

Staff in care homes require training, especially regarding medications and dementia care (National Collaborating Centre for Mental Health, 2007; Deeks et al., 2016). Training and education of care home staff can also be informed from the findings. Awareness needs to be raised regarding the common practice of modifying the original form of the medicine; staff should be provided information and support to choose safe and effective alternative strategies when administering medicines. Medicine-focused training, such as the use of alternative formulations, is suggested as a solution to overcome barriers to the administration of medicines to residents with dementia. Other areas highlighted by the findings as requiring education concerned how medications are administered and recognising signs of swallowing difficulties.

Care home staff experienced organisational and patient-related distractions during medication rounds that affected the residents’ medications and stressed staff. Recommendations should be targeted towards organisational factors, such as the availability of more staff, education about distractions, and making medication rounds flexible (by allowing staff freedom to organise the logistics based on residents’ needs). Care home managers should be involved in the implementation and auditing of these recommendations. Pharmacists can be utilised to assist with medication-related factors, such as conducting medication reviews for appropriateness of medications and formulations, choosing the right formulation that is acceptable for the resident, and observing medication administration to identify difficulties and resolve them accordingly. This could facilitate informed and tailored recommendations by the pharmacist to optimise medication use in the care home setting (Gilmartin, 2015b).
Previous research has demonstrated that PLWD in care homes are prescribed potentially inappropriate medications (Parsons et al., 2012), and that the pharmacist and GP should be utilised in this care setting to optimise medication use (Verrue et al., 2009; Smith et al., 2010; Patterson et al., 2012; Spinewine et al., 2012; Alldred et al., 2013; Royal Pharmaceutical Society, 2014; Wright et al., 2015b; Alldred et al., 2016; Deeks et al., 2016; Royal Pharmaceutical Society, 2016). The current findings support a multidisciplinary team in every care home; the team would also include a pharmacist to provide their expertise in reviewing medication issues and resolving them accordingly. Regular reviews of residents’ medications should be made in care homes and the pharmacist is advocated to perform them. Better communication between HCPs was also suggested by staff. Promoting better communication between HCPs in care home assists in improving services in care homes (Fahrni et al., 2014).

NICE published a full guideline on managing medications in care homes to provide recommendations for care (NICE, 2014). They support the inclusion of the resident, their family caregiver and a pharmacist in reviewing medications. Care home staff should also acknowledge the resident’s right to refuse medications. Furthermore, staff should be aware of how to administer different formulations. These are all advocated by the study’s findings. These are all available and easily accessible as a NICE pathway (NICE, 2015).

**Information and support**

Providing more information resources and raising awareness of available outlets for services and support regarding medication use is needed and can help increase utilisation of these services. These services and informational support should be updated regularly and standardised to avoid repetition and confusion to service users, as well take into account the change in support needs of caregivers and PLWD along dementia progression. Helping the family caregiver anticipate and prepare for their role and what it entails along the dementia trajectory by providing information and support along designated time points is advocated, as caregivers may become overwhelmed and may feel ill-prepared for their role. Information regarding changes to medication use along dementia progression and suggested recommendations (as seen in Figure 7.1) can be generated as a leaflet to be provided to caregivers and PLWD to assist them in anticipating changes. This standardised leaflet can be available for caregivers and PLWD from both their GP and pharmacist.
Support groups that emphasise peer support and social activities are shown to be beneficial for PLWD (Martin et al., 2012). Creating a support group for PLWD and their caregivers that discuss medication issues can also be beneficial as they can feel reassured they are not alone and are made aware of solutions to issues they might face. This was suggested by some of the participants. These can be organised by the Alzheimer’s Society once a month during their dementia cafés.

Adapting the FCMAHS for caregivers of PLWD

Recognising caregiver burden relating to medication use is essential for policy makers when deciding on new health care services and the provision of support for family caregivers (Hoefman et al., 2013). Furthermore, optimising the medication use process where challenges are anticipated and tackled before growing can ease caregiver burden relating to medication use. Section 8.2.1 has already discussed how the findings have helped in identifying areas contributing to caregiver burden in relation to medication use that are not available in the FCMAHS. It is recommended that the tool be adapted to family caregivers of PLWD by the addition of new domains and sub-domains to reflect the study findings. This would enable the tool to be used both as a diagnostic tool (to measure caregiver burden and identify areas contributing to this burden) and a research tool (to use in measuring reduction in caregiver burden in intervention studies). The tool may also enable identifying changes in medication use by including sub-domains sensitive to changes.

The tool and its domains were previously discussed in Chapter 3 (section 3.8.2). The study findings have highlighted areas that should be added to the FCMAHS to adapt it for caregivers of PLWD. Furthermore, the original tool has 4 domains, and the study findings suggest the addition of an extra domain to take into account partnership issues. The suggested additions and justification are found below in table 8.1.
Table 8.1: Suggested additions for the FCMAHS

<table>
<thead>
<tr>
<th>FCMAHS Domain and suggested additions</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Domain 1: Information</strong></td>
<td></td>
</tr>
<tr>
<td>Understanding future medication needs along dementia progression</td>
<td>All participants had concerns about the future. This can enable a discussion between the HCP and caregiver.</td>
</tr>
<tr>
<td>Getting information about alternative formulations</td>
<td>To identify if caregivers know where to receive this information and provide it.</td>
</tr>
<tr>
<td>Getting information about medication interactions with food</td>
<td>Some participants gave medications with food but had concerns.</td>
</tr>
<tr>
<td>Receiving information about changes/additions to medication regimen</td>
<td>Participants expressed this as a hassle in interviews.</td>
</tr>
<tr>
<td><strong>Domain 2: Scheduling logistics</strong></td>
<td></td>
</tr>
<tr>
<td>Administering medications to PLWD with swallowing difficulties</td>
<td>To recognise if PLWD has swallowing difficulties and assess how caregivers overcome them.</td>
</tr>
<tr>
<td>Explaining to the PLWD how to take/use a medication</td>
<td>Experienced by participants. Also to recognise decline in cognition.</td>
</tr>
<tr>
<td>Knowing how to administer a variety of formulations (tablets, capsules, liquids, patches, eye drops, etc.)</td>
<td>To identify issues with formulations (acceptability, appropriateness).</td>
</tr>
<tr>
<td>Having a contingency plan if unable to manage medications</td>
<td>To identify need for plan for future.</td>
</tr>
<tr>
<td><strong>Domain 3: Safety issues</strong></td>
<td></td>
</tr>
<tr>
<td>Recognising side effects when PLWD is unable to communicate</td>
<td>This was experienced with some caregivers who were concerned. Also to recognise decline in cognition.</td>
</tr>
<tr>
<td><strong>Domain 4: Polypharmacy concerns</strong></td>
<td></td>
</tr>
<tr>
<td>Managing the addition to or change in medication regimen</td>
<td>To identify issues with managing multiple medications.</td>
</tr>
<tr>
<td><strong>Domain 5: Partnership issues</strong></td>
<td></td>
</tr>
<tr>
<td>Feeling comfortable about making medication decisions with the PLWD</td>
<td>Participants were concerned with decision-making. Also to identify PLWD’s involvement and autonomy.</td>
</tr>
</tbody>
</table>
### FCMAHS Domain and suggested additions

<table>
<thead>
<tr>
<th>Activity</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arguing/negotiating when the PLWD refuses a dose</td>
<td>Participants reported this as a hassle in the interviews.</td>
</tr>
<tr>
<td>Knowing what to do if the PLWD refuses a dose</td>
<td>Participants reported this as a hassle in the interviews. To identify how caregivers maintain PLWD’s autonomy.</td>
</tr>
<tr>
<td>Sharing medication-related responsibilities with the PLWD (scheduling, keeping stock, etc.)</td>
<td>To identify the PLWD’s involvement in the medication use process.</td>
</tr>
</tbody>
</table>

### 8.4.2. Recommendations for the pharmaceutical industry

Research has highlighted the growing need for medications tailored for the geriatric population, and the pharmaceutical industry should take notice and act on research recommendations (Stegemann et al., 2010; Perrie et al., 2012; Wahlich et al., 2013; Orlu-Gul et al., 2014; Stegemann et al., 2014; Messina et al., 2015; Hakes, 2016; Page et al., 2016; Quinn et al., 2016; Stegemann, 2016; Stegemann et al., 2016). A patient-centric approach should be undertaken whereby the formulation is designed and developed in accordance to the PLWD and/or their caregiver needs. During the design and development stage, certain factors should be considered such as swallowing ability of the patient population, the involvement of the caregiver in medication administration and the likelihood of medication modification. Furthermore, patient and caregiver acceptability is paramount to ensure medications are taken as intended and achieve therapeutic outcomes (European Medicines Agency, 2017).

The inclusion of both PLWD and their caregivers’ views on the acceptability of formulations is imperative to this process to ensure medications are taken as intended and meet their needs, which this study has achieved. Recommendations for the pharmaceutical industry and the EMA require the direct involvement and input of PLWD and their caregivers.
The findings have identified specific formulation issues that require improvement to optimise medication use in PLWD. Although some preferences were individualised, nevertheless there were general issues that affected acceptability of formulations. The study findings assist in informing recommendations for regulatory bodies, such as the EMA, and the pharmaceutical industry. A pilot study conducting by the EMA has shown the feasibility of gaining patient preferences to support regulatory review (Postmus et al., 2016).

It is recommended that other routes of administration in PLWD are considered or ways to make certain formulations (inhalers, pessaries, eye drops) more suitable. Ways to improve the use of inhaled medication is either through choice of device, addition of a spacer, or switching to a nebuliser. The pharmaceutical industry should endeavour to improve the administration device to overcome limitations of coordination and breathing of the PLWD, or develop a better formulation. The dosing accuracy and coordination ability of the PLWD should be considered in the pharmaceutical product design stage of inhaler and spacer devices. There is the potential of achieving therapeutic outcomes that can be met by another route of administration, such as developing a parenteral formulation.

As discussed in earlier sections, swallowing difficulties can be overcome with the design and development of improved formulations, such as ODTs, ODFs and multi-particulates. In addition, it should be recognised that older people may require flexible doses so tablets are sometimes broken in half (or for ease of swallowing). Tablets should not fragment and be easier to manipulate (European Medicines Agency, 2015; van Riet-Nales et al., 2016). To avoid confusion when medications are changed between manufacturers, the EMA has encouraged companies producing generic medications to adopt similar appearances regarding medications (such as colour, size and shape), which is advocated by the community participants (European Medicines Agency, 2017). Below are specific recommendations from the present study to the pharmaceutical industry. These recommendations add to a growing body of knowledge to inform future pharmaceutical developments:

- The development of formulations that provide flexible doses (such as multi-particulates)
- Consider the size of SODF (small SODF may be easier to swallow but they are difficult to handle)
• Develop more formulations for PLWD that overcome swallowing difficulties (such as ODTs and ODFs)
• The development of common medications in a variety of formulations to suit preferences (such as SODF, liquids, etc.), as focusing only on developing liquids may not always be appropriate as they may not always be acceptable
• Develop medications with less frequent dosing (such as in sustained or modified release)
• Develop user-friendly packaging (such as safe foil backing) that is able to be used by caregivers and PLWD with reduced manual dexterity
• Ensure leaflets have simplified instructions and contain relevant information including modifying medications (such as addition with food), interactions with food, and the implications of changing the dose time.
• Ensuring tablets that can be halved and do not fragment
• Focusing on designing dementia-friendly inhalers and devices (such as spacer devices that are acceptable)
• Develop formulations that overcome issues with the route of administration (such as pessaries, eye drops, etc.)
8.5. Future direction of research

Some of the recommendations and interventions suggested require further research to assess their feasibility and validity. With regards to the FCMAHS, future research should include adapting it for caregivers of PLWD based on the recommendations seen previously. Furthermore, its ability to assess caregiver burden in this patient population and to study the tool’s sensitivity to changes should also be assessed. The adapted tool can be used to assess the effectiveness of interventions that lower caregiver burden related to medication use. It is important to assess caregiver burden regularly to ensure caregivers and PLWD are supported. The first step after adapting the new tool is to pilot it in a sample population; this sample can be recruited from the Alzheimer’s Society. The participants would also be interviewed to assess the wording of the questions in the tool and face validity. The tool can then be revised based on the participants’ interviews.

Patient and public involvement should also be used in designing information services and support and assessing their acceptability by PLWD and their caregivers. This can be undertaken with a public engagement event inviting caregivers and PLWD to discuss the recommendations of this study (information leaflets, improved consultations, tailored MURs).

Future work should also focus on implementing the recommendations seen in section 8.4.1 concerning designing and testing a simple guideline to be used by GPs in consultations with PLWD and their caregivers. Focus groups with GPs can be conducted to assess the feasibility of its use and acceptability of its wording. After adapting the tool following their feedback, it can be piloted in a sample of GP surgeries and the GPs interviewed to assess its ease of use. Furthermore, caregivers and PLWD who attend these consultations can be asked to be interviewed to evaluate the effectiveness and acceptability of this guideline. The same can be done with the adapted MUR tool (section 8.4.1.). There should also be a focus on developing a methodology and tool to assess PLWD and caregivers’ acceptability of formulations to assist in prescribing appropriate formulations. Pharmacists may also be able to assess the acceptability of medications using the medication acceptability questionnaire (MAQ) which has been tested by pharmacists within the pharmacy environment on older patients (Liu et al., 2016).
Research should study the feasibility and effectiveness of these interventions in optimising medication use and alleviating caregiver burden. The adapted FCMAHS can be used before and after these interventions to assess their ability in alleviating caregiver burden. Furthermore, perspectives from HCPs, PLWD and their caregivers gathered to update the content and/or operational aspects of these interventions.

Future research should focus on interventions with a wider scope that do not focus on adherence but on the medication use process to improve medicines use for this population. An example of a successful intervention was the inclusion of home visits and telephone counselling by nurses and social workers for caregivers of PLWD (Lingler et al., 2016). Content of the intervention included caregiver responsibilities in medication management, common problems in medication administration/taking, preventing medication errors, talking to HCPs about medications, community resources, contingency planning and changes in medication taking. Caregiver interventions to reduce burden are most effective when they can be tailored; examples include information about dementia, guidance on decision-making, and advice about managing the PLWD (Beinart et al., 2012). A similar intervention can be tested in a sample of PLWD and their caregivers from the community.

In the care home setting, the interventions recommended previously should be assessed for their feasibility. The recommendations can be piloted in a sample of care homes, and staff interviewed afterwards to evaluate them. Assessing whether staff have implemented a person-centred approach is through the use of a validated tool. The CARES observational tool can be used by another HCP, such as pharmacist, to audit and assess staff approach (Gaugler et al., 2013).

As the researcher is from Kuwait, future research in the Middle East context is also of importance. A short discussion can be found in Appendix 16.
8.6. Conclusion

Medication use in PLWD is a complex process and is influenced by a variety of medication and person-related factors. The progression of dementia and care setting also impose changes on medication use. The study has identified challenges to medication use in PLWD and their caregivers along dementia progression. Conceptual models were developed to highlight these challenges in each care setting, as well as along dementia progression, and solutions suggested to overcome them. The main findings and recommendations are outlined below.

What is already known:

- Medication management is a complex process in PLWD and involves a family caregiver for assistance.
- Caregivers of PLWD take on a challenging role and have higher burden scores that those of other older people. 
- Challenges to medication use in this patient population are known regarding the administration and management of medications, such as issues with behaviour and scheduling logistics.

What this study adds:

- The study demonstrated the decision-making process regarding the choice of formulation, and provided ways to help PLWD and their caregivers with self-management.
- The findings demonstrated how a tool (FCMAHS) can be adapted to ensure all domains concerning PLWD and their caregivers can be reflected, which can be used as a measurement or diagnostic tool for caregivers of PLWD. 
- Engaging the PLWD will lead to effective therapy, and findings identified strategies in both community and care home settings to involve them in the medication use process.

A variety of changes occur along the dementia trajectory that need to be addressed at 3 stages; prescribing, scheduling and administering medications. The findings have demonstrated that these changes do not have uniform presentation, but are variable and may occur at any stage. Examples include the impact of swallowing difficulties on medication use; inappropriate formulations are prescribed which led to modifying
or omitting medications by PLWD and their caregivers. Key concerns include appropriateness of formulations (from the medication to the packaging) as dementia declines and physical abilities of PLWD and their caregivers’ decline (eye sight, manual dexterity, swallowing ability). HCPs need to assess swallowing ability, issues when handling medications and packaging, and issues concerning formulation characteristics such as taste, texture, colour, size and quantity. The ease of use by the caregiver should also be considered, as they administer medications in most cases.

The caregivers’ burden also changes along the dementia trajectory and HCPs need to address their own health needs as they themselves are getting older and require support with their medication-role. Previous studies have indicated this, but have not elaborated on how to alleviate caregiver burden in light of dementia progression. Focusing on the caregivers’ accounts and understanding caregiver burden in relation to their medication role, as well as their relationship with the PLWD and transition in their role, has identified where challenges are experienced. Areas identified from the current findings that may assist in alleviating caregiver burden include preparing caregivers for the medication-related activities and anticipating how their responsibilities may change as dementia progresses (such as changing how medications are administered to fit their and the PLWD’s needs), discussing with caregivers the position of the PLWD’s autonomy within the medication use process and recommending medication management strategies that respect the PLWD’s autonomy, including caregivers in consultations and decisions about the PLWD’s medications, meeting the caregivers’ informational needs relating to medications to support decision-making at home, and ensuring caregivers are coping well with the PLWD’s regimen, such as fitting it in their daily routine. The findings have identified what information is needed by caregivers and PLWD which include information concerning the addition of and/or change in medications and why, alternative formulations in case a switch is required, the correct modification of medication if required, side effects and how to identify them if the PLWD is unable to communicate effectively, and the effectiveness and need for medications.

Changes to caregiver burden associated with medication use can be identified using a tailored tool, which the present study has achieved by proposing additions to the Family Caregiver Medication Administration Hassles Scale (FCMAHS). These include recognising side effects if the PLWD is unable to communicate, having a
contingency plan if unable to administer medications, and administering medication to a PLWD with swallowing difficulties.

Respecting the PLWD’s autonomy at every stage of dementia, irrespective of their mental capacity, is essential in optimising medication use. PLWD’s autonomy was closely linked with the challenges associated with medication use; allowing them to be part of the process of organising and scheduling medications was advocated by participants. This is beneficial for strengthening the partnership between the caregiver and PLWD and sharing these responsibilities may alleviate caregiver burden. Involving PLWD in their medication decisions and providing them with choices increase their feelings of worth, and caregivers are central in enabling this. The findings from the present study provide insight into how care home staff endeavour to respect residents’ autonomy with medication administration by providing choices and subtle supervision. In addition, staff that adopted an individualised approach by understanding the residents’ preferences with how medications are administered and which formulations they preferred reported fewer issues with behaviour.

The findings have demonstrated that drug design should focus on the impairments of the PLWD. These include physical impairments as well as cognitive impairments. Medication characteristics prioritised by participants that require improvement include dose flexibility, route of administration (ease of administration), swallowability, instructions and formulation characteristics. Examples include the size of SODF which should be considered for manual dexterity, swallowing difficulties, and reduced eyesight (inability to swallow large sized SODF, while small SODF are difficult to handle and see). Cognitive impairments affect the ability to use inhalers, which was seen in both care settings, where instructions were difficult to understand and follow (even for family caregivers) and the PLWD’s inability to coordinate their breathing. Hence, the route of administration should also be considered in this patient population. Product packaging and the administration device are an integral part of drug design and have an impact on medication use. This was seen in both care settings where the packaging of some of the MCAs prepared by pharmacies posed difficulties for some family caregivers and even staff in care homes to retrieve the medications from, with some participants being injured and having to resort to using sharp objects to remove the backing. Dementia-friendly formulations should not be restricted to medications for dementia, such as multiparticulates, ODTs and ODFs that have been developed for donepezil. The same approach should be
applied to other commonly used medications in older people and PLWD, such as medications for cardiovascular diseases. The overall message is to ensure the PLWD and their caregivers are able to self-manage their medications without the need to resort to unsafe methods to modify these medications or their packaging (such as crushing tablets or adding medications to food) or completely missing their doses, in order to maintain optimal medication use.

The study has enabled the perspectives of family caregivers, PLWD and care home staff to contribute to recommendations for prescribing and administration of medicines for PLWD across settings to ensure that person-centred care is achieved. These informed recommendations aim to optimise medication use and alleviate caregiver burden.
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Appendix 1: Quality of reporting in the 12 included qualitative studies according to Consolidated Criteria for Reporting Qualitative Research (COREQ)

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<td>Clarity of minor themes</td>
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Appendix 2.1: PLWD consent form

Consent form for Care recipients

SCHOOL OF PHARMACY

Participant Identification Number for this study:

CONSENT FORM

Title of Project: Medicines for Older People with Memory Problems: Experiences of Patients and Caregivers

Name of Researcher: Dalal Alsaeed (PhD student)

1. I confirm that I have read the information sheet dated............... (version.........) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I agree to being audio-recorded, only the researcher will hear the recording

3. I agree to the use of quotes anonymously in any publication

4. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

5. (If appropriate) I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.

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

Name of Participant ___________________________ Date ___________________________ Signature ___________________________

Name of Person taking consent ___________________________ Date ___________________________ Signature ___________________________

When completed: 1 for participant; 1 for researcher site file.

PLWD consent form
Version 4
26/02/15
Appendix 2.2: Family caregiver consent form

Consent form for Caregivers

SCHOOL OF PHARMACY

Participant Identification Number for this study:

CONSENT FORM

Title of Project: Medicines for Older People with Memory Problems: Experiences of Patients and Caregivers

Name of Researcher: Dalal Alsaeed (PhD student)

1. I confirm that I have read the information sheet dated .......... (version ...........) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I agree to being audio-recorded, only the researcher will hear the recording

3. I agree to the use of quotes anonymously in any publication

4. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

5. (If appropriate) I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.

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

______________________________  __________________________  __________________________
Name of Participant            Date                          Signature

______________________________  __________________________  __________________________
Name of Person taking consent  Date                          Signature

When completed: 1 for participant; 1 for researcher site file

Caregiver consent form
Version 4
26/02/15
Appendix 2.3: Care home staff consent form

Consent form for Care home staff

UCL
SCHOOL OF PHARMACY

Participant Identification Number for this study:

CONSENT FORM

Title of Project: Medicines Use Optimisation in People Living with Dementia

Name of Researcher: Dalal Alsaed (PhD student)

Please initial box

1. I confirm that I have read the information sheet dated 26/02/2015 (version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I agree to being audio-recorded, only the researcher will hear the recording

3. I agree to the use of quotes anonymously in any publication

4. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

5. (If appropriate) I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.

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

________________________  __________________________  __________________________
Name of Participant       Date                      Signature

________________________  __________________________  __________________________
Name of Person taking consent  Date                      Signature

When completed: 1 for participant; 1 for researcher site file.

Care home staff consent form
Version 4
26/02/15
Appendix 3.1: Provisional ethics letter

Health Research Authority

NRES Committee South East Coast - Surrey
Bristol Research Ethics Committee Centre
Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT
Telephone: 0117 342 1380

10 February 2015

Professor Felicity Smith
Department of Practice and Policy
UCL School of Pharmacy
23-39 Brunswick Square
London
WC1N 1AX

Dear Professor Smith

Study Title: Medicines Use Optimisation in People Living with Dementia

REC reference: 15/LO/0177
IRAS project ID: 166149

The Research Ethics Committee reviewed the above application at the meeting held on 03 February 2015. Thank you to Miss Dalal Alsaeed for attending on your behalf to discuss the application.

The Committee thought the application was a really good piece of research.

Provisional opinion

The Committee would be content to give a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information set out below.

Authority to consider your response and to confirm the Committee’s final opinion has been delegated to the Chair.

Further information or clarification required

1. Make the following changes to the Care Home Staff Participant Information Sheet.
   a. Add a statement making clear to the participant the process to follow if they experience distress or become upset and what further support is in place to support them (to include contact names and numbers for the appropriate professionals).
b. Add a statement confirming the rules applicable to group interviews (i.e. confidentiality, allowing others to speak etc).

c. Under the heading “Who has reviewed the study?” replace the final sentence with “This study has been reviewed and received favourable opinion by South East-Coast Surrey Research Ethics Committee”.

2. Make the following changes to the Caregivers Participant Information Sheet:
   a. Add a statement making clear to the participant the process to follow if they experience distress or become upset and what further support is in place to support them (to include contact names and numbers for the appropriate professionals).
   b. Add a statement making clear to the participant the process to follow if bad practice is observed within the care home/home (to include contact names and numbers for the appropriate professionals).
   c. Add a statement confirming the rules applicable to group interviews (i.e. confidentiality, allowing others to speak etc).
   d. Under the heading “Who has reviewed the study?” replace the final sentence with “This study has been reviewed and received favourable opinion by South East-Coast Surrey Research Ethics Committee”.

3. Make the following changes to the PLWD Participant Information Sheet:
   a. Add a statement making clear to the participant the process to follow if they experience distress or become upset and what further support is in place to support them (to include contact names and numbers for the appropriate professionals).
   b. Add a statement making clear to the participant the process to follow if bad practice is observed within the care home/home (to include contact names and numbers for the appropriate professionals).
   c. Add a statement confirming the rules applicable to group interviewees (i.e. confidentiality, allowing others to speak etc).
   d. Under the heading “Who has reviewed the study?” replace the final sentence with “This study has been reviewed and received favourable opinion by South East-Coast Surrey Research Ethics Committee”.

4. Add a header to each Participant Information Sheet and Consent Form to make them easily identifiable.

5. Provide Lone Worker Policy.

If you would find it helpful to discuss any of the matters raised above or seek further clarification from a member of the Committee, you are welcome to contact the REC Manager, Miss Gemma Oakes on 0117 342 1380 or nrescommittee.secoast-surrey@nhs.net.

When submitting a response to the Committee, the requested information should be electronically submitted from IRAS. A step-by-step guide on submitting your response to the REC provisional opinion is available on the HRA website using the following link:
http://www.hra.nhs.uk/nhs-research-ethics-committee-rec-submitting-response-provisional-opinion/

Please submit revised documentation where appropriate underlining or otherwise highlighting the changes which have been made and giving revised version numbers and dates. You do not have to make any changes to the REC application form unless you have been specifically requested to do so by the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 20 March 2015.

Summary of the discussion at the meeting

- Social or scientific value; scientific design and conduct of the study

The Committee noted Miss Alsaeed was from Kuwait, an enquired whether the study findings would be translatable in Kuwait.

Miss Alsaeed confirmed this was not the case as the healthcare system was not the same there and the level of awareness was not available either.

The Committee were satisfied with Miss Alsaeed’s response.

- Care and protection of research participants; respect for potential and enrolled participants’ welfare and dignity

The Committee noted it was a very large and challenging study including participants living with dementia ("PLWD") on all spectrums; their carers, residential workers and nurses. The Committee enquired how the interviews would be conducted and whether they would take place in groups.

Miss Alsaeed confirmed participants would be encouraged to interview in groups but if that was not possible due to work constraints then participants would be interviewed individually at the care home.

The Committee were satisfied with Miss Alsaeed’s response.

The Committee enquired whether the PLWD would complete the Caregiver Activity Survey alongside the caregiver.

Miss Alsaeed confirmed only the family care group would complete the survey.

The Committee were satisfied with Miss Alsaeed’s response.

The Committee enquired whether PLWD would already be in medical care due to their condition.

Miss Alsaeed confirmed she would not know, but to contact the GP or to check medical records would involve further consent and take longer.

The Committee were satisfied with Miss Alsaeed’s response.
• Informed consent process and the adequacy and completeness of participant information

The Committee noted on the PLWD participant information sheet, Miss Alsaeed as well as the Caregiver would make the decision on whether PLWD participants had capacity to consent, and enquired how it would be established objectively.

*Misif Alsaeed confirmed prior to the first home visit, participants would receive an invitation letter and participant information sheet. At the first home visit, it would be checked with the participant alongside the caregiver that the participant had read it and understood their involvement. If concerns were raised about capacity to consent then they would not be recruited.*

The Committee were satisfied with Miss Alsaeed’s response.

The Committee stated there should be a process in place should bad practice be observed in the care home/home and confirmed this should be included in the participant information sheets.

*Miss Alsaeed confirmed this would be included.*

The Committee were satisfied with Miss Alsaeed’s response.

The Committee stated the following changes should be made to Care Home Staff Participant Information Sheet:

- Add a statement making clear to the participant the process to follow if they experience distress or become upset and what further support is in place to support them (to include contact names and numbers for the appropriate professionals).
- Add a statement confirming the rules applicable to group interviews (i.e. confidentiality, allowing others to speak etc).
- Under the heading “Who has reviewed the study?” replace the final sentence with “This study has been reviewed and received favourable opinion by South East-Coast Surrey Research Ethics Committee”.

The Committee stated the following changes should be made to Caregivers Participant Information Sheet:

- Add a statement making clear to the participant the process to follow if they experience distress or become upset and what further support is in place to support them (to include contact names and numbers for the appropriate professionals).
- Add a statement making clear to the participant the process to follow if bad practice is observed within the care home/home (to include contact names and numbers for the appropriate professionals).
- Add a statement confirming the rules applicable to group interviews (i.e. confidentiality, allowing others to speak etc).
- Under the heading “Who has reviewed the study?” replace the final sentence with “This study has been reviewed and received favourable opinion by South East-Coast Surrey Research Ethics Committee”.
The Committee stated the following changes should be made to Participant Information Sheet:

- Add a statement making clear to the participant the process to follow if they experience distress or become upset and what further support is in place to support them (to include contact names and numbers for the appropriate professionals).
- Add a statement making clear to the participant the process to follow if bad practice is observed within the care home/home (to include contact names and numbers for the appropriate professionals).
- Add a statement confirming the rules applicable to group interviewees (i.e. confidentiality, allowing others to speak etc.).
- Under the heading "Who has reviewed the study?" replace the final sentence with "This study has been reviewed and received favourable opinion by South East-Coast Surrey Research Ethics Committee".

Suitability of supporting information

The Committee enquired whether the HASSLES Questionnaire was a validated questionnaire.

Miss Alsaeed confirmed this was the case.

The Committee were satisfied with Miss Alsaeed’s response.

The Committee stated as the caregiver interviews would take place at home that a Lone Worker Policy was required.

Miss Alsaeed confirmed she would provide that.

The Committee were satisfied with Miss Alsaeed’s response.

Other general comments

The Committee noted the Protocol [pg 17] noted the terms ‘carer’ or ‘caregiver’ would not be used but the term ‘caregiver’ was referred to throughout the participant documentation.

Miss Alsaeed apologised for the confusion and confirmed it was in relation to the term ‘unpaid caregiver’ as it had negative connotations towards it, as indicated a lack of appreciation and further confirmed only ‘carer’ or ‘caregiver’ would be used.

The Committee were satisfied with Miss Alsaeed’s response.

Other ethical issues were raised and resolved in preliminary discussion before your attendance at the meeting.

Documents reviewed

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<td>Participant information sheet (PIS) [Participant information leaflet for care home staff]</td>
<td>2</td>
<td>18 November 2014</td>
</tr>
<tr>
<td>Participant information sheet (PIS) [Participant information leaflet for caregivers]</td>
<td>2</td>
<td>18 November 2014</td>
</tr>
<tr>
<td>Participant information sheet (PIS) [Participant information leaflet for PLWD]</td>
<td>2</td>
<td>18 November 2014</td>
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<td></td>
<td>14 January 2015</td>
</tr>
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<td>Referee's report or other scientific critique report [Peer review]</td>
<td></td>
<td>08 December 2014</td>
</tr>
<tr>
<td>Research protocol or project proposal [Research protocol]</td>
<td>3</td>
<td>02 December 2014</td>
</tr>
<tr>
<td>Summary CV for Chief Investigator (CI) [Felicity Smith's CV]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary CV for student [Dalal Alsaedi's CV]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary CV for supervisor (student research) [Mine Orlu-Gul's CV]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary, synopsis or diagram (flowchart) of protocol in non-technical language [Flowchart of protocol]</td>
<td>2</td>
<td>14 November 2014</td>
</tr>
<tr>
<td>Validated questionnaire [Family Caregiver Medication Administration Hassles Scale]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Validated questionnaire [The Caregiver Activity Survey]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet

There were no Declarations of Interest.
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

15/LO/0177  Please quote this number on all correspondence

Yours sincerely

pp Prof David Russell-Jones
Chair

Email: nrescommittee.secoast-surrey@nhs.net

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments.

Copy to: Ms Suzanna Emerton, Suzanna.Emerton@uclh.nhs.uk
Appendix 3.2: Final ethics letter

Health Research Authority

NRES Committee South East Coast - Surrey
Bristol Research Ethics Committee Centre
Whitefiars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT

Telephone: 0117 342 1380

17 March 2015

Professor Felicity Smith
Department of Practice and Policy, UCL School of Pharmacy
29-39 Brunswick Square, London
WC1N 1AX

Dear Professor Smith

Study title: Medicines Use Optimisation in People Living with Dementia
REC reference: 15/LO/0177
IRAS project ID: 166149

Thank you for your letter of 27 February 2015, responding to the Committee’s request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this 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 the REC Manager, Miss Gemma Oakes, nrescommittee.secoast-surrey@nhs.net. 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.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.
Conditions of the favourable opinion

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

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NIHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).
### Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covering letter on headed paper [Covering Letter to REC]</td>
<td></td>
<td>14 January 2015</td>
</tr>
<tr>
<td>Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)</td>
<td>(Ref: B1262 F10153314)</td>
<td>14 July 2014</td>
</tr>
<tr>
<td>Interview schedules or topic guides for participants [Care home staff topic guide]</td>
<td>2</td>
<td>14 November 2014</td>
</tr>
<tr>
<td>Interview schedules or topic guides for participants [Caregiver topic guide]</td>
<td>2</td>
<td>14 November 2014</td>
</tr>
<tr>
<td>Interview schedules or topic guides for participants [PLWD topic guide]</td>
<td>2</td>
<td>14 November 2014</td>
</tr>
<tr>
<td>IRAS Checklist XML [Checklist_27022015]</td>
<td></td>
<td>27 February 2015</td>
</tr>
<tr>
<td>Letter from sponsor [Letter from sponsor]</td>
<td></td>
<td>03 November 2014</td>
</tr>
<tr>
<td>Letters of invitation to participant [Care home invitation letter and reply slip]</td>
<td>2</td>
<td>21 November 2014</td>
</tr>
<tr>
<td>Letters of invitation to participant [Care home staff invitation letter and reply slip]</td>
<td>3</td>
<td>02 December 2014</td>
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<td>Letters of invitation to participant [Caregiver invitation letter and reply slip]</td>
<td>3</td>
<td>02 December 2014</td>
</tr>
<tr>
<td>Letters of invitation to participant [Carer centre invitation letter and reply slip]</td>
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<td>21 November 2014</td>
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<tr>
<td>Letters of invitation to participant [PLWD invitation letter and reply slip]</td>
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<tr>
<td>Other [Care home profile]</td>
<td></td>
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<tr>
<td>Other [Data collection tool]</td>
<td></td>
<td>14 November 2014</td>
</tr>
<tr>
<td>Other [Covering letter to REC after amendments to supporting documents]</td>
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<td>27 February 2015</td>
</tr>
<tr>
<td>Participant consent form [Care home staff consent form (clean version)]</td>
<td>version 4</td>
<td>26 February 2015</td>
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<tr>
<td>Participant consent form [Care home staff consent form (with tracked changes)]</td>
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<td>26 February 2015</td>
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<tr>
<td>Participant consent form [Caregivers consent form (clean version)]</td>
<td>4</td>
<td>26 February 2015</td>
</tr>
<tr>
<td>Participant consent form [Caregivers consent form (with tracked changes)]</td>
<td>4</td>
<td>26 February 2015</td>
</tr>
<tr>
<td>Participant consent form [PLWD consent form (clean version)]</td>
<td>4</td>
<td>26 February 2015</td>
</tr>
<tr>
<td>Participant consent form [PLWD consent form (with tracked changes)]</td>
<td>4</td>
<td>26 February 2015</td>
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<tr>
<td>Participant information sheet (PIS) [Participant information leaflet for care home staff (clean version)]</td>
<td>3</td>
<td>26 February 2015</td>
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<tr>
<td>Participant information sheet (PIS) [Participant information leaflet for care home staff (with tracked changes)]</td>
<td>3</td>
<td>26 February 2015</td>
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<tr>
<td>Participant information sheet (PIS) [Participant information leaflet for caregivers (clean version)]</td>
<td>3</td>
<td>26 February 2015</td>
</tr>
<tr>
<td>Participant information sheet (PIS) [Participant information leaflet for caregivers (with tracked changes)]</td>
<td>3</td>
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</tr>
<tr>
<td>Participant information sheet (PIS) [Participant information leaflet for PLWD (clean version)]</td>
<td>3</td>
<td>26 February 2015</td>
</tr>
</tbody>
</table>
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at

http://www.hra.nhs.uk/hra-training/
With the Committee’s best wishes for the success of this project.

Yours sincerely

Prof David Russell-Jones
Chair

Email: nrescommittee.secoast-surrey@nhs.net

Enclosures: “After ethical review – guidance for researchers” [SL-AR2]

Copy to: Ms Suzanna Emerton, Suzanne.Emerton@uclh.nhs.uk
Appendix 4.1: Alzheimer’s Society application form

Research with service users: Application form

All applicants please note:

- The principal investigator must be sponsored by a UK based recognised higher education learning institute (e.g. a University)
- The principal investigator must be studying at PhD level OR has already achieved a PhD Or higher Clinical qualification or we can offer, alternatively we can process your application to post on Talking Point
- The project must have received ethics consent
- The project must be of local interest and show benefit or value to the Society
- The applicant must prove sufficient experience of working with vulnerable adults, knowledge of the intricacies of working with people with dementia and/or their carers and empathy towards the challenges associated with living with dementia
- Please submit the form to research@alzheimers.org.uk

Please attach with your application form:
- Proof of DBS clearance for working with vulnerable adults
- Any additional information which will enhance your application.
- ALL attachments and supporting documentation and the final letter of consent.

Date submitted:

<table>
<thead>
<tr>
<th>Principal Applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title and full name</td>
</tr>
<tr>
<td>Institution</td>
</tr>
<tr>
<td>Post held</td>
</tr>
<tr>
<td>Department and address</td>
</tr>
<tr>
<td>Contact details</td>
</tr>
</tbody>
</table>

If you are a student please state the degree you will attain on completion of this research project

PhD

Please note: if you are below PhD level your application will be processed as an application to post on Talking Point. We cannot offer you recruitment through our services

Please list other applicants and institutes involved in:

<table>
<thead>
<tr>
<th>Applicant</th>
<th>Institute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professor Felicity Smith</td>
<td>UCL School of Pharmacy</td>
</tr>
<tr>
<td>Research title</td>
<td>Medicines Use Optimisation in People Living with Dementia</td>
</tr>
<tr>
<td>----------------</td>
<td>----------------------------------------------------------</td>
</tr>
<tr>
<td>Does this research have ethics approval from NRES?</td>
<td>Yes / No</td>
</tr>
<tr>
<td>If yes, please include a full scanned copy of the IRAS application including ALL attachments and supporting documentation and the final letter of consent.</td>
<td></td>
</tr>
<tr>
<td>Research dates</td>
<td>Start date: 15/04/2015 Finish date: 01/10/2016</td>
</tr>
<tr>
<td>Participants (please circle all that apply)</td>
<td>Staff Volunteers Persons with dementia Carers Family members None</td>
</tr>
<tr>
<td>Please detail the areas where you are aiming to recruit participants (i.e. town/city/region)</td>
<td>Hackney and City, London Westminster, London Croydon, London</td>
</tr>
<tr>
<td>Is funding allocated to supporting any costs incurred by the Society in the application?</td>
<td>Yes / No</td>
</tr>
<tr>
<td>Have you contacted anyone within Alzheimer's Society about the proposal?</td>
<td>Yes / No</td>
</tr>
<tr>
<td>If yes, please provide contact details and dates</td>
<td></td>
</tr>
<tr>
<td>Are there any conflicts of interest? (e.g. do you work or volunteer at the Society?)</td>
<td>No</td>
</tr>
<tr>
<td>How specifically do you hope that Alzheimer's Society will be involved?</td>
<td>I hope that the Alzheimer's Society will assist in recruitment of persons with dementia and their family caregivers by identifying eligible participants and passing on to them a letter package prepared by the researcher</td>
</tr>
<tr>
<td>When do you expect Alzheimer's Society involvement to start and finish?</td>
<td>Start date: 07/07/2015 Finish date: 01/10/2016</td>
</tr>
<tr>
<td>How do you intend to feed back the results to participants?</td>
<td>A summary of the findings will be sent to participants at the end of the study</td>
</tr>
<tr>
<td>Why do you consider Alzheimer's Society to be an appropriate partner for your research proposal?</td>
<td>The Alzheimer's Society is an appropriate partner for recruitment, as it is a large organisation dedicated to people living with dementia and their caregivers. As a major research and support charity, with branches all over London, the society will be able to offer a diverse sample of people who are willing and able to be included in research.</td>
</tr>
<tr>
<td>Please detail your experience of working with people with dementia or other vulnerable groups</td>
<td>I have conducted a group discussion with elderly caregivers, as well as facilitated in 2 public engagement events with older people.</td>
</tr>
</tbody>
</table>
Summary of project

Please include project aim and objectives, a detailed methodology (including recruitment, anticipated number and location of participants) and details of dissemination plans to a maximum of 1000 words.

Please attach all appropriate documents with your submission including:
- consent forms
- information forms
- questionnaires
- interview templates

The aim is to identify the challenges to optimal therapy from the perspective of people living with dementia (PLWD), at different levels of disease severity, and their caregivers in both the community and care home setting, help maintain optimal therapy for this patient population and make recommendations for assistance for patients and carers to help alleviate carer burden and improve the patients’ quality of life. The objectives include: to identify the frequency, range and acceptability of medicines and dosage forms used at the different settings and any transition in dosage forms used (e.g. tablets/capsules to liquids to patches); to gather PLWD and caregivers views and experiences of medicines use and the perceived advantages and difficulties in the community; to understand problems faced by family carers at home and nursing/carer staff in care homes regarding barriers to optimal therapy and medicines administration to PLWD and the support available to them; to identify if PLWD in the community have difficulties swallowing medicines and its impact on them, their family carers, and nursing/carer staff in care homes; to identify changes in the caregivers’ and care recipients’ role regarding medicines management and support needs required at different stages of their journey and patients’ disease severity and the problems encountered managing medicines as the disease progresses and its impact on them and the care recipient; to understand service use and support uptake, relating to medicines use, from the patients’ and family carers’ point of view in the community and what changes need to be made; to produce tailored recommendations to overcome barriers to maintain optimal medicines use, improve clinical outcomes and alleviate caregiver burden.

Semi-structured interviews will be conducted with PLWD and their family caregivers living in the community, including open and structured questions. PLWD will not be included in any group interviews; some may have been recently diagnosed and they may find it difficult to talk about certain issues in front of others. Interviews will be conducted at a place of the participants’ convenience, which most likely will be their home. The interviews will be done separately with each of them, but this can be flexible and be done together if the patient does not feel comfortable. Interviews will be anticipated to last between 20-40 minutes. A request will be made to audio-record the interviews using a digital audio-recording device, then transcribed later by the researcher. Those who do not wish to be audio-recorded will not be excluded, but the researcher will take notes during their interview.

As this study focuses on medicines use and one of the objectives is to understand its impact on the caregiver, the tool chosen is the Family Caregiver Medication Administration Hassles Scale (FCMAHS) (Travis et al., 2003). Other information to be gathered includes patient and caregiver sociodemographic characteristics. The present study will not use a scale to measure disease severity. This is because some scales, such as the MMSE, can be upsetting to PLWD. The number of hours spent caregiving can be used to determine the severity of the patient’s disease. This can be retrieved by providing the family caregivers the Caregiver Activity Scale to fill (Davis et al., 1997).
Three different boroughs in the London area have been chosen for this study; Croydon, Westminster and Hackney. Purposive sampling will be employed to ensure that the participants are relevant to fulfill the research objectives. A starting sample of 30 caregivers of PLWD in the community, and if possible the people they are taking care of (approx. 10), is enough to achieve the objectives.

Eligibility criteria for PLWD:
- Having mild cognitive impairment (MCI) or dementia
- Lives at home
- English speaking
- Participant is willing and able to give informed consent for participation in the study.

Eligibility criteria of family caregivers:
- Male or female aged ≥18 years old
- Family caregiver (unpaid)
- English speaking
- Must provide some assistance to the patient with medicines use, even if minimal
- Participant is willing and able to give informed consent for participation in the study.

Recruitment of the PLWD and their family caregivers living in the community will be conducted through carer centres and groups local to each borough chosen by the researcher. The managers of the centres will be initially contacted by the researcher by telephone/email to introduce the study and establish whether they would like to take part in the study. If the manager agrees to the study taking place, letter packages will be given by the manager to staff at the centres to be distributed by them to eligible caregivers. The researcher will inform the manager of the eligibility criteria. It will be made clear to the manager to inform staff distributing the letter packages to eligible caregivers that participation is voluntary and there is no obligation to participate if they take the letter package. The letter package contains separate invitation letters for the caregivers and the PLWD they take care of, with reply slips and information leaflets; the caregiver will make the decision about whether the care recipient is able to participate before giving them the invitation letter and information leaflet. The leaflets will explain the purpose of the study, what the participant’s involvement will be, confidentiality issues, a picture of and information about the researcher, and the participant’s rights. The eligible caregivers and the PLWD they take care of will have all the information in advance and have time to make a decision. Interviews can be arranged for those who have consented to be included, by returning the reply slip in a prepaid envelope or by directly contacting the researcher. Those who have consented will be telephoned for confirmation and to set an interview date. Written consent from both the patient and caregiver will be taken on the day of the interview.

Dissemination of the findings will be through various methods; publication in scientific journals, presentation at conferences, and summary of findings will be distributed to participants who wish to see them. We will acknowledge the Alzheimer’s Society in our publications.
Appendix 4.2: DBS check
Appendix 5.1: Contents of letter package for PLWD

Invitation Letter

Study Title: Medicines for Older People with Memory Problems: Experiences of Patients and Caregivers (A UCL School of Pharmacy research study)

Dear Care recipient,

A research team from University College London (UCL) School of Pharmacy have asked us to distribute the enclosed letter package to some of the caregivers at our centre, and those they provide care for, who may be suitable to participate in their study. This study is being undertaken as part of a PhD degree.

What is the purpose of the study?

The purpose of the study is to identify the experiences and problems of people with memory problems and their caregivers, both family and care home staff, with any aspect of using or assistance with medicines and any preferences regarding different types of medicines. The researchers would like to discuss and understand the type of issues faced by people with memory problems when taking medicines, as well as issues faced by their caregivers when giving medicines such as taking/giving a variety of medicines several times a day, difficulty swallowing different forms of medicines (e.g. capsules, tablets, liquids) and problems with managing medicines.

What does your participation involve?

The researchers are working with a number of carer centres and care homes to invite caregivers and care recipients to take part. You have been invited to take part in this study as gaining your views and experiences is important. Healthcare professionals are not always aware of care recipient and caregiver experiences when taking and giving medicines.

What happens to the information you give?

If you consent, an interview will be done at a place of your choice. This will be audio-taped and transcribed by the main researcher. The purpose of audio-taping the discussion is to be able to acquire all the information given while focusing on the discussion without taking extensive notes. All information will be kept anonymous and confidential, and the audio-tape will be erased as soon as the discussion is transcribed.
Please find enclosed:

1. An information sheet about the study; and
2. A reply slip; and
3. A stamped addressed envelope to return the reply slip

If you would like to join the study, or have any questions regarding this study, please contact the researcher (Dalal Alsaeed), a PhD student at UCL School of Pharmacy, by:

1. Filling in the reply slip and posting it back to Dalal (no stamp is needed); OR
2. Telephoning Dalal on __________________ OR
3. Sending an email to Dalal: dalal.alsaeed.12@ucl.ac.uk

Please note that UCL researchers do not and will not have any personal details of who this letter is being sent to until you return the form to Dalal expressing a willingness to be contacted.

Yours sincerely,

Dalal Alsaeed
REPLY SLIP

If you would like to take part in this study, please fill in the information below.

Your name (please print)..............................................................................................................

Your telephone number...................................................................................................................

The best time to call...........................................................................................................................

Please return this reply slip in the pre-paid envelope provided
(no stamp required)

Thank you for your time
Will doing the research help you?

- The information collected will help healthcare professionals and people providing medication-related assistance to people with memory problems in understanding the issues involved and provide better support in the future to ultimately make medicine use acceptable for the patient.

What will happen when the study ends?

- The results of this study will be published as a report that will be available online and in journal articles.
- No participant will be identifiable in published reports.
- Copies of the report can be provided for you after the study is complete. If you are interested in receiving one, please contact Dalal by phone, email or letter.

Who has reviewed the study?

- All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and received favourable opinion by South-Coast Surrey Research Ethics Committee.

Would you like more information or would like to take part in this study?

Contact details:
Dalal Alsaeed (MPharm MSc)
PhD student
UCL School of Pharmacy
20-39 Brunswick Square
London WC1N 1AX

Email:
dalal.alsaeed.12@ucl.ac.uk

Phone:

Research team contact numbers:

Participant information leaflet for Care recipients

SCHOOL OF PHARMACY

Medicines for Older People with Memory Problems: Experiences of Patients and Caregivers

ARE YOU INTERESTED IN HELPING IN A RESEARCH STUDY?
Summary:
- We would like to talk to people with memory problems who receive assistance taking their regular medicines.
- We would also like to talk to the family caregivers providing assistance with medicines.
- Please read this leaflet carefully before deciding if you would like to participate in this study. Feel free to discuss this with other people.
- If you would like further information and/or would like to take part, please contact Dalal (details overleaf).

Why is this study being done?
- There are many older people in the community who require help with taking their medicines, especially those with memory problems. This help is usually from family, friends and some staff in care homes.
- We are interested in finding out what you find helpful and what problems you experienced when taking medicines to enable us to improve services relating to medicines use for others.
- This study is part of a PhD degree at UCL School of Pharmacy.

Who will be in this study?
- We are visiting care centres to invite family and friends who assist a person with memory problems taking their regular medicines at home;
- We are inviting people with memory problems receiving help with medicines at home through family and friends;
- We are visiting care homes and inviting staff who administer medicines to residents with memory problems to participate in this study.

What will happen in the study?
- After having been given the letter package (containing this leaflet, an invitation letter and a reply slip) from your caregiver, you can either return the reply slip attached, call, or email the researcher (Dalal Alsaheed), if you decide to participate in this study.
- We will set a date for an interview convenient to you to hear your experience with receiving assistance with your medicines and how they are used.
- Dalal will meet you, either at your home or at a place of your convenience, and ask you to sign a consent form. We anticipate the interview to last between 20-40 minutes. You will be asked about your experiences with receiving medicine-related care.
- You have the option of being interviewed individually or together with the person providing medicine-related assistance.
- The interview will be audio-recorded if agreeable to you, otherwise handwritten notes will be taken.
- You will be contacted once for an interview and if you agree, you will be contacted at a later date for a follow-up talk to see if there are any changes.

Participant information leaflet
for Care recipients

Will I be paid?
- No, we cannot pay you for your participation.

Do you have to take part?
- No, it is up to you if you would like to take part or not.
- If you decide to not take part, we will not contact you again.
- You can withdraw at any time during the study, without giving a reason. Your decision will not affect you or the person providing you care.

What if there is a problem?
- If you wish to complain or have any concerns about the way you were approached or treated by members of staff during this study, you can do so through an independent complaints mechanism through UCL (email research.incidents@ucl.ac.uk).
- Alternatively, if you have any concerns following the interview, you can contact Dalal or the other members of the research team to discuss them (contact details overleaf).

Who will know if you are in the study and what you talked about?
- All information collected from you will be anonymised and kept confidential; no information will be identifiable. Information will be kept secure electronically and on paper at University College London (UCL). The study will comply with the 1998 Data Protection Act.
- Only researchers involved in this study will be able to see the information.
- Should a cause for concern be identified, this will be discussed within the research team regarding the appropriate action.
Appendix 5.2: Contents of letter package for family caregivers

Invitation Letter

Study Title: Medicines for Older People with Memory Problems: Experiences of Patients and Caregivers (A UCL School of Pharmacy research study)

Dear Caregiver,

A research team from University College London (UCL) School of Pharmacy have asked us to distribute the enclosed letter package to some of the caregivers at our centre, and those they provide care for, who may be suitable to participate in their study. This study is being undertaken as part of a PhD degree.

What is the purpose of the study?

The purpose of the study is to identify the experiences and problems of people with memory problems and their caregivers, both family and care home staff, with any aspect of using or assistance with medicines and any preferences regarding different types of medicines. The researchers would like to discuss and understand the type of issues faced by people with memory problems when taking medicines, as well as issues faced by their caregivers when giving medicines such as taking/giving a variety of medicines several times a day, difficulty swallowing different forms of medicines (e.g. capsules, tablets, liquids) and problems with managing medicines. The researchers would also like to identify any ways or solutions that have been used to overcome any issues encountered and what support is available in the community for family caregivers with regards to medicines use.

What does your participation involve?

The researchers are working with a number of carer centres and care homes to invite caregivers and care recipients to take part. You have been invited to take part in this study as gaining your views and experiences is important. Healthcare professionals are not always aware of care recipient and caregiver experiences when taking and giving medicines. If possible, the researchers would also like to interview the person you are providing medicine-related assistance to. A separate letter, reply slip and information leaflet are enclosed; please provide them to the care recipient if they would like to participate.

What happens to the information you give?

If you consent, an interview will be done at a place of your choice. This will be audio-taped and transcribed by the main researcher. The purpose of audio-taping the discussion is to be able to acquire all the information given while focusing on the discussion without taking extensive notes. All information will be kept anonymous and confidential, and the audio-tape will be erased as soon as the discussion is transcribed.
Please find enclosed:

1. An information sheet about the study; and
2. A reply slip; and
3. A stamped addressed envelope to return the reply slip

If you would like to join the study, or have any questions regarding this study, please contact the researcher (Dalal Alsaeed), a PhD student at UCL School of Pharmacy, by:

1. Filling in the reply slip and posting it back to Dalal (no stamp is needed); OR
2. Telephoning Dalal on ___________ OR
3. Sending an email to Dalal: dalal.alsaeed.12@ucl.ac.uk

Please note that UCL researchers do not and will not have any personal details of who this letter is being sent to until you return the form to Dalal expressing a willingness to be contacted.

Yours sincerely,

Dalal Alsaeed
REPLY SLIP

If you would like to take part in this study, please fill in the information below.

Your name (please print) .................................................................

Your telephone number ............................................................... 

The best time to call ......................................................................

Please return this reply slip in the pre-paid envelope provided
(no stamp required)

Thank you for your time
Will doing the research help you?

• The information collected will help healthcare professionals and people providing medication-related assistance to people with memory problems in understanding the issues involved and provide better support in the future to ultimately make medicine use acceptable for the patient.

What will happen when the study ends?

• The results of this study will be published as a report that will be available online and in journal articles.
• No participant will be identifiable in published reports.
• Copies of the report can be provided for you after the study is complete. If you are interested in receiving one, please contact Dalal by phone, email or letter.

Who has reviewed the study?

• All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and received favourable opinion by South-Coast Surrey Research Ethics Committee.

Would you like more information or would like to take part in this study?

Contact details:
Dalal Alsaedd (MPharm MSc)
PhD student
UCL School of Pharmacy
29-39 Brunswick Square
London WC1N 1AX

Email:
dalal.alsaedd.12@ucl.ac.uk

Phone

Research team contact numbers:

ARE YOU INTERESTED IN HELPING IN A RESEARCH STUDY?
Summary:
- We would like to talk to people who help people with memory problems take their regular medicines
- We would also like to talk to the care recipient receiving the assistance with their medicines
- Please read this leaflet carefully before deciding if you would like to participate in this study. Feel free to discuss this with other people.
- If you would like further information and/or would like to take part, please contact Dalal [details overleaf]

Why is this study being done?
- There are many older people in the community who require help with taking their medicines, especially those with memory problems. This help is usually from family, friends and some staff in care homes.
- We are interested in finding out what you find helpful and what problems you experienced when giving medicines to enable us to improve services relating to medicines use for others.
- This study is part of a PhD degree at UCL School of Pharmacy

Who will be in this study?
- We are visiting care centres to invite family and friends who assist a person with memory problems taking their regular medicines at home;
- We are inviting people with memory problems receiving help with medicines at home through family and friends;
- We are visiting care homes and inviting staff who administer medicines to residents with memory problems to participate in this study.

What will happen in the study?
- After having been approached by carer centre staff and given the letter package (containing this leaflet, an invitation letter and a reply slip), you can either return the reply slip attached, call, or email the researcher (Dalal Alsaedi), if you decide to participate in this study.
- We will set a date for an interview convenient to you as a family member or friend providing help with medicines to a person with memory problems to learn about your thoughts and concerns with the assistance you are providing.
- If possible, we would also like to hear the care recipient’s experience with receiving assistance with their medicines and how they are used. Please provide them with the attached letter package addressed to the care recipient.
- Dalal will meet you, either at your home or at a place of your convenience, and ask you to sign a consent form. We anticipate the interview to last between 20-40 minutes. You will be asked about your experiences with providing medicine-related care.
- If the person you are caring for would also like to be interviewed, you have the option of being interviewed individually or together.
- You will be contacted once for an interview and if you agree, you will be contacted at a later date for a follow-up talk to see if there are any changes.

Participant information leaflet for Caregivers

Will I be paid?
- No, we cannot pay you for your participation.

Do you have to take part?
- No, it is up to you if you like to take part or not.
- If you decide to not take part, we will not contact you again.
- You can withdraw at any time during the study, without giving a reason. Your decision will not affect you or the person you are caring for.

What if there is a problem?
- If you wish to complain or have any concerns about the way you were approached or treated by members of staff during this study, you can do so through an independent complaints mechanism through UCL (email: research-incidents@ucl.ac.uk).
- Alternatively, if you have any concerns following the interview, you can contact Dalal or the other members of the research team to discuss them (contact details overleaf).

Who will know if you are in the study and what you talked about?
- All information collected from you will be anonymized and kept confidential; no information will be identifiable. Information will be kept secure electronically and on paper at University College London (UCL). The study will comply with the 1998 Data Protection Act.
- Only researchers involved in this study will be able to see the information.
- Should a cause for concern be identified, this will be discussed within the research team regarding the appropriate action.
Appendix 6.1: Care home manager invitation letter

[Date]

Dear [Care home name] Management,

Medicines Use Optimisation in People Living with Dementia
(A UCL School of Pharmacy research study)

We are currently conducting a study to better understand the use of medicines in people living with dementia. Research on the use of medicines in this patient population has been very minimal and has mainly focused on adherence. We are interested in understanding how medicines are being administered to people living with dementia in care homes and all the issues surrounding it. By gaining insight into how medicines are being administered and the concerns involved with this, we will be able to develop recommendations to optimise this process and therefore ensure the effective and safe delivery of medicines to dementia patients in care homes.

This study is being carried out independently by researchers from University College London, School of Pharmacy; the research in undertaken as part of a PhD degree.

We would like to invite your care home to participate in this study. Your participation requires the involvement of care home staff members that are looking after patients who are suffering from dementia in group discussions. This enables us to gain their perspectives on medicines administration within the dynamics of a group. If not possible, individual interviews can be done to accommodate staff. These discussions will be aimed to last a maximum of 40 minutes. In addition, the researcher will be involved in observing the process of medicines administration to dementia patients in the care home. This is to familiarise themselves with the procedures involved and will not affect the staff in any way. If you agree, I would like to arrange a convenient time to come and visit your care home to conduct the study.

An information leaflet has been enclosed with this letter which provides further information concerning the study. You may wish to read this and decide if you would like your care home to take part in this study. All information will be kept strictly confidential.

If you would like your care home to take part in the study, I would be most grateful if you would complete the reply slip attached to this letter and return it in the pre-paid envelope provided.
If you would like to further discuss taking part in the study before you complete the reply slip, then please feel free to contact me by telephone on - or please email dalal.alsaeed.12@ucl.ac.uk

I look forward to hearing from you.

Yours sincerely

Dalal Alsaeed, PhD student
Department of Practice and Policy,
University College London School of Pharmacy
Tel: -
Email: dalal.alsaeed.12@ucl.ac.uk
REPLY SLIP

Name of care home (please print)..........................................................................................

Your name (please print) ........................................................................................................

If you would like your care home to take part in the study please complete the following section so that I can contact you to arrange a suitable time for my visit and answer any questions you may have.

Your telephone number........................................................................................................

Your address..........................................................................................................................
...........................................................................................................................................

Please return this reply slip in the pre-paid envelope provided
(no stamp required)

Thank you for your time
Appendix 6.2: Contents of letter package for care home staff

[Date]

Invitation Letter

Study Title: Medicines Use Optimisation in People Living with Dementia
(A UCL School of Pharmacy research study)

Dear [care home name] staff member,

A research team from University College London (UCL) School of Pharmacy have asked us to distribute the enclosed letter package to some of the staff at our care home who may be suitable to participate in their study. This study is being undertaken as part of a PhD degree.

What is the purpose of the study?

The purpose of the study is to identify the experiences and problems of people with memory problems and their caregivers, both family and care home staff, with any aspect of using or assistance with medicines and any preferences regarding different types of medicines. The researchers would like to discuss and understand the type of issues faced by people with memory problems when taking medicines, as well as issues faced by their caregivers when giving medicines such as taking/giving a variety of medicines several times a day, difficulty swallowing certain formulations and problems with managing medicines. The researchers would also like to identify any ways or solutions that have been used to overcome any issues encountered and what support is available for staff with regards to medicines use.

What does your participation involve?

You have been invited to take part in this study as gaining your views and experiences as formal caregivers in care homes is important. There is little research on the problems encountered when administering medicines to patients with dementia. The researcher will be involved in observing the process of medicines administration to dementia patients in the care home. This is to familiarise themselves with the procedures involved and will not affect you in any way.

What happens to the information you give?

If you consent, the researcher will set up a date convenient to yourself to be either included in an individual or group interview. The discussion will be audio-taped and transcribed by the main researcher. The purpose of audio-taping the discussion is to be able to acquire all the information given while focusing on the discussion without taking extensive notes. All information will be kept anonymous and confidential and the audio-tape erased as soon as the discussion is transcribed.

Page 1 of 3
Please find enclosed:

1. An information sheet about the study; and
2. A reply slip; and
3. A stamped addressed envelope to return the reply slip

If you would like to join the study, or have any questions regarding this study, please contact the researcher (Dalal Alsaeeed), a PhD student at UCL School of Pharmacy, by:

1. Filling in the reply slip and posting it back to Dalal (no stamp is needed); OR
2. Telephoning Dalal on ____________________________ OR
3. Sending an email to Dalal: dalalalsaeeed.12@ucl.ac.uk

Please note that UCL researchers do not and will not have any personal details of who this letter is being sent to until you return the form to Dalal expressing a willingness to be contacted.

Yours sincerely,
REPLY SLIP

If you would like to take part in this study, please fill in the information below

Your name (please print)........................................................................................................

Name of care home (please print).........................................................................................

Care home address..................................................................................................................

..............................................................................................................................................

..............................................................................................................................................

Your telephone number...........................................................................................................

The best time to call...................................................................................................................

Please return this reply slip in the pre-paid envelope provided
(no stamp required)

Thank you for your time

Page 3 of 3  Care home staff invitation letter and reply slip
Version 3
2/12/14
Will doing the research help you?

- The information collected will help healthcare professionals and people providing medication-related assistance to people with memory problems in understanding the issues involved and provide better support in the future to ultimately make medicine use acceptable for the patient.

What will happen when the study ends?

- The results of this study will be published as a report that will be available online and in journal articles.
- No participant will be identifiable in published reports.
- Copies of the report can be provided for you after the study is complete. If you are interested in receiving one, please contact Dalal by phone, email or letter.

Who has reviewed the study?

- All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and received favourable opinion by South-Coast Surrey Research Ethics Committee.

Would you like more information or would like to take part in this study?

Contact details:
Dalal Alsaed (MPharm MSc) 
PhD student
UCL School of Pharmacy
29-39 Brunswick Square
London WC1N 1AX

Email: dalal.alsaed.12@ucl.ac.uk

Research team contact numbers:
Summary:
- We would like to talk to staff members involved in administering medicines to patients with dementia.
- Please read this leaflet carefully before deciding if you would like to participate in this study. Feel free to discuss this with other people.
- If you would like further information and/or would like to take part, please contact Dalal (details overleaf).

Why is this study being done?
- There are many older people in the community who require help with taking their medicines, especially those with memory problems. This help is usually from family, friends and some staff in care homes.
- We are interested in finding out what you find helpful and what problems you experienced when giving medicines to enable us to improve services relating to medicines use for others.
- This study is part of a PhD degree at UCL School of Pharmacy.

Who will be in this study?
- We are visiting care centres to invite family and friends who assist a person with dementia taking their regular medicines at home.
- We are inviting people with dementia receiving help with medicines at home through family and friends.
- We are visiting care homes and inviting staff who administer medicines to residents with dementia to participate in this study.

What will happen in the study?
- After having been approached by the care home manager and given a letter package (containing this leaflet, an invitation letter and a reply slip), you can either return the reply slip attached call, or email the researcher (Dalal Akheer), if you decide to participate in this study.
- The researcher will be visiting on a date set with the care home manager to observe the administration of medicines for 1 day. This is to familiarise herself with the procedures in each care home.
- We will set a date for an interview at a place and time convenient to you.
- Dalal will meet you, either at the care home or at a place of your convenience, and ask you to sign a consent form. We anticipate the interview to last between 20-40 minutes. You will be asked about your experiences with administering medicines to patients with dementia and the difficulties encountered.
- Depending on your time, these interviews can either be done individually or as groups of 2 or more.
- If you agree to participate in a group interview, please ensure that all information discussed is kept confidential. We would like to hear everyone's opinion, so please allow everyone to speak and give their views.

Participant information leaflet for care home staff

Will I be paid?
- No, we cannot pay you for your participation.

Do you have to take part?
- No, it is up to you if you like to take part or not.
- If you decide to not take part, we will not contact you again.
- You can withdraw at any time during the study, without giving a reason. Your decision will not affect you.

Will there be problems if you take part?
- As a care home staff member, being observed and/or participating in an interview will not affect your work in any negative or positive way.
- If you wish to complain or have any concerns about the way you were approached or treated by members of staff during this study, you can do so through an independent complaints mechanism through UCL (email: research_incidents@ucl.ac.uk).
- Alternatively, if you have any concerns following the interview, you can contact Dalal or the other members of the research team to discuss them (contact details overleaf).

Who will know if you are in the study and what you talked about?
- All information collected from you will be anonymised and kept confidential; no information will be identifiable. Information will be kept secure electronically and on paper at University College London (UCL). The study will comply with the 1998 Data Protection Act.
- Only researchers involved in this study will be able to see the information.
- Should a cause for concern be identified, this will be discussed within the research team regarding the appropriate action.
Appendix 7.1: PLWD interview schedule

Medicines Use Optimisation in People Living with Dementia

- Introduce myself and purpose of study and interview, discuss confidentiality to assure participants
- Review consent
- Before each topic, I will give a brief statement to introduce it before delving into the questions. The questions in each topic will not necessarily be in the same order; it depends on how the discussion goes.

- Ice breaker (no longer using as not necessary)
  1. What did you think expect when you were asked to take part in this interview? (This is to check understanding and consent and to establish rapport)

- Organisation and scheduling logistics
  2. Do you manage your medicines (prompt: obtaining, storing, tracking, scheduling)?
     a. If yes, what are your experiences (negative-positive)
     b. If no, who helps and what are their thoughts on assistance (negative-positive)

  3. What do you think about the medicines you are taking and how they are scheduled during the day?
     a. Prompt with number (how many), type and frequency of medicines
     b. What concerns do you have about your medications? (Ex: when taking outside home?)

- Medicine use and administration procedures
  4. What are your experiences with the medicines you are taking?
     a. Try to probe about any advantages/disadvantages that they perceive
     b. Probe about taste, shape, size, colour, brand Vs generic
     c. Probe about knowledge about what each medication is for and how it affects the medication use process
     d. Try to probe about different dosage forms (tablets, capsules, liquids, patches, inhalers, topical, O2, suppositories, pessaries), what was easy and what wasn’t
     e. Probe about any transition in formulations used (SODF-liquid-patches) and why
     f. Probe about the addition of new temporary or long term medications (such as antibiotics) and changes to medications (size, shape, colour, dose) without their knowledge and how it affects taking the medications
     g. What suggestions do you have from your point of view that would make taking medications easier/simpler?
5. You’ve discussed the variety of medications that you have been taking. Have you ever experienced difficulties swallowing the medications?
   a. Any specific formulations? (tablets and size, capsules and size, liquids and if syrup or suspension)
   b. Probe about impact on them and caregiver
   c. Probe about if anything was done about it such as telling GP or pharmacist, asking for different formulations, using thickeners or modifying medicines

6. What medication related support is available for you? How have your support needs changed over time? (since you first started requiring help with your medication until now)

   • Impact on PLWD and Partnership with caregiver
   7. You mentioned earlier that you are receiving help with managing your medicines.
      a. Tell me about the assistance you are receiving?
      b. Probe about how transitioned from self to carer-led
      c. How has this affected you?

8. How do you make decisions about medications with your caregiver?
   a. Can you elaborate on it further about your thoughts about it (even if it’s the same, how so? Is it working well?)

   • Interface with formal care
   9. Can you discuss that type of relationship you have with your GP, pharmacist and other HCPs?
      a. What needs improvement?

We are interested in helping older people with memory issues and those taking care of them to get the best out of their medicines, and gaining your views can shed light on different aspects. Is there anything else you feel we missed in our discussion that you would like to add?

Thank you for your time.

<table>
<thead>
<tr>
<th>Generic prompts:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Could you explain further?</td>
</tr>
<tr>
<td>Can you give an example/s?</td>
</tr>
<tr>
<td>Does anyone else have a similar experience?</td>
</tr>
<tr>
<td>In what ways?</td>
</tr>
<tr>
<td>Why do you think?</td>
</tr>
</tbody>
</table>

Page 2 of 2

PLWD topic guide
Version 2 (updated 5/5/2016)
Appendix 7.2: Family caregiver interview schedule

Medicines Use Optimisation in People Living with Dementia

- Introduce myself and purpose of study and interview, discuss confidentiality to assure participants
- Review consent
- Before each topic, I will give a brief statement to introduce it before delving into the questions. The questions in each topic will not necessarily be in the same order; it depends on how the discussion goes.

- Ice breaker (no longer using as not necessary)
  1. What did you think/expect when you were asked to take part in this interview? (This is to establish rapport)

- Organisation and scheduling logistics
  2. As a person assisting an older person with memory issues with their medicines, can you tell me about your experiences with the medicines you are managing/giving?
     a. Probe about obtaining, storing, tracking, scheduling (as well as alongside their own medications)
     b. Try to probe about any advantages/disadvantages that they perceive (what concerns do you have when managing/giving medications?)
     c. Try to probe about different dosage forms (tablets, capsules, liquids, patches, inhalers, topical, eye drops, O2, suppositories, pessaries), what was easy and what wasn’t
     d. Probe about handling medications (such as small tablets) and if using blister packs their thoughts about their use, and writing on labels and leaflets
     e. Probe about PLWD refusing/spitting/hiding in cheeks/chewing medications and how they deal with it
     f. Probe about PLWD knowledge about what medications are for and how it affects medication use
     g. Probe about giving/scheduling medications when outside home such as on outings/appointments/vacation
     h. Probe about the addition of new temporary or long term medications (such as antibiotics) and changes to medications (size, shape, colour, dose) with/out their knowledge and how it affects the managing of medications and administering them to the PLWD

3. What do you think about the number of medicines you are giving and how they are scheduled during the day?
   a. Prompt with number, type (dosage form) and frequency of medicines
   b. How many medications do you give?
   c. Probe about how often medications get reviewed by GP and their thoughts about it
   d. Probe about any changes made to medications and if so why? (in type of medication or transition in dosage form)

Page 1 of 3  Caregiver topic guide  Version 2 (updated 5/5/16)
e. Probe about generic Vs branded medications and issues surrounding it (taste, side effects, etc)

f. Probe about suggestions from experience/point of view that would make managing and giving medications easier/simpler

g. Probe about strategies developed to help them when managing/giving medications (like medications charts, laying out medications for PLWD, etc)

- Medicine use and administration procedures
  4. You’ve discussed the variety of medications that you have been giving. Does the person you are caring for ever experience any difficulties with swallowing the medicines?
    a. Any specific dosage forms? (tablets and size, capsules and size, liquids consistency)
    b. Probe about impact on them and PLWD
    c. Probe about if anything was done about it such as telling GP or pharmacist, asking for different formulations, using thickeners or modifying medicines/placing in food
    d. Probe about their thoughts/justification for modifying medications or covert administration

- Impact on caregiver and PLWD and their partnership

  5. When did your experience with providing assistance with medicines begin? What sort of things made you start?
    a. Do you recall any important situations/events/development that happened? These could be to yourself or the person you’re providing care for.
    b. How has the other person accepted your assistance? Probe about importance of autonomy and need for independence
    c. How do you perceive your role with providing assistance with medicines has changed? (Comparing from the beginning till now.)
      a. Relating to your role with medicines management? Ex: ordering medicines, medicine administration, etc.
      b. Relating to decision making on behalf of the patient about their treatment (how are medication-related decisions are made between them and the process behind it) elaborate on it
    d. How do you decide when the person with dementia needs a certain medication, such as those for pain relief? Do you have any concerns about them?
6. What means of support with medicines have you been receiving? (From beginning up till now, and prompt with the types available such as from GP or pharmacist or support groups).
   a. Are you aware of any other means of medicine support available for people taking care of people with memory problems that you might not have chosen?
   b. How is this provided?
   c. What do you think about ways to improve them?
   d. **Probe about support from memory clinics and if it is adequate**
   e. In your opinion, how do medicine supports needs change over time? (Ex: support needed at point of diagnosis differs than that needed later on along disease progression)
   f. What types of medicine support were needed at different times in your experience that you can reflect on?

7. How have your experiences with providing assistance with medicines had an impact on you/affected you or your daily life/had a change? (ex: time commitments, frequency of being with the patient, helping with administration of medicines, etc.)
   a. How have you handled these?
   b. How has your own health affected your role with providing help with medicines?

- **Interface with formal care**

8. Can you discuss the type of relationship you have with your GP, pharmacist and other HCPs?
   a. What needs improvement?

We are interested in helping older people with memory issues and those taking care of them to get the best out of their medicines, and gaining your views can shed light on different aspects. Is there anything else you feel we missed in our discussion that you would like to add?

Thank you for your time.

**Generic prompts:**

<table>
<thead>
<tr>
<th>Could you explain further?</th>
<th>What do you think are the reasons for?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can you give an example/s?</td>
<td>What other issues are important regarding this?</td>
</tr>
<tr>
<td>Does anyone else have a similar experience?</td>
<td>Does anyone have a different view?</td>
</tr>
<tr>
<td>In what ways?</td>
<td>How often?</td>
</tr>
<tr>
<td>Why do you think?</td>
<td>I would like now to move on to a different topic</td>
</tr>
</tbody>
</table>
Appendix 7.3: Care home staff interview schedule

Medicines Use Optimisation in People Living with Dementia

- Introduce myself and purpose of study and interview, discuss confidentiality to assure participants
- Review consent
- Before each topic, I will give a brief statement to introduce it before delving into the questions. The questions in each topic will not necessarily be in the same order; it depends on how the discussion goes.

- Ice breaker
  1. What did you think/expect when you were asked to take part in this interview? (This is to establish rapport)

- Medicines use and administration procedures
  2. As a nurse/carer administering medicines to people with dementia, tell me about your experiences with the medicines you are giving?
     a. Probe about the average number of medicines the residents are taking and the variety of dosage forms taken, which is the most common and least common
     b. Try to probe about any advantages/disadvantages that they perceive
     c. Try to probe about different formulations (tablets, capsules, liquids, patches, inhalers, topical, O2, suppositories, pessaries, mini tablets, orodispersible), what was easy and what wasn’t
     d. Try to probe about problems encountered with branded and generic medicines
     e. Try to probe about difficulties handling the medicines (such as small tablets) and packaging/containers/blister packs
     f. Try to probe about factors that make the time administering medicines longer
     g. Probe about issues encountered with new residents or those coming from hospital with new medicines
     h. Probe about how aggressive behaviour affects the medicines process and how they deal with it
     i. Probe about how their relationship/trust with the PLWD affects the medicine process
     j. Probe about importance of ensuring PLWD’s autonomy regarding medications
     k. Probe about how the PLWD feel about their medications based on how they take them
3. You’ve discussed the variety of medications that you have been giving. Does the person you are caring for ever experience any difficulties with swallowing the medicines?
   a. Any specific formulations? (tablets and size, capsules and size, liquids and if syrup or suspension)
   b. Probe about impact on them and PLWD
   c. Probe about if anything was done about it such as telling GP or pharmacist, asking for different formulations or a different drug from the same class that’s available in an appropriate formulation, using thickeners, or modifying formulation/covert administration in food
   d. Probe about their thoughts/justification for modifying medications or covert administration, if it’s done on the spot or beforehand, what might assist them, and which medicines (brands) that they usually modify
   e. Probe about reasons behind switching from one dosage form to another (do liquids pose a problem and is it always a solution?)

- Interface with formal care

4. What guidelines/procedures are available to assist you with problems/issues with medicines administration?
   a. Probe about their thoughts on improvements

5. How would you describe the role of the pharmacist within the care home?
   a. In what ways does the pharmacist assist in the medicines use process? How can they be more supportive of the care home?
   b. How often do you ask the pharmacist for help? What was the most recent interaction and what help was received?
   c. Probe about communication with the pharmacist/liaise with one person or more (if issues with communication with more than one source)

6. How does that healthcare team (GP, pharmacist, nurse) and interactions with them affect the medicines use process?
   a. Try to probe about any advantages/disadvantages that they perceive
   b. Try to probe about ways to improve
   c. Try to probe about how their role compares with other HCPs, and how their medicine duties compare to their other duties
7. Overall, from all the issues that we have discussed, what improvements/solutions would you suggest to make the medicines use process easier and better?

We are interested in helping older people with memory issues and those taking care of them to get the best out of their medicines, and gaining your views can shed light on different aspects. Is there anything else you feel we missed in our discussion that you would like to add?

Thank you for your time.

Generic prompts:

<table>
<thead>
<tr>
<th>Could you explain further?</th>
<th>What do you think are the reasons for?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can you give an example?</td>
<td>What other issues are important regarding this?</td>
</tr>
<tr>
<td>Does anyone else have a similar experience?</td>
<td>Does anyone have a different view?</td>
</tr>
<tr>
<td>In what ways?</td>
<td>How often?</td>
</tr>
<tr>
<td>Why do you think?</td>
<td>I would like now to move on to a different topic</td>
</tr>
</tbody>
</table>
Appendix 7.4: Family caregiver follow-up invitation letter and interview schedule

Follow-up Letter

Study Title: Medicines for Older People with Memory Problems: Experiences of Patients and Caregivers (A UCL School of Pharmacy research study)

Dear Caregiver/Care recipient,

My name is Dalal and I am a PhD student from University College London, School of Pharmacy. You may remember that I came to your home earlier this year to interview you and/or the person you’re providing care for about your experiences with medications.

After the interview, you kindly agreed for me to contact you at a later date for me to follow-up.

I would like to contact you by phone for a very short talk at a day and time convenient for you. I will just ask about any changes in medications, care provided, or overall experiences with medications since I talked to you last time.

As with the previous interview, all information provided will be kept anonymous and confidential.

You kindly provided me with your number and I plan to call you next week to set a day and time to have our chat. In the meantime, please feel free to call me/text me on [insert number] if you have any questions.

Yours sincerely,

Dalal Alsaeed
Follow up discussion:

1. Introduce myself again
2. Ask if anything has changed since then?
   a. Prompt about medications (have list in front of me) and dosage forms, reviewed recently
   b. Prompt about things that have become more difficult and how
   c. Prompt about things that have become easier and how
   d. Prompt about how dementia has progressed and how it has affected medication use
3. Refer to any things similar they said last time
4. Tell them important things said by other caregivers, and what they would like to add to that
Appendix 8: Table of caregiver burden measures

<table>
<thead>
<tr>
<th>Carer burden measure</th>
<th>(Author, year)</th>
<th>Population</th>
<th>Description of scale</th>
<th>Types of strain measured</th>
<th>Reliability</th>
<th>Disadvantages</th>
<th>Advantages</th>
</tr>
</thead>
</table>
| Caregiver Strain Index       | (Robinson, 1983)| Carers of elderly patients discharged from hospital with arteriosclerotic heart disease or hip surgery | 13-item inventory, scores range from 0-13 with no=0 and yes=1.                        | Perception of caregiving, care-recipient characteristics, and emotional status.                                                              | Has good internal reliability ($\alpha=0.86$) | *Can only answer yes or no
*Questions need to be clear
*Might not be applicable in dementia population
*does not measure subjective burden                                                                                                       | *Short
*Easy to administer
*Easy to score                                                                                                                             |
| Zarit Burden Interview       | (Zarit et al., 1985) | Carers of dementia patients                                                 | 22-item inventory, 5-point scale (ranging from never to nearly always present)       | Burden associated with functional and behavioural problems in the home care setting. Deals with issues relating to health, finance, social life, and interpersonal relationships. | Has high internal reliability ($\alpha=0.91$) | *The wording of the questions can mislead the carer’s emotions
*Focuses on the consequences of caregiving, need to use another checklist by the same authors to measure problems of the patient and stress relating to them.
*Lacks measure of caregiver-centred problems                                                                                               | *Can capture burden beyond that relating to impairment when used with the Memory and Behaviour Checklist, and offers a complete view of problems of the impaired elder and caregiver responses to these problems |
| Gillear Strain Index         | (Gilleard, 1984) | Carers of dementia patients                                                 | 13-item inventory, each rated from 1-3 (ranging from never to a great deal of time)   | Strain involved in caring for an elderly person, covering depression, worry, fear of accidents, restrictions on social life, demands by their dependent, and coping. | Has good internal reliability ($\alpha=0.87$) | *Not a highly sensitive measure to capture changes in burden
*Is not broad enough to capture all aspects of carer burden                                                                                     | *Short
*Easy to administer
*Easy to score                                                                                                                             |
<table>
<thead>
<tr>
<th>Carer burden measure</th>
<th>(Author, year)</th>
<th>Population</th>
<th>Description of scale</th>
<th>Types of strain measured</th>
<th>Reliability</th>
<th>Disadvantages</th>
<th>Advantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relatives’ Stress Scale</td>
<td>(Greene et al., 1982)</td>
<td>Carers of dementia patients</td>
<td>15-item inventory scored on a 5-point scale (ranging from not at all to considerably)</td>
<td>Severity of affective responses and disruption of family and social life</td>
<td>Has good internal reliability ($\alpha = 0.85$).</td>
<td>*Needs to be used with the Behaviour and Mood Disturbance scale by the same authors to capture more information *Provides no link between subjective and objective aspects of carer burden</td>
<td>*Short *Easy to administer *Easy to score</td>
</tr>
<tr>
<td>Structured Interview</td>
<td>(Rabins et al., 1982)</td>
<td>Carers of dementia patients</td>
<td>52-item structured interview, rated on a 4-point scale (ranging from not occurring, to causing serious problems).</td>
<td>Similar measure as the Zarit Burden Interview but also includes an assessment of the prevalence of problems associated with the care of an individual with dementia.</td>
<td>NA</td>
<td>*Long and time consuming *No psychometric data available for this measure</td>
<td>*Responses not only capture how often problems occur but also their severity (so both objective and subjective burden)</td>
</tr>
<tr>
<td>Montgomery Burden Scale</td>
<td>(Montgomery et al., 1985)</td>
<td>Carers of the frail elderly</td>
<td>9-item and 13-item inventory, rated using a 5-point scale</td>
<td>Objective burden (defined as changes and disruptions) and covers finances, privacy, social activity, health, and interpersonal relationships. Subjective burden (defined as attitudes and emotional responses of the caregivers).</td>
<td>Has good internal reliability ($\alpha = 0.85$).</td>
<td>*No conceptual correspondence between the items on each scale *Difficulty in identifying which specific demands are distressing to the caregiver.</td>
<td>*Short *Easy to administer *Easy to score</td>
</tr>
<tr>
<td>Carer burden measure</td>
<td>(Author, year)</td>
<td>Population</td>
<td>Description of scale</td>
<td>Types of strain measured</td>
<td>Reliability</td>
<td>Disadvantages</td>
<td>Advantages</td>
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</tr>
<tr>
<td>Caregiver Appraisal Measure</td>
<td>(Lawton et al., 1989)</td>
<td>Carers of dementia patients</td>
<td>47-item inventory rated using a 5-point scale</td>
<td>Subjective caregiver burden, caregiver satisfaction, caregiver impact, caregiver mastery, and traditional caregiver ideology</td>
<td>Has good internal reliability ($\alpha = 0.85$).</td>
<td>*Long and time consuming</td>
<td>*Takes into account both negative and positive qualities of carer/patient relationship</td>
</tr>
<tr>
<td>Caregiver Hassles Scale</td>
<td>(Kinney and Stephens, 1989)</td>
<td>Carers of patients with Alzheimer’s disease</td>
<td>42-item inventory, scored for occurrence over the past week (yes vs. no), and for those that occurred, rated on a 4-point scale ranging from “not at all a hassle” to “a great deal of a hassle.”</td>
<td>Hassles associated with assistance with basic and instrumental activities of daily living (9 and 7 items, respectively), care recipient cognitive status (9 items) and behaviour (12 items), and caregiver support network (5 items).</td>
<td>Has high internal reliability ($\alpha = 0.91$).</td>
<td>*Captures information about the occurrence and degree of hassle associated with each item, but does not measure subjective burden in relation to that item. *Limits responses to occurrence over the past week.</td>
<td>*Items specific to population of individuals with Alzheimer’s disease and their carers.</td>
</tr>
<tr>
<td>Caregiver Burden Inventory</td>
<td>(Novak and Guest, 1989)</td>
<td>Carers of patients with Alzheimer’s disease</td>
<td>24-item inventory, scored from 0 (not at all descriptive) to 4 (very descriptive)</td>
<td>time-dependence burden, developmental burden, physical burden, social burden, and emotional burden</td>
<td>Has good internal reliability ($\alpha = 0.85$).</td>
<td>*Needs evidence of construct validity.</td>
<td>*Short. *Good measure of both subjective and objective burden. *Subscale scores can be used to generate a caregiver burden profile.</td>
</tr>
<tr>
<td>Carer burden measure</td>
<td>(Author, year)</td>
<td>Population</td>
<td>Description of scale</td>
<td>Types of strain measured</td>
<td>Reliability</td>
<td>Disadvantages</td>
<td>Advantages</td>
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<tr>
<td>Screen for Caregiver Burden</td>
<td>(Vitaliano et al., 1991)</td>
<td>Carers of patients with Alzheimer’s disease</td>
<td>25-item inventory, scores ranging from 1-4 to assess the severity of distress.</td>
<td>Stress related to care recipient behaviours, disruptions in family and social life, and caregiver affective responses.</td>
<td>Has good internal reliability ($\alpha = 0.85$ for the objective burden and $\alpha = 0.88$ for the subjective burden)</td>
<td>*Specific to spouses of patients with Alzheimer’s disease *Objective burden scale contains subjective statements which may affect its validity</td>
<td>*Good measure of both subjective and objective burden *Short and comprehensive *Sensitive measure for changes in carer burden</td>
</tr>
<tr>
<td>Caregiver Reaction Assessment</td>
<td>(Given et al., 1992)</td>
<td>Carers of patients with physical impairments, Alzheimer’s Disease, or cancer</td>
<td>24-item inventory with a 5 point Likert scale</td>
<td>Collects information on esteem, lack of family support, finances, schedule, and health.</td>
<td>Internal reliability for each subscale ($\alpha = 0.82$, $0.90$, $0.85$, $0.80$, $0.81$)</td>
<td>*Wording of the questions may be misleading *Overlap between items in some subscales</td>
<td>*Good measure of both subjective and objective burden *Short and comprehensive *Sensitive measure for changes in carer burden</td>
</tr>
<tr>
<td>Caregiver Burden Scale</td>
<td>(Macera et al., 1993)</td>
<td>Carers of patients with Alzheimer’s disease and dementia</td>
<td>15-item inventory with yes/no answers</td>
<td>Caregivers rate the care recipient on functional ability, type of care provided, and related stress.</td>
<td>Has good internal reliability ($\alpha = 0.87$).</td>
<td>*Can only answer yes or no *Does not measure subjective burden</td>
<td>*Short *Easy to administer *Easy to score</td>
</tr>
<tr>
<td>Carer burden measure</td>
<td>(Author, year)</td>
<td>Population</td>
<td>Description of scale</td>
<td>Types of strain measured</td>
<td>Reliability</td>
<td>Disadvantages</td>
<td>Advantages</td>
</tr>
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<td>---------------------------------------</td>
</tr>
<tr>
<td>Caregiver Activity Survey</td>
<td>(Davis et al., 1997)</td>
<td>Carers of patients with Alzheimer’s disease</td>
<td>6-item inventory where carers score each by writing the amount of time in minutes spent on each activity.</td>
<td>Collects information on how much time family carers spend on supervision, communication, dressing, eating, looking after the patient, appearance, and transportation during a typical 24-hour period.</td>
<td>Has good internal reliability (α = 0.88).</td>
<td>*Only measures objective burden and not subjective burden</td>
<td>*Short *Easy to administer</td>
</tr>
<tr>
<td>Family Caregiver Medication Administration Hassles Scale</td>
<td>(Travis et al., 2003)</td>
<td>Carers of elderly patients</td>
<td>24-item inventory with scoring from 0= not a hassle to 5=one of the worst of all hassles</td>
<td>Captures burden relating to information seeking/sharing, scheduling logistics, safety issues, and polypharmacy Concerns</td>
<td>Has high internal reliability (α = 0.95).</td>
<td>*Not specific to carers of dementia patients</td>
<td>*Addresses medication administration issues *Short *Easy to administer</td>
</tr>
<tr>
<td>Impact of Alzheimer’s Disease on Caregiver Questionnaire</td>
<td>(Cole et al., 2014)</td>
<td>Carers of patients with Alzheimer’s disease</td>
<td>12-item inventory with a 5 point Likert scale</td>
<td>Captures information relating to emotional, physical, social, time, sleep, and financial impact.</td>
<td>Has high internal reliability (α = 0.93).</td>
<td>*Relies on 7-day recall which may cause recall bias</td>
<td>*Short *Easy to administer</td>
</tr>
</tbody>
</table>
Appendix 9: Family Caregiver Medication Administration Hassles Scale
Appendix 10: Caregiver Activity Survey

I. Communicating with the person

Please consider the following examples of activities:

- Answering the same question again and again
- Trying to make sense of what the person says
- Leaving reminders for the person

Thinking back over the past day, how much time did you and others spend in the last 24 hours (day and night) doing these types of activities?

------------- hours ------------- minutes

II. Using transportation

Please consider the following examples of activities:

- Reminding the person about means of transportation
- Taking the person to various places (other than shopping) by car or public transportation or taxi

Thinking back over the past day, how much time did you and others spend in the last 24 hours (day and night) doing these types of activities?

------------- hours ------------- minutes
III. Dressing

Please consider the following examples of activities:

- Reminding the person to dress
- Choosing what to wear
- Laying out clothes
- Helping the person to dress or undress
- Supervising the person dressing
- Keeping the person from undressing at the wrong time

Thinking back over the past day, how much time did you and others spend in the last 24 hours (day and night) doing these types of activities?

------------- hours ------------- minutes

IV. Eating

Please consider the following examples of activities:

- Reminding the person to eat
- Setting up utensils and food
- Cutting or arranging food on the plate
- Supervising or encouraging the person to eat
- Cleaning the person after eating

Thinking back over the past day, how much time did you and others spend in the last 24 hours (day and night) doing these types of activities?

------------- hours ------------- minutes
V. Looking after one's appearance

Please consider the following examples of activities:

- Reminding the person to brush their teeth, brush their hair, apply cosmetics, shave or care for nails
- Helping the person to groom
- Setting out items for grooming activities
- Maintaining the person's appearance over the course of the day

Thinking back over the past day, how much time did you and others spend in the last 24 hours (day and night) doing these types of activities?

-------------hours -------------minutes

VI. Supervising the person

Please consider the following examples of activities:

- Keeping an eye on the person to be sure that they do not wander off or get into some kind of difficulty
- Looking out for the person
- Preventing the person from getting lost
- Finding the person if they get lost

Thinking back over the past day, how much time did you and others spend in the last 24 hours (day and night) doing these types of activities?

-------------hours -------------minutes
About you

Please answer the following questions about yourself and your situation if you are filling out these forms for the first time.

1. What is your relationship to the person you provided care for?
   (Please circle one number)
   1 Spouse
   2 Daughter, son or other relative
   3 Friend or neighbour
   4 Other (please specify)-------------------

2. Do you live in the same household as the person you provided care for?
   (Please circle one number)
   1 Yes
   2 No

3. In what year were you born?------------------
Appendix 11.1: Community data collection tool

<table>
<thead>
<tr>
<th>Patient reference number:</th>
<th>Family caregiver details:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Caretaker reference number:</td>
</tr>
<tr>
<td></td>
<td>Age:</td>
</tr>
<tr>
<td></td>
<td>Sex:</td>
</tr>
<tr>
<td></td>
<td>Relationship to patient:</td>
</tr>
<tr>
<td></td>
<td>Ethnicity:</td>
</tr>
<tr>
<td></td>
<td>Education level:</td>
</tr>
<tr>
<td></td>
<td>Severity of dementia:</td>
</tr>
<tr>
<td></td>
<td>Employment status:</td>
</tr>
<tr>
<td></td>
<td>Employment:</td>
</tr>
<tr>
<td></td>
<td>Spouse caring (from CAS):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient reference number:</th>
<th>Family caregiver details:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Caretaker reference number:</td>
</tr>
<tr>
<td></td>
<td>Age:</td>
</tr>
<tr>
<td></td>
<td>Sex:</td>
</tr>
<tr>
<td></td>
<td>Relationship to patient:</td>
</tr>
<tr>
<td></td>
<td>Ethnicity:</td>
</tr>
<tr>
<td></td>
<td>Education level:</td>
</tr>
<tr>
<td></td>
<td>Severity of dementia:</td>
</tr>
<tr>
<td></td>
<td>Employment status:</td>
</tr>
<tr>
<td></td>
<td>Employment:</td>
</tr>
<tr>
<td></td>
<td>Spouse caring (from CAS):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medication details:</th>
<th>Dose/Frequency:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td>Active ingredient</td>
</tr>
<tr>
<td>Formulation:</td>
<td></td>
</tr>
</tbody>
</table>

Updated data collection tool caregivers and P.M. 4/5/2016
Appendix 11.2: Care home data collection tool

<table>
<thead>
<tr>
<th>Staff details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Staff identification number:</strong></td>
</tr>
<tr>
<td><strong>Initials:</strong></td>
</tr>
<tr>
<td><strong>Job title:</strong></td>
</tr>
<tr>
<td><strong>Age:</strong></td>
</tr>
<tr>
<td><strong>Sex:</strong></td>
</tr>
<tr>
<td><strong>Ethnicity:</strong></td>
</tr>
<tr>
<td><strong>Education level:</strong></td>
</tr>
<tr>
<td><strong>Years working:</strong></td>
</tr>
</tbody>
</table>
Appendix 11.3: Data collection for care home observations

Field notes for observations

Date:
Care home code:

Include descriptions and accounts of people, tasks, events, behaviour and conversation:

Time of day/medication round:

Ratio of carer:resident for medication round:

Unit and number of patients/occupied beds:

Account of medicines being administered:

Number of medicines observed for each resident:

<table>
<thead>
<tr>
<th>Resident number (M/F)</th>
<th>Medication numbers and details</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

Difficulties/anomalies observed:

<table>
<thead>
<tr>
<th>Modifications (observe which drugs)</th>
<th>PEG tubing (observe which drugs)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

Description of round: (think about time spent, priority of round over other activities, self-administration, carer and resident behaviour)
### Appendix 12: Coding frame

<table>
<thead>
<tr>
<th>Domain</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Organisation and scheduling logistics</strong></td>
<td>• Obtaining medications</td>
</tr>
<tr>
<td></td>
<td>• Organising medications</td>
</tr>
<tr>
<td></td>
<td>• Scheduling medications</td>
</tr>
<tr>
<td></td>
<td>• Change in medications</td>
</tr>
<tr>
<td></td>
<td>• The medication round</td>
</tr>
<tr>
<td></td>
<td>• Strategies for easier process</td>
</tr>
<tr>
<td></td>
<td>• Suggestions for future</td>
</tr>
<tr>
<td><strong>Formulations and administration procedures</strong></td>
<td>• Knowledge about medications</td>
</tr>
<tr>
<td></td>
<td>• Swallowing difficulties</td>
</tr>
<tr>
<td></td>
<td>• Formulations</td>
</tr>
<tr>
<td></td>
<td>• Interchangeability of medicines</td>
</tr>
<tr>
<td></td>
<td>• Number of medications</td>
</tr>
<tr>
<td></td>
<td>• Environment/surroundings</td>
</tr>
<tr>
<td></td>
<td>• Handling medications and packaging</td>
</tr>
<tr>
<td></td>
<td>• Approach when administering</td>
</tr>
<tr>
<td></td>
<td>• Method of administering medications</td>
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<tr>
<td></td>
<td>• Modifying medications</td>
</tr>
<tr>
<td></td>
<td>• Behaviour</td>
</tr>
<tr>
<td></td>
<td>• Suggestions for easier administration and use</td>
</tr>
<tr>
<td></td>
<td>• Identifying problems and monitoring</td>
</tr>
<tr>
<td><strong>Partnership between caregiver and PLWD</strong></td>
<td>• Transition in care</td>
</tr>
<tr>
<td></td>
<td>• Relationship between dyad</td>
</tr>
<tr>
<td></td>
<td>• Decision-making</td>
</tr>
<tr>
<td><strong>Impact on PLWD</strong></td>
<td>• Decline in cognition</td>
</tr>
<tr>
<td></td>
<td>• Preferences towards medications</td>
</tr>
<tr>
<td></td>
<td>• Communication/language difficulties</td>
</tr>
<tr>
<td></td>
<td>• Decline in activities of daily living</td>
</tr>
<tr>
<td></td>
<td>• PLWD’s autonomy</td>
</tr>
<tr>
<td></td>
<td>• Individualised care</td>
</tr>
<tr>
<td></td>
<td>• Other health conditions</td>
</tr>
<tr>
<td></td>
<td>• Consequences of missing medications</td>
</tr>
<tr>
<td><strong>Impact on caregiver</strong></td>
<td>• Family caregiver journey</td>
</tr>
<tr>
<td></td>
<td>• Impact on family caregiver’s health</td>
</tr>
<tr>
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<td>• Impact on family caregiver’s daily life</td>
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<tr>
<td></td>
<td>• Family caregiver’s previous experience</td>
</tr>
<tr>
<td></td>
<td>• Expectations for the future</td>
</tr>
<tr>
<td></td>
<td>• Impact on the care home staff</td>
</tr>
<tr>
<td></td>
<td>• Impact on formal/paid carers</td>
</tr>
<tr>
<td>Domain</td>
<td>Code</td>
</tr>
<tr>
<td>--------------------------------</td>
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</tr>
<tr>
<td>Interface with formal care</td>
<td>• Relationship between dyad and GP</td>
</tr>
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<td>• Relationship between dyad and pharmacist</td>
</tr>
<tr>
<td></td>
<td>• Interface between family caregiver and care home</td>
</tr>
<tr>
<td></td>
<td>• Relationship between PLWD and care home staff</td>
</tr>
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<td></td>
<td>• Relationship between dyad and formal/paid carers</td>
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<td></td>
<td>• Memory clinics</td>
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<td>• Medication-related support and services</td>
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<td>• Multidisciplinary team</td>
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Appendix 13: Thematic map of factors affecting medication use in the community setting
Appendix 14: Thematic map of factors affecting medication use in the care home setting
Appendix 15: Publications and dissemination

- The literature review (Chapter 2) was published in 2016 (Alsaeed et al., 2016b)
- The preliminary findings were presented as a poster at the International Social Pharmacy Workshop Conference in Aberdeen in 2016. The poster abstract was published in the International Journal of Pharmacy Practice.
- The full findings were presented as a poster at the Alzheimer’s Disease International Conference in Kyoto, Japan in 2017. The poster abstract was published on their website as part of the conference handbook.

Other publications not part of this PhD thesis include:

Appendix 16: Future research strategy for Kuwait

The population in the Middle East, as is in the rest of the world, is ageing. There is limited research concerning dementia in the Middle East (Abdulrazak, 2014; Rizzi et al., 2014). This is due in part to a lack of awareness concerning dementia from the public, healthcare professionals, and policy makers. It is estimated that there will be 1.9 million PLWD in North Africa and the Middle East in 2020 (Rizzi et al., 2014). There are no care homes in Kuwait, and older people are usually taken care of by their children. In most cases, daughters adopt the caregiver role or employ a paid carer. The parent usually moves into the daughter/son’s home.

With that said, it is imperative that research should be started in the region to prepare for a future with dementia. There are no studies or statistics concerning dementia in Kuwait. Therefore, it is hoped to raise awareness concerning dementia in the Ministry of Health. Furthermore, it is anticipated to collaborate with other HCPs to identify the number of PLWD in Kuwait and the prescribing patterns of anti-dementia medications to get a wider scope on the dementia status in the country. Furthermore, efforts have already been undertaken to establish an Alzheimer’s charity as there are none; the researcher has spoken with a representative from Alzheimer’s Disease International for advice on how to establish an Alzheimer’s association in Kuwait. The charity will help in raising awareness about dementia in the public, offer information for PLWD and their caregivers, and be a centre for research.

Conducting a study in Kuwait similar to the current one may not be feasible; this is due to the differences in the health care system, demographics and culture. This affects sampling, recruitment, and data collection. As there are no care homes, there are only the community and hospital settings. Potential participants can be recruited from hospital and GP appointments or identified from the Alzheimer’s charity once it has been established. Focus groups may not be feasible due to cultural issues, as people do not like to talk about their medical issues in front of others or want others to know that someone has dementia. Joint or individual interviews with the PLWD and their caregiver may be utilised. Paid caregivers may also be included to gather all perspectives. This will identify the challenges to medication use in the Kuwait to be able to inform services and healthcare practice. It may seem like an ambitious endeavour, but it is one the researcher is passionate about and will hopefully be able to achieve.