Medicines Management in Care Homes

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By

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Summary

There is an increasing demand on health and social care to provide high quality care to older adults in the UK as the population of this vulnerable group grows. These services should meet the needs of individuals who can have a range of acute and chronic conditions. The capacity for NHS services to meet these demands is limited and therefore care homes provide accommodation and health services to meet this unmet need. In the lay press, there have been concerns regarding medication management in care homes and there is evidence in the literature that this process is sub-optimal. The aim of this thesis therefore was to explore medicines management in care homes focusing on the areas of prescribing, administration and medicines waste. A retrospective analysis of anonymised medication administration records (MAR charts) and an audit of medicines waste was employed to achieve this aim. The analysis revealed that a significant number of residents (84%) were exposed to polypharmacy, potentially inappropriate medications (87%), anticholinergic burden (5% with an AEC score ≥ 5), and a significant number of administration errors (6 administration errors per resident per week). The study also demonstrated a significant volume of wasted medicines in care homes. As a consequence of these issues residents in care homes are potentially exposed to practices that may lead to harm and will likely increase the demand on health and social care resources. Careful consideration of prescribing practices is needed to reduce medicines burden and efforts should be made to embed a multidisciplinary approach to the care residents. In conclusion, further study of the clinical consequences of prescribing and medication errors in care homes should be explored as a matter of urgency and efforts should be made to maximise the therapeutic benefits of medications and reduce the cost of wasted medicines.

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Chapter 1 General Introduction

1.1 Care Homes

In the United Kingdom, institutional long-term care for older adults is principally provided by independently owned care homes, which provide accommodation, together with nursing and/or personal care. Older adults enter care homes because it is no longer possible to provide the level of care required at home either due to insufficient capacity within domiciliary care or the services provided by domiciliary care providers do not meet the individual's needs. According to the Care Standards Act 2000 Part 1 Section 3, the Department of Health states "*a care home is an establishment that provides accommodation, together with nursing or personal care, for persons who are or have been ill, who have or have had a mental disorder, who are disabled or infirm and who are or have been dependent on alcohol or drugs, it does not include hospitals, independent clinics or children's homes*" (Department of Health 2003).

Care homes can largely be divided into two categories, residential and nursing homes that are distinguished by the extent of care provided to residents. Prior to the introduction of the Care Standards Act 2000, which was implemented in April 2002, there was a definitive difference between these two main types of care homes. Residential care homes were defined as "*An establishment which provides residential care, not including nursing, for disabled or elderly infirm people including the elderly mentally ill*" (Heath 2006), whilst nursing homes were defined as "An establishment which provides residential and nursing care for sick, disabled or elderly infirm people, including the elderly mentally ill ... run usually by the private or voluntary sector. Some nursing homes are dually registered as nursing and residential homes" (Age UK 2018a). Now, all homes are termed 'care' homes, with the distinction that nursing care homes are registered to provide nursing care on a 24-hour basis. The terms 'residential' and 'nursing' home have also ceased to apply formally following the implementation of the Care Standards Act although the terms are still used in common parlance. In

essence nursing homes, have 24-hour on-site nursing care available from registered nurses to support residents who require a continuous nursing care. In residential care homes healthcare assistants or 'carers' support residents with their daily activities such as eating, taking medicines, washing and dressing but do not provide continuous nursing care.

Increasingly care homes are adopting a mixed approach and provide both residential and nursing places. If a care home has different 'wings' or 'wards' for nursing and personal care that together form one registered premise, the entire site is regarded as a care home with nursing provision (National Institute for Health Research 2016b).

Whilst the majority of care homes provide services for older adults, some care homes principally support those with mental or sensory impairments (including dementia) and a number of care homes provide specialist care for particular patient cohorts such as those requiring palliative care (Centre for Policy on Ageing 2011). As such, care homes are categorised according to the services provided and the types of residents' that a care home caters for (Lievesley et al. 2011)(Centre for Policy on Ageing, 2011).

1.1.1 The Care Home Population in the UK

At the time of this study, within the UK there are reported to be 4,699 nursing homes and 6,023 residential homes supporting an estimated 421,100 residents that are aged 65 and over (Age UK 2018b). For comparison, there are 142,000 hospital beds in the UK which indicates that the care home population is nearly 3 times greater than the secondary care population (Ewbank et al. 2017). The average size of a care home in the UK is 20 beds and only 10% of care homes have more than 50 beds with almost 3,000 homes operating with five or fewer beds.

In Wales, there are a total of 22,706 beds across 673 care homes with an average of 34 beds per home (Moultrie and Rattle 2015). This is approximately twice the

number of beds available in secondary care (10,934 beds) (Smith 2017). Ownership is distributed between local authorities, larger group providers (15 groups with 4 or more care homes), smaller group providers (51 groups with 2 or 3 care homes) and single home providers (363 providers). Larger group providers tend to operate homes with higher numbers of beds than other operators (see **Table 1.1**).

Table 1.1 Average number of beds by type of care home provider in Wales. Adapted from (Moultrie and Rattle 2015)

Type of provider	Number of homes (n = 673)	Average number of beds (range)
Large groups (≥ 4 care homes)	113	46 (25 – 78)
Small groups (2 - 3 care homes)	113	32
Single provider	363	31
Local authority	84	30

1.1.2 Regulation of Care Homes

In England and Wales, care homes are governed by the Care Standards Act 2000, in Scotland by the Regulation of Care Act (Scotland) 2001 and in Northern Ireland by the Health and Personal Social Services Act (Northern Ireland) 2002. These legislative acts have resulted in the introduction of a series of national minimum standards by the Department of Health, the Scottish Executive and the Welsh Assembly (see CQC 2014). These represent the minimum standards that care homes must meet to retain their registration. The Care Standards Act gives the secretary of state, the power to introduce new standards at any time without any further legislation (CQC 2014).

Each standard is prefaced by a statement of good practice and also an outcome is detailed for each standard (**see Table 1.2**). Underneath each standard is a set of requirements all of which need to be met to achieve compliance with the standard.

Table 1.2 Minimum standards for care homes set out in Care Homes for Older People: National Minimum Standards (CQC 2014)

Standard	Outcome
Choice of home	
1. Information	Prospective service users have the information they need to make an informed choice about where to live.
2. Contract	Each service user has a written contract/statement of terms and conditions with the home
3. Needs Assessment	No service user moves into the home without having had his/her needs assessed and been assured that these will be met.
4. Meeting Needs	Service users and their representatives know that the home they enter will meet their needs.
5. Trial Visits	Prospective service users and their relatives and friends have an opportunity to visit and assess the quality, facilities and suitability of the home.
6. Intermediate Care	Service users assessed and referred solely for intermediate care are helped to maximise their independence and return home.
Health and Personal Care	
7. Service User Plan	The service user's health, personal and social care needs are set out in an individual plan of care.
8. Health Care	Service users make decisions about their lives with assistance as needed.
9. Medication	Service users, where appropriate, are responsible for their own medication, and are protected by the home's policies and procedures for dealing with medicines.
10. Privacy and Dignity	Service users feel they are treated with respect and their right to privacy is upheld.
11. Dying and Death	Service users are assured that at the time of their death, staff will treat them and their family with care, sensitivity and respect.
Daily Life and Social Activities	
12. Social Contact and Activities	Service users find the lifestyle experienced in the home matches their expectations and preferences, and satisfies their social, cultural, religious and recreational interests and needs.
13. Community Contact	Service users maintain contact with family/friends /representatives and the local community as they wish.
14. Autonomy and Choice	Service users are helped to exercise choice and control over their lives.
15. Meals and Mealtimes	Service users receive a wholesome appealing balanced diet in pleasing surroundings at times convenient to them.
Complaints and Protection	
16. Complaints	Service users and their relatives and friends are confident that their complaints will be listened to, taken seriously and acted upon.
17. Rights	Service users' legal rights are protected.
18. Protection	Service users are protected from abuse.

Environment	
19. Premises	Service users live in a safe, well-maintained environment.
20. Shared Facilities	Service users have access to safe and comfortable indoor and outdoor communal facilities.
21. Lavatories and Washing Facilities	Service users have sufficient and suitable lavatories and washing facilities.
22. Adaptations and Equipment	Service users have the specialist equipment they require to maximise their independence.
23. Individual Accommodation: Space Requirements	Service users' own rooms suit their needs.
24. Furniture and Fittings	Service users live in safe, comfortable bedrooms with their own possessions around them.
25. Heating and Lighting	Service users live in safe, comfortable surroundings.
26. Hygiene and Control of Infection	The home is clean, pleasant and hygienic.
Staffing	
27. Staff Complement	Service users' needs are met by the numbers and skill mix of staff.
28. Qualifications	Service users are in safe hands at all times.
29. Recruitment	Service users are supported and protected by the home's recruitment policy and practices.
30. Staff Training	Staff are trained and competent to do their jobs.
Management and Administration	
31. Day to Day Operations	Service users live in a home which is run and managed by a person who is fit to be in charge, of good character and able to discharge his or her responsibilities fully.
32. Ethos	Service users benefit from the ethos, leadership and management approach of the home.
33. Quality Assurance	The home is run in the best interests of service users.
34. Financial Procedures	Service users are safeguarded by the accounting and financial procedures of the home.
35. Service User's Money	Service users' financial interests are safeguarded.
36. Staff Supervision	Staff are appropriately supervised.
37. Record Keeping	Service users' rights and best interests are safeguarded by the home's record keeping policies and procedures.
38. Safe Working Practices	The health, safety and welfare of service users and staff are promoted and protected.

Standard 9 specifically relates to medicines and is concerned with the safe and effective use of medicines by care home residents. The outcome essentially states that residents should retain responsibility for their own medication wherever practicable but should be protected by the specific medicines related policies and practices developed by the care home. The standard describes a number of requirements for the use and management of medicines in the home (see **Table 1.3**)

Table 1.3 Standard 9 requirements for medicines in care homes (adapted from (Department of Health 2003)

Standard 9 requirements	
9.1	The registered person ensures that there is a policy and staff adhere to procedures, for the receipt, recording, storage, handling, administration and disposal of medicines, and service users are able to take responsibility for their own medication if they wish, within a risk management framework.
9.2	The service user, following assessment as able to self-administer medication, has a lockable space in which to store medication, to which suitably trained, designated care staff may have access with the service user's permission.
9.3	Records are kept of all medicines received, administered and leaving the home or disposed of to ensure that there is no mishandling. A record is maintained of current medication for each service user (including those self-administering).
9.4	Medicines in the custody of the home are handled according to the requirements of the Medicines Act 1968, guidelines from the Royal Pharmaceutical Society, the requirements of the Misuse of Drugs Act 1971 and nursing staff abide by the UKCC Standards for the administration of medicines.
9.5	Controlled Drugs administered by staff are stored in a metal cupboard, which complies with the Misuse of Drugs (Safe Custody) Regulations 1973.
9.6	Medicines, including Controlled Drugs, for service users receiving nursing care, are administered by a medical practitioner or registered nurse.
9.7	In residential care homes, all medicines, including Controlled Drugs, (except those for self-administration) are administered by designated and appropriately trained staff. The administration of Controlled Drugs is witnessed by another designated, appropriately trained member of staff. The training for care staff must be accredited and must include: (i) basic knowledge of how medicines are used and how to recognise and deal with problems in use; (ii) the principles behind all aspects of the home's policy on medicines handling and records.
9.8	Receipt, administration and disposal of Controlled Drugs are recorded in a Controlled Drugs register.
9.9	The registered manager seeks information and advice from a pharmacist regarding medicines policies within the home and medicines dispensed for individuals in the home.
9.10	Staff monitor the condition of the service user on medication and call in the GP if staff are concerned about any change in condition that may be a result of medication, and prompt the review of medication on a regular basis.
9.11	When a service user dies, medicines should be retained for a period of seven days in case there is a coroner's inquest.

Care homes are regulated to ensure these standards are maintained. In England, this is by the Care Quality Commission (CQC), Care Inspectorate Wales (CIW) in Wales, the Care Inspectorate (CI) in Scotland and Regulation and Quality

Improvement Authority (RQIA) in Northern Ireland. In Wales, the responsibility of CIW is to regulate care providers to ensure that they provide effective, safe and high-quality care to their service users according to legislative and regulatory requirements. CIW regulate and inspect a variety of care settings. These include (i) care homes which provide services for both children and adults; (ii) domiciliary support service that provide home care; (iii) adult placement schemes; (iv) child minders; (v) children's day care; (vi) independent fostering agencies; (vii) voluntary adoption agencies; (viii) residential family centre services, and (ix) adoption support services (Care Inspectorate Wales 2018a).

With respect to care homes, CIW inspect homes against the minimum standards for care homes (see **Table 1.2**) which are specified by the Care and Social Act 2008. Where concerns or issues are identified, CIW has the power to enforce a range of actions including issuing non-compliance notices, cancelling the registration of the care home, and in extreme cases initiating criminal prosecution proceedings where an individual(s) in the care home is subject to or at risk of significant harm (Care Inspectorate Wales 2018b).

In addition to the Care Act 2008, care homes and their staff will also be subject to a range of ancillary standards set out by a variety of agencies and professional bodies. For example, healthcare professionals working in care homes will be subject to professional standards set by their regulatory body (e.g. the Nursing and Midwifery Council for nurses) and care homes will be subject to national and/or EU quality standards for example related to relevant health and safety acts and safeguarding the confidentiality of residents' information as set out in the Data Protection Act 1998.

1.1.3 Staff in care homes

Care homes (both residential and nursing) employ a variety of staff to support the personal and health care needs of their residents. Standards 27 – 30 of the National Minimum Standards were developed to ensure that (i) the health and personal care needs of residents are met both in terms of the number and skills

mix of staff (Std 27); (ii) the staff complement have appropriate qualifications (50% with NVQ level 2 or equivalent (Std 28); (iii) the care home has a formal recruitment process to ensure the protection of service users (Std 29) and (iv) ongoing staff training and development to ensure staff are competent (Std 30).

All nursing homes must employ registered nurses (RN) i.e. they are currently on the NMC register and both nursing homes and residential homes will employ care assistants CA who are defined as "*a person offering personal care to older people who may or may not have NVQs*" (Heath 2006); care assistants with NVQ level 2 or greater are commonly described as 'qualifieds'.

In homes with nursing care, registered nurses are employed to provide specialist nursing care and to supervise the care provided by care assistants. There will be registered nursing cover continuously over a full 24-hour period (Department of Health Social Services and Public Safety 2015). In residential care homes i.e. those without nursing, registered nurses from community and primary care services visit the home to provide nursing care when required and to provide guidance and support to care assistants (Spilsbury et al. 2015).

The registered nursing workforce in care homes has primarily been trained to care for patients in primary or secondary care, rather than specifically for those in the care home setting. As a consequence, nurses are often poorly prepared to meet the complex needs of older people in care homes and there is limited formal nursing education to address this knowledge and skills gap (Royal College of Nursing 2012; Spilsbury et al. 2016; Stevens 2011). Concerns have been raised about the quality of nursing care provided to people living in care homes (CQC 2014). In recent years, the status of the nursing workforce in care homes has emerged as a matter of public policy concern due to the significant problems with recruitment and retention of nurses. In addition, workforce data indicates that the number of nurses working in community health services has declined over recent years, and the number working in senior 'district nurse' posts has fallen dramatically, creating a growing demand–capacity gap which will

consequently reduce their recruitment into care homes (NHS Improvement 2016). Compounding this issue, has been the high rate of staff turnover in care homes and then the difficulty in recruiting staff with the appropriate skills mix as often new starters lack the necessary skills which they must then learn 'on the job' (Royal College of Nursing 2012). Recent NICE Guidance (2015) has highlighted the importance of care homes employing nursing staff with the right knowledge, attitudes and approach to ensure nurses are competent, appreciate the challenges of working in the sector and understand how to promote quality of care. This includes working with primary and community care services to ensure appropriate management of the health needs of residents and to minimise the risk of unnecessary hospital admissions(NICE 2014; NICE 2015). Ensuring older people can access high quality nursing care in care homes is crucial particularly as there is now a considerable overlap in the dependency levels and care needs amongst residents in care homes with and without nursing (Lievesley et al. 2011).

Backhaus and colleagues, identified through the literature and their professional network, the importance of developing competencies for care home staff. They highlighted the increasing number of bachelor-educated registered nurses (i.e. those with University degrees) working in care homes which they indicated might lead to an improvement in quality of life and quality of care for nursing home residents; similar improvements have been identified in secondary care. The study highlighted that such individuals have an improved ability to manage increasingly complex patients in an increasingly constrained healthcare setting (Backhaus et al. 2015), although there is no clear evidence that nurses with a university degree provide better care. Another study by Heath and one by Nolan, sought to identify the distinct contribution of nurses in the care home setting by comparing the outcomes of care interventions delivered by registered nurses (RNs) with those of care assistants in nursing homes for older people in the UK. The study concluded that the RNs role is broad and multifunctional in the care homes and their knowledge, experience, skills and caring approach strongly

influences resident outcomes (Nolan et al. 2008; Heath 2010) .

1.2 Residents of care homes

In England and Wales there are estimated to be 9.2 million people aged 65 years and over and this number is expected to increase to around 19 million by 2050. More than 80% of this population will likely require some form of institutional care which could include admission to a care home (Moore and Hanratty 2013). As of 2017, there are over 420K people in the UK aged 65 and over residing in care homes (Age UK 2018b) and nearly half of these are aged 85 and over (Smith et al. 2015).

People who live in care homes are commonly described as service users, residents or clients; the term 'resident' will be used throughout this thesis. Such residents have always varied in terms of their health needs however, in the past decade, the resident population has changed dramatically to include people living with 'severe' frailty and illness (Dudman et al. 2018). Historically, residents of nursing homes have required more intensive care than those in residential homes. However, the pressures on health and social care services in the UK have blurred the boundaries between nursing and residential care. As a consequence, carers are now providing increasingly complex types of care to residents that have traditionally been delivered by registered nurses. This shift towards care homes housing residents with more complex health and social care needs has been partly driven by government policy to keep people in their own homes for as long as possible by improving domiciliary care. As a result, individuals become residents of care homes when their health and social needs are more advanced and when it is impractical to manage their conditions at home (National Institute for health Research 2016a).

The average care home resident is likely to be female aged 85 or over with six or more clinical diagnoses, taking seven or more medications, and living with significant physical disabilities, mental health problems and cognitive impairment (Gladman et al. 2015). Such patients are commonly said to suffer

from '*Geriatric Syndrome'* (Won et al. 2013) a broad definition of clinical conditions such as delirium, falls, frailty, dizziness, syncope and urinary incontinence. Combined, these syndromes have a significant impact on a resident quality of life and result in high levels of disability (see **Chapter 2** for further details). Indeed, 75% of all residents in care homes are classed as severely disabled and estimates suggest that as many as 76% of residents either require assistance with their mobility or are immobile. As a consequence, falls are common in care homes where rates vary from 3 to 13 falls per 1,000 bed days (Burns and Nair 2014). UK care home residents fall on average two to six times per year and up to a third of falls in care homes result in injury and 1 in 20 results in a fracture (Rubenstein et al. 1996). It is worth noting that falls in older people is a major precipitant of people moving from their own home to long-term nursing or residential care (Oliver et al. 2007).

In addition, some 78% of care home residents have at least one form of cognitive impairment (NHS England 2016a). Dementia is one of the major causes of cognitive impairment and although there is a spectrum of dementias, Alzheimer's disease has been reported to be the most common cause of progressive dementia in care homes (comprising 62% of all residents with dementia) followed by dementia related to vascular causes (27% of residents with dementia) (The Alzheimer's Society demographics and statistics, 2013). Dementia is associated with behavioral and psychological symptoms such as changes in mood, memory loss, apathy, confusion, anxiety, and difficulty in finding the right words and progressive difficulty with task that need planning. These symptoms generally result in a reduced quality of life and impede the ability of individuals to communicate medicine-related problems (Matthews 2002; Alldred 2007).

Meeting the health and care needs of this vulnerable population is made more challenging by their average life expectancy on arrival at the home which is as little as 12-30 months (Baylis and Perks-Baker 2017).

1.3 Reasons for admission to care homes

The reason for admission to care homes is multifactorial. In their seminal work Andersen & Aday indicated that entry into a nursing home could be attributed to three variables: (i) personal attributes that predispose individuals to seek care; (ii) enabling factors that influence access to care and (iii) need factors as reflected by health status, disease and functional disability (Andersen and Ann Aday 1978). Subsequently, a range of studies have examined the predictors for care home admission and have found that the most common risk factors for admission were older age, biological sex (women), reduced levels of Personal and Instrumental Activities of Daily Living, cognitive impairment, living alone and the presence of key medical conditions (Sinclair et al. 1988). These medical conditions include stroke and dementia where for example in Belgium they have been associated with 36% and 43% of admissions to nursing home respectively (Van Rensbergen and Nawrot 2010). In another study Banaszak et al. identified heart disease, urinary incontinence and dementia as significant predictors of nursing home admission (Banaszak-Holl et al. 2004). Similarly McNabney et al. demonstrated that more than 40% of residents admitted to nursing homes had at least one of four chronic medical diagnoses: congestive heart failure, chronic obstructive pulmonary disease, diabetes mellitus or Parkinson's disease (McNabney et al. 2007).

1.4 Medicines use in care homes and polypharmacy

One of the factors that places residents at high risk of adverse health outcomes is polypharmacy. There are a number of definitions of polypharmacy including quantitative (normally individuals prescribed 5 or more medicines) or qualitative (medicines prescribed without an appropriate clinical diagnosis) (Masnoon et al. 2017). Care home residents commonly meet the range of definitions for polypharmacy. Indeed, the mean number of medicines prescribed per resident in care homes has increased substantially from 4.9 in 1998 to 8.0 in 2007 (Furniss et al. 2000). Whilst the mean number of medicines has now somewhat stabilised at 8 per resident, it is not uncommon to find residents taking as many as 20

medicines (Alldred et al. 2009). In addition to prescribed medications and dietary supplements, there is evidence that residents take over-the-counter drugs and complementary and alternative medicines; these are often provided by the resident's relatives (Duerden M 2013).

The consequences of polypharmacy and inappropriate prescribing in older adults in primary and secondary care settings is well established (Maher et al. 2014). For example, polypharmacy has been shown to be associated with an increased risk of adverse drug events (ADEs) in older adults and is responsible for up to 12% of all hospitalisations in the elderly population (Parameswaran Nair et al. 2016). It also has an impact on medicines adherence rates in older adults which has been shown to be directly proportionate to the number of drugs prescribed (Colley and Lucas 1993) with more frequent doses missed resulting in increased financial burden to health service providers (Kojima et al. 2012; Maher et al. 2014). In contrast, there is a paucity of literature examining the consequences of polypharmacy in care homes.

1.4.1 The management of medicines in care homes

Unlike in an individual's home where they manage their own medicines, in care homes medicines are generally managed by staff, although residents retain the right to administer their own medicines wherever possible. Medicines management is a complex multifactorial process and represents an important and understudied element of a resident's care. It is a resource intensive process and has been shown to account for as much as 40-50% of care home staff time (Alldred et al. 2009).

Medication management broadly includes six key components: (i) the care home orders the residents' medicines; (ii) a prescriber prescribes the medicines; (iii) the medicines are dispensing from a community pharmacy and supplied to the care homes; (iv) the medicines are stored at the care home; (v) the medicines are administered to residents in the care home – this is associated with recording and monitoring processes and (vi) any unused medicines are returned at the end

of the month. It is clear that a range of healthcare professionals play a role in medicines related activities prior to the medicine reaching the resident and various legislative and regulatory mechanisms must be in place to ensure effective medicines management procedures.

1.4.1.1 The prescribing process

In the United Kingdom (UK), good practice guidance on prescribing is provided by relevant professional bodies such as the General Medical Council (GMC) (2013) and the General Pharmaceutical Council (GPhC) (2015). Prescribing is a complex process that requires a comprehensive approach by clinicians, considering key aspects such as:

- Patient understanding, choice and consent for treatment
- Appropriate knowledge of the health condition(s) to be addressed
- Appropriate medicines prescribed to treat or prevent diseases
- Prescribing decision making supported by evidence based clinical guidance (local and/or national)
- Potential adverse reactions to drugs are recognised and mitigated
- Potential drug-drug interactions are recognised and addressed (Royal Pharmaceutical Society 2014)

Any failure to address these key aspects may ultimately lead to potentially inappropriate prescribing (PIP). The term 'inappropriate prescribing' broadly covers three activities: (i) over-prescribing (prescribing a drug without a valid indication); (ii) miss-prescribing (incorrectly prescribing a drug for a valid indication) and (iii) under-prescribing 'failure to prescribe an indicated drug' (Anrys et al. 2015).

The majority of care homes are serviced by more than one general practice. Traditionally, the General Practitioner (GP) that an individual is registered with remains responsible for their medical care (including prescribing) when they enter the care home. However, prescribing interventions may also arise from

other practitioners including secondary care doctors (as a consequence of a hospital admission or for specialist care), allied healthcare practitioners (dentists, non-medical prescribers etc.) and out-of-hours doctors. Ultimately this results in multiple sources of prescribing interventions by individuals who may not have full access to the resident's health and medication records.

Critically, quality of prescribing is an important determinant of wellbeing for older adults with inappropriate or excessive use of medicines shown to increase mortality, hospital admission, falls, functional impairment, and cognitive decline. For example, Ruggiero and colleagues found that care home residents receiving two or more potentially inappropriate medications (PIMs) had a 75% higher risk of being hospitalised, (hazard ratio [HR] 1.73; 95% CI 1.14, 2.60), during a 12-month follow up period (Ruggiero et al. 2010). Similarly, Klarin and colleagues studied an older adult (>75 years old) population in Sweden for a three-year period. They reported that almost ~20% of the population received an inappropriate drug and this resulted in an increased risk of at least one acute hospitalisation (odds ratio 2.72 (95% CI 1.64, 4.51) (Klarin et al. 2005).

The prevalence of potentially inappropriate prescribing (PIP) in care homes is reasonably well documented but varies depending on the study. In their seminal systematic review, Morin and colleagues found the prevalence of inappropriate prescribing ranged from 27% in the USA to nearly 50% in some European countries (Morin et al. 2016). In England and Wales nearly 30% of all residents in care homes have been prescribed at least one PIM; most commonly this was an antipsychotic or anticholinergic (Shah et al. 2012). Of note, Cox and colleagues identified a 3-fold increase in the rate of falls in nursing home residents who were prescribed an antipsychotic and antidepressant drugs. (Hartikainen et al. 2007; Cox et al. 2016).

In addition, inappropriate prescribing has been shown to lead to an increase in healthcare expenditure, for example as a consequence of the cost of hospitalisation due to preventable adverse drug reactions (Chiatti et al. 2012)

(Maher et al. 2014) which has been estimated to be nearly US$2 billion (Rocchiccioli et al. 2007) in the US.

1.4.1.2 Ordering and dispensing

Dispensing is another important element of the medicines management process in care homes. The general mechanism is that each care home will be registered to a single community pharmacy. Towards the end of a medicines cycle (28 days), staff in the care home will order medicines for the next cycle from the community pharmacy. The community pharmacy then requests the prescriptions from the relevant GP practice(s). On receipt of the prescription, the pharmacist will clinically check the prescription before members of the pharmacy team (normally technicians) assemble and dispense the medications on the prescription; standard operating procedures support these activities in the community pharmacy. Prior to sending the medicines to the care home, the pharmacist or an accredited checking technician will undertake a final accuracy check of the medicines. There are two ways in which medicines are supplied to care homes: (i) in individual packs, labelled with resident's name and dosage details or (ii) using monitored dosage systems (MDS). This depends on both the request of the care home manager or owner, and whether the community pharmacy to which they are registered offers an MDS service (Alldred et al. 2009).

1.4.1.3 Monitored Dosage Systems

MDS is a storage device for solid medications aimed at simplifying the administration of medication by or to patients / residents. It is a type of Multi-Compartment Compliance Aid (MCA). They are usually filled at the point of dispensing in a pharmacy and can be particularly useful in care homes where medication is administered to a large number of residents. MDS has been reported to have a number of benefits including enhancing the adherence of residents to a medication regimen and minimising errors related to the dose of the medication (Bhattacharya 2005). MDS is not without disadvantages

however. In general, the system is only suitable for oral solid medications although there are specialist systems (e.g. Biodose) that allows for liquid dosage forms. However none of the systems are suitable for 'when required' medications. Estimates suggest that approximately 40% of all medicines in a care home are packaged in MDS systems (Alldred et al. 2009). The Royal Pharmaceutical Society state that MDS is not recommended for some medications including on demand medication, drugs with potential cytotoxicity, drugs with variable dosing and hygroscopic or photosensitive drugs (Pountney 2010). Nevertheless, MDS remains the most common system used in Care Homes for medicines management.

1.4.1.4 The medication administration process in care homes

Medication administration is one of the most important functions for staff in care homes. In nursing homes, nurses fulfil this task whilst in care homes it is trained carers. Usually, there are four drug administration rounds per day which, in most cases, coincide with residents' meal times (8:00, 12:00, 16:00 and 20:00). Generally, one member of staff will conduct the drug administration round which can take anywhere between 30 minutes to two hours depending on the number of residents and number of medications administered in each care home (Alldred et al. 2009).

Medicines administration in the care home setting has become more complex in the past 40 years as a result of the increasing number of drugs and routes available to treat residents who have increasingly complex conditions and co-morbidities. Medications are supplied by different drug companies and can have different brand names and packaging and this compounds the complexity of medicines administration particularly where MDS is not implemented (Joshi et al 2007)(Edwards and Axe 2015). Ultimately, there must be clear and up to date written procedures for administering medicines in the care home and care home managers should ensure that these procedures are followed (Wilson D et al. 2011).

The administration of medicines in care homes is highly regulated through a series of standards and legislative mechanisms in the Health and Social Care Act 2008:

1. Regulation 13 which states “The registered Person must protect service users against the risks associated with the unsafe use and management of medicines, by means of making appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposed of medicines used for the purposes of the regulated activity.”

2. Outcome 9 (Management of Medicines) of the Essential Standards of Quality and Safety states “People who use services:
    I. Will have their medicines at the times they need them, and in a safe way. ii. Wherever possible will have information about the medicine being prescribed made available to them or others acting on their behalf.

In turn this means providers “must handle medicines safely, securely and appropriately, ensure that medicines are prescribed and given by people safely and follow published guidance about how to use medicines safely.” (Oxfordshire Clinical Commissioning Group 2015).

A number of professional organisations have recognised the issues that can occur in care homes during medicines administration rounds and have produced corresponding guidelines (Centre for Policy on Aging 2011). For example, the Royal Pharmaceutical Society has published a variety of guidelines including ‘Improving Pharmaceutical Care in Care Homes’ (Royal Pharmaceutical Society in Scotland 2012), ‘Improving Medicines Use for Care Home Residents’ (Royal Pharmaceutical Society Wales 2016) and ‘The handling of medicines in social care’ (Royal Pharceutical Soceity of Great Britain 2007) aimed at improving the quality of care for care home residents with an emphasis on safe handling of

medicines. The key points in these documents were: (i) the need to deliver personalised pharmaceutical care to care home residents based on individual need; (ii) ensuring equity of care by delivering the same standards of care to residents in care home as would be received by their peers living in their own home; (iii) quality of care should be enhanced by developing the knowledge and skills of all healthcare professionals involved in providing care to residents; (iv) the need for integrated partnership working and communication with other healthcare professionals to ensure pharmacists will be able to maximise their expertise in the pharmaceutical care of residents; (v) the importance of sharing best practice between pharmacists working in the care homes setting to reduce any unwarranted variation in care; and (vi) empowering frontline practitioners to deliver change by working with residents and staff in care home to overcome any issue that may impact the delivery of care and the medicines management process (Royal Pharmaceutical Society in Scotland 2012).

In addition, the Nursing and Midwifery Council has produced a set of guidelines called the 'Standards for medicines management' that outlines the principles of safe and effective management and administration of medicines. The guideline provides 26 standards that aim to ensure all medicines related activities adhere to best practice for safe and effective administration of medicines (Standards for medicine management 2010).

Essentially, these regulations and guidelines focus on ensuring commissioners and service providers regularly review and audit their policies, processes and local governance arrangements to guarantee quality system are in place in care homes. Further, they ensure clear lines of accountability and responsibility in the effective management and administration of medicines in care homes (NICE 2014).

1.5 Medicines administration errors

Despite policies and procedures that seek to regulate, and quality assure medicines management (including administration) in care homes, there is

evidence within the literature of failures in systems and processes that lead to errors in medicines administration.

The seminal UK study in this area is the 'Care Homes Use of Medicines Study' or CHUMS study. In this study, the investigators reviewed the medicines administration process in 55 care homes in England. Two drug rounds were observed for each of the 256 residents included in the study. The authors determined that care home staff spend as much as 40-50% of their time on activities that are related to medicines administration and that errors occur in 8.4% of all administrations per medication round. The authors also observed that ~70% of residents were exposed to at least one medication error per day. Of the errors observed, approximately 50% were dose 'omissions' and more than 20% were incorrect doses. The areas identified for "priority attention" in the report included the Medication Administration Record (MAR) chart, the medication round itself and in particular dealing with interruptions and distractions, as well as improving lines of communication between the medicine provider (generally a pharmacy) and care home staff (Alldred et al. 2009).

The CHUMS study is by no means the only example of poor medicines management in care homes. Szczepura et al, (2011), undertook a prospective analysis of 13 care homes (9 residential and 4 nursing) over 3-month period observing ~ 190,000 medicines administrations. The authors examined both the incidence and types of medicines administration errors (MAEs). A total of 2,289 potential MAEs were identified over the 3-month study period from a total of 188,249 administrations. More than 90% of the residents were exposed to at least one error with 51% of the residents exposed to a serious error; a serious error was defined as 'any attempt to give medication to the wrong resident or to give medication which had been discontinued'. Of note, less than a third of the staff involved in administering medicines (12/41) were aware of the potential for error in their care homes. In those who recognized the potential for error, interruptions and distractions were cited in around 50% of cases as a

contributory factor that may lead to administration errors. Similarly, 50% of staff indicated they were "'stressed' or 'under pressure to complete the round'"; issues of stress and time pressures were said to be more prevalent in residential homes compared to nursing homes (Szczepura et al. 2011).

A number of studies have also reported on the impact of interruptions and distractions on medicines administrations, Scott-Cawiezell and colleagues for example have reported a positive relationship between interruptions and rate of administration errors with ($p < 0.099$) through observing 44 medication administration for 907 residents in 5 nursing homes (Scott-Cawiezell et al. 2007). Similarly, Biron and colleagues reported on the rate of interruptions experienced by nursing staff during medicines administration rounds. In an observational study the authors reported an overall interruption rate of 6.3 interruptions per hour. In the main these distractions were from other nurse colleagues (29.3%) or as a result of 'system failures' that included missing medication or equipment (22.8%) during the preparation phase and from self-initiation e.g. to undertake secondary tasks (16.9%) and patients (16.0%) during the administration phase. Whilst the authors did not investigate the clinical consequences of these interruptions, they indicated that medicines administration rounds were not protected from interruptions and this posed significant risks to residents. (Biron et al. 2009).

Issues associated with medicines administrations in care homes are not confined to the UK. A study of Dutch care homes found examples of administration errors including staff failing to supervise residents taking their medication (this was particularly concerning for those with dementia), and irregular timing of medicines administration with medications frequently administered more than an hour early or late (van den Bemt et al. 2009). A study in the US by Pierson et al. reported on the implementation of a web-based error reporting system introduced in nursing homes in North Carolina. Of the 25 homes that volunteered to take part in the study, 23 entered error reports into the system

during the one-year study period. Six hundred and thirty-one error reports were made related to 2,731 discrete error instances. The most common errors reported were dose omission (32%), overdose (14%), under dose (7%), administration to the wrong patient (6%), and wrong medicine administered (6%), and wrong strength of medicine administered (6%). Most errors occurred during the administration round itself (47%) and 67% of the errors that were deemed to have the most impact on patient health were at the point of patient administration. Around 50% of the errors were determined to be as a consequence of basic human error (Pierson et al. 2007).

Van den Bemt and co-workers quantified errors in medicines administrations in a trio of nursing homes in the Netherlands serving 127 residents. The study was a disguised observational study over a two-week period but limited to observations on Monday, Wednesday, Thursday and Friday. Of the 2,025 administrations observed, errors were observed in 428, an error rate of ~ 21%. Staff frequently failed to supervise residents taking their medications and medicines were often inappropriately handled for example enteric coated and modified release formulations were frequently crushed prior to administration (van den Bemt et al. 2009). Particular classes of drugs were noted to be problematic, for example patients prescribed antibiotics had a higher risk of a medicine administration error. A study in care homes in the county of Gwent in South Wales by Hussain and Walker revealed similar findings. In a two-year period, 18% of antibiotic regimens prescribed were administered inappropriately (500 of 2,859 courses) (Hussain and Walker 1999).

Of note the timing of the administration round appears to play a role in the prevalence of errors. Van den Bemt and colleagues reported the morning (7am – 10am) and lunch (10am – 2pm) rounds lead to greater incidence of errors with odds ratios of 2.28 and 1.96 respectively compared to afternoon and evening rounds where no change in the incidence of error was observed. It was hypothesised that this was largely due to the higher workload placed on staff in

the morning where medicines administration rounds are just one part of the normal morning routine which includes amongst other things helping residents out of bed, personal hygiene routines, getting residents dressed and having their breakfast. One suggested solution to the pressures on staff at the morning round was for pharmacists to determine whether a medicine needs to be administered in the morning round(s) or whether they could be moved to the afternoon. Where a prescription indicates for example the medicine should be administered once daily the default is to administer the medicine at the first medicines round. This means that the volume of medicines administered in the morning is often significantly higher than in later rounds (van den Bemt et al. 2009).

Deshmukh and Sommerville compared drug administration records before and after a series of interventions by pharmacists at two private nursing homes in Norfolk. A total of 173 interventions were made classified into three categories: (i) interventions related to residents' therapy; (ii) interventions related to nurse administration; and (iii) interventions related to blood tests. The baseline analysis indicated that although the two homes had written procedures for medicines administration, only 58% of all administrations were being administered in accordance with these guidelines. The most frequent deviation from the written procedures was a failure to formally identify the resident prior to administration and recording the administration without witnessing consumption. In addition, there was a failure to administer medicines in accordance with the prescriber's intentions in 21.2% of all administration for regular medications and 79.2% of all administrations for 'when required' drugs. Of note 2.7% and 18.9% of administrations of regular and 'when required medicines' were not recorded at all (Deshmukh and Sommerville 1996).

There is limited anecdotal evidence that the landscape is similar in Wales, for example in 2006 the national service framework for older people in Wales indicated that medication administration errors occur frequently both in

hospitals and care homes. The report stated that "*administration errors especially non-administration occur relatively frequently both in hospital and care settings*" (Welsh Assembly Government 2006). However, no quantitative data was provided. To date then, there has been little work examining the scale of the issues in Care Homes in Wales. To guard against medication errors, regulations and national minimum standards have been established in Wales(Welsh Assembly Government 2004) and in England(CQC 2016) to help to improve the quality of medicines management in care homes. Nevertheless, care homes continue to have difficulties in achieving a satisfactory performance in medicines management. The CQC in England for example reported that nearly 30% of care homes in England failed to meet the standards on medicines management in 2015-16 (CQC 2016).

Identifying the root causes of medication errors in Care Homes is an important and necessary step in establishing solutions to the problem. However, the evidence is equivocal, and it has been difficult to determine the primary cause(s) of medication errors in care homes. This has been as a consequence of a number of factors not least a general lack of research in the care home setting and varying methodological approaches to identify medication errors. Nevertheless, a number of causative factors have been identified. For instance, in the CHUMs study, staff workload, lack of medicines training, interruptions during administration rounds together with a lack of team work between health care professionals were factors cited as contributors to medicine errors (Alldred et al. 2009). Other studies have highlighted that the appropriate education and training of staff is key in ensuring appropriate care for residents with staff discussion and problem-solving activities leading to positive outcomes without necessarily the need for a formal educational programme. (Nolan et al. 2008)

Human factors also plays a role with for example Ulanimo and colleagues reporting that tiredness and exhaustion of staff were responsible for nearly 33%

of medication errors in nursing homes with 45% of these errors attributed to not checking the patient's name (Ulanimo et al. 2007).

Interruptions during the administration process is also acknowledged to be a cause of administration errors impacting on the efficiency, quality, and safety of administration processes (Thomson et al. 2009). The literature broadly distinguishes between three types of interruption: interruptions mid task, interruptions between tasks, and system failures (e.g. poor access to equipment and supplies) (King's College London 2010).

Ultimately, irrespective of the cause of medicines related errors in the care home, they have the capacity to result in significant harm to the resident. Such harm may increase the risk of an unintended health intervention, hospital admission, A&E visit or in the most extreme cases death. Moreover, these outcomes are associated with significant human resource and financial burden. The financial burden is not only associated with the cost of any intervention but also from the generation of medicines waste which is estimated to be £300M per annum (Hazell and Robson 2015). Given the predicted £30bn funding gap in the NHS (NHS England 2016b), reducing the financial burden associated with ineffective medicines management is a priority.

1.6 Scope of thesis

The increasing population of older adults in the UK is associated with an increasing demand for health and social care services to provide high quality care to meet the needs of individuals with a range of acute and chronic conditions. The drive to keep individuals in primary care and prevent their admission to the secondary care setting along with the bed constraints within the hospital setting has placed significant strain on domiciliary care services. As a consequence, the number of older adults living in care homes has increased. One of the primary functions of care homes is to support residents to take their medicines appropriately. There is evidence in the literature however that medicines management is not optimal and that this may result in resident harm. Therefore,

the research in this thesis is driven by an objective to explore medicines management in care homes focussing primarily on prescribing, administration and waste.

The objective in **Chapter 2** was to evaluate the prescribing landscape in ten care homes in the South Wales region. Using a retrospective analysis of Medicines Administration Records (MAR charts), the extent of polypharmacy (>5 medicines prescribed) (Jiron et al. 2015) and excessive polypharmacy (>10 medicines prescribed) was evaluated for each resident and the number of residents receiving potentially inappropriate medicines was calculated. Similarly, the anticholinergic burden was calculated for all residents. Anticholinergic burden is associated with cognitive impairment and increased risk of falls (amongst other adverse drug reactions) in older adults. More generally, the extent of prescribing by therapeutic class was evaluated to provide an overview of the medicines prescribed to care home residents.

Chapter 3 builds on the findings in **Chapter 2** by exploring the quality of medicines management in home residents using the same MAR charts that were used in **Chapter 2**. Errors were classified into five primary categories: administration, MAR chart errors, stock errors, regulatory errors and miscellaneous errors that could not be fully categorised based on MAR charts alone. A particular focus of the study was on administration errors i.e. doses omitted, extra doses given, a deviation from the prescribed dose, an administration at the wrong time etc. This was used to calculate an administration error rate as a function of the total number of opportunities for error and the error rate by resident. The administration errors associated with PIMs were also described.

In **Chapter 4**, the medicines waste generated in care homes was explored. Data was extracted from the monthly return books and physical counts of medicines in the home were also made. Using medicines prices listed in the British National Formulary, the total value of medicines wasted in the homes investigated was

calculated. The waste was categorised according to therapeutic class and whether it was a medicine prescribed on a regular or when required basis.

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Chapter 2. Prescribing for care home residents

2.1 Introduction

2.1.1 An Aging population

Across the globe, the population of adults over 65 years of age (older adults) is increasing. A major study in 2010 predicted that as a consequence of increased life expectancy, in both developed and developing countries, the older adult population would continue to rise for the next 4 decades (Stegemann et al. 2010); this increase is mostly seen for people aged 80 years and over. **Table 2.1** illustrates the predicted changes in the older adult population over the next 40 years. Unfortunately, overall life expectancy is increasing faster than healthy life expectancy i.e. the average number of years lived in good health. In the UK, the trend in the older adult population is similar with an expected rise in the number of people aged 65 and over from 11.8M in 2018 to more than 16M by 2040 (Age UK 2018); at this point the older adult population will represent almost a quarter of the UK population.

Table 2.1 predicted changes in the population of people aged >65 over the next 40 years in both developed and developing countries. (adapted from (Stegemann et al. 2010)

	2010	2020	2030	2040	2050
Developed countries [people in millions]					
Total population	1,365,899	1,397,353	1,411,479	1,412,224	1,402,753
Population ≥ 65 years	204,140	248,215	298,215	327,122	343,396
% of total population	14.9	17.8	21.1	23.2	24.5
Developing countries [people in millions]					
Total population	5,539,491	6,267,938	6,903,864	7,408,412	7,785,103
Population ≥ 65 years	323,716	467,255	671,557	919,185	1,122,963
% of total population	5.8	7.5	9.7	12.4	14.4

This dramatic shift in the population is predicted to place extra pressure on healthcare services in both primary and secondary care. The older adult population is, at least in part, susceptible to multiple chronic co-morbidities and vulnerable to polypharmacy and as a result adverse drug reactions. At around 75 years of age there is an inflexion point where the number of adults reporting that they are 'disabled' is greater than the number reporting 'good health' (see **Figure 2.1)** These factors are likely to place significant burden on an already

constrained health service and increase costs associated with the provision of healthcare to such individuals (Bonaga et al. 2018). In addition, there is an ongoing trend to develop more complex therapeutic modalities and advanced formulations to treat a range of emerging and complex conditions including Alzheimer's, cancer and resistant infections as the older adult population continue to live longer (Brown 2015).

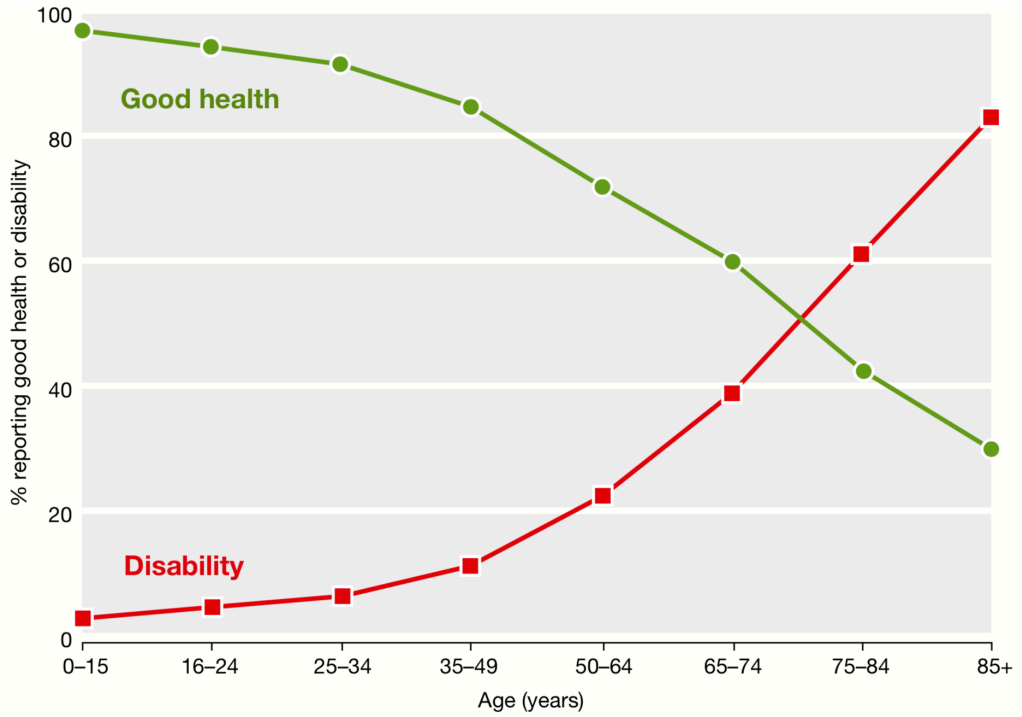

Figure 2.1 Percentage of people in England & Wales 2011 reporting 'Good health', or 'Disability' in different age ranges. Taken from (Brown 2015)

2.1.2 The normal aging process

Aging is a gradual progressive process characterised by physiological changes and an observable decline in body functions together with an increase in the susceptibility to the adverse effects of drugs (Mangoni and Jackson 2003). In addition to physiological decline, there are age-related neurological deficits that can result in visual, motor and cognitive impairment which can reduce quality of life and indeed impede an individual's ability to manage their medications safely

and effectively. The major physiological and functional changes that occur with aging along with the consequence of such changes on pharmacokinetics are shown in **Table 2.2** (adapted from (Stegemann et al. 2010)). These changes impact the absorption, metabolism, distribution and elimination of drugs which can be unpredictable and subject to significant inter- and intra- patient variability but ultimately may lead to adverse drug reactions (Stegemann et al. 2010). As a consequence, careful consideration should be made when prescribing for this population.

Table 2.2 Age-related physiological changes and their pharmacokinetic consequences.

Physiological changes in older adults	Pharmacokinetic consequences
• Increased gastric pH • Delayed gastric emptying • Reduced splanchnic blood flow • Decreased gastrointestinal mobility	Slightly decreased absorption (rarely clinical significant)
• Increased body fat • Decreased lean body mass	Increased volume of distribution and half-life of lipophilic drugs
• Decreased total water	Increased plasma concentration of hydrophilic drugs
• Decreased serum albumin	Increased free fraction in plasma of a few highly protein-bound acidic drugs
• Increased α 1-acid glycoprotein	Decreased free fraction of basic drugs
• Decreased hepatic blood flow	First-pass metabolism can be less effective
• Decreased hepatic mass	Phase I metabolism of some drugs may be slightly impaired
• Decreased renal blood flow and glomerular filtration rate	Renal elimination of drugs can be impaired

There are also potential age-related changes in the pharmacological response to drug therapy however, these changes are generally related to specific drugs. For instance, the use of the same dose of β-adrenoceptor blockers in older adults can be less effective compared to younger adults due to a decrease in the sensitivity of β-adrenoceptors in the heart with aging. Conversely, benzodiazepines, which are frequently used to treat sleep disturbance in older adults, are subject to increased sensitivity and the dose should be decreased by 2-3 fold in older adults (Woodward 1999).

2.1.3 Geriatric Syndromes

Some older adults are susceptible to a spectrum of clinical conditions that are categorised as geriatric syndromes. Although there is no global consensus defining the range of geriatric syndromes (Won et al. 2013), the most commonly cited syndromes are frailty, falls, urinary incontinence, osteoporosis, unintentional weight loss, sleep disturbances, delirium, dementia and cognitive impairment (see below for description). The reasons for the development of each syndrome is multifactorial but there are likely to be shared risk factors and ultimately, accumulation of such syndromes is likely to have a significant impact on an individuals' quality of life.

2.1.3.1 Commonly cited geriatric syndromes

(i) Delirium is characterised by a sudden decline in attention and cognitive function and can follow two primary forms (i) hyperactive with agitation or (ii) hypoactive with lethargy. Delirium has an incidence of 14-56% in older adults and is associated with a significant mortality rate in hospitalised patients (Fong et al. 2009). Nearly half the cases of delirium in secondary care are thought to be preventable by interventions such as 'The Hospital Elder Life Programme' (HELP)(Inouye et al. 2000) which is considered one of the most effective intervention to reduce both the incidence of delirium rate and the resultant hospital costs.

(ii) Falls represent a life-threatening issue that affects more than 30% of older adults (Inouye et al. 2007). It can result in an unintended hospital admission, long term institutionalisation, functional decline and increased health care expenditure (Tinetti et al. 1994). A variety of risk factors are associated with falls including adverse drug reactions, visual acuity problems, physical weakness, arthritis and the individual's physical environment. A number of educational interventions have been conducted to reduce the risk of falls including raising falls awareness among older adults using media, brochures, lectures etc. and through

educational programmes to health care providers (AGS PANEL ON FALLS PREVENTION 2001).

(iii) Frailty is a syndrome that affects nearly 10% of older adults and is primarily associated with the female sex. Frailty is a consequence of a variety of factors including weight loss, muscle weakness, slow walking speed, exhaustion and low physical activity (Collard et al. 2012)(Bonaga et al. 2018).

(iv) Dementia is a common problem that affects nearly 25% of adults aged 80 and over (Health in Aging.org 2017b) of which Alzheimer's disease is the main type. Dementia is associated with a decline in memory and cognition and can affect an individual's ability to perform normal tasks. There are broadly two types of interventions to ameliorate dementia, and these are (i) non-pharmacological interventions such as Cognitive Stimulation Therapy (CST), or (ii) pharmacological interventions which aim to slow the progress of cognitive impairment (Conn and Seitz 2010).

(v) Urinary incontinence is a highly prevalent condition which affects about 30-65% of older adults and is particularly prevalent in females (Cook and Sobeski 2013). It may occur due to age-related changes in the urinary tract, urinary infections or other unrelated causes such as cancer, diabetes, cognitive impairment and stroke. The most effective intervention remains pelvic floor muscle strengthening training to reduce urgency of urinary incontinence. (Roe et al. 2011)

(vi) Sleep disturbances are a common problem that affects the quality of an individual's life and may lead to falls, depression and a range of other health issues (Health in Aging.org 2017a). Some 57% of older adults in the US are reported to have chronic insomnia (Abad and Guilleminault 2018). A number of contributory factors lead to sleep problems including socioeconomic status, certain medications, acute and chronic medical conditions (e.g. heart disease, persistent cough and depression). Interventions such as improving sleep hygiene and avoiding stimuli are

preferred to pharmacological interventions (Sagayadevan et al. 2017; Suzuki et al. 2017).

(vii) Osteoporosis is a progressive disease that affects nearly 42% of older adults in the UK, causing bone fragility that can result in debilitating fractures (National Osteoporosis Society 2015). It is characterised by decreased bone mass and therefore it should be mandatory for adults over 70 years of age to have a bone mass density test. Increased calcium and vitamin D supplements are effective intervention to prevent osteoporotic fractures in addition to weight-bearing and strength training exercises (Daware 2014).

(viii) Unintentional weight loss (> 5% of body mass loss in the last year) is another common problem that affects older adults and may lead to weakness, falls, and other health issues. It is reported to affect 13% of the older adult population (Ruscin et al. 2005). Diminished sense of taste is one of the main causes however, medications and other medical conditions also contribute. Limited evidence is available on the beneficial effect of either nutritional or pharmacological interventions on improving weight in the frail older adult population (Stajkovic et al 2011).

Many of these syndromes overlap or are a causative factor of each other and as a consequence of geriatric syndromes, older adults are likely be prescribed a greater number and range of medicines and are likely to require additional support to take such medications effectively and to reduce the risk of adverse drug reactions (Duerden 2013).

2.1.4 Polypharmacy

The complex medical conditions, long term illnesses, multiple co-morbidities and geriatric syndromes that affect some older adults often require multiple drug therapies as the primary intervention to either cure, prevent, treat, control or improve the quality of life of individuals. Given the age-related changes in pharmacokinetics and pharmacodynamics in this population, this makes the

appropriate use of medicines more challenging. Ultimately, the incidence of polypharmacy in older adults is significant and the negative consequences of this can be more pronounced. There are more than 24 definitions of polypharmacy (see Bushardt et al. 2008), although the majority focus on the absolute number of medications prescribed (see **Table 2.3**). In a recent systematic review of the definitions of polypharmacy, over 80% of the identified definitions were purely numerical and half of these defined polypharmacy as the use of five or more medications on a daily basis (Masnoon et al. 2017).

Table 2.3 Numerical definition of polypharmacy and associated terms by duration of therapy/ healthcare setting (adapted from Masnoon et al. 2017)

Term	Number of medications	References
Polypharmacy	≥ 2 for 240 days (long term)	(Veehof et al. 2000)
	≥ 5 medications in the same month	(Jiron et al. 2015)
	> 5 medications for ≥ 90 days	(Narayan and Nishtala 2015)
	≥ 5 medications in the same quarter of a year	(Kann et al. 2015)
	≥ 5 medicines at hospital discharge	(Nobili et al. 2011)
	5 to 9 medicines on the same day of maximum number of prescriptions of the study year	(Chan et al. 2009b)
	5 to 9 medications for ≥ 90 days	(Nishtala and Salahudeen 2015)
	5 to 9 medicines during hospital stay	
	≥ 10 medicines during hospital stay	(Sganga et al. 2014)
Major polypharmacy	≥ 10 on the day of maximum number of prescriptions of the study year	(Chan et al. 2009b)
Hyper-polypharmacy	≥ 10 medications for ≥ 90 days	Nishtala and Salahudeen 2015)
Excessive polypharmacy	≥ 10 medications in the same quarter of a year	(Kann et al. 2015)
	≥ 10 medications during hospital stay	(Vetrano et al. 2014)
Persistent polypharmacy	≥ 5 medications for 181 days	(Chan et al. 2009a)
Chronic polypharmacy	≥ 5 medications in 1 month for 6 months (consecutive or not) in a year	(Franchi et al. 2013)

Other studies have defined polypharmacy according to the appropriateness of medicines being prescribed rather than the absolute number (see **Table 2.4**). Here, polypharmacy is either described as appropriate polypharmacy "*medication used to treat complex or multiple conditions where medicines have*

to be optimised or prescribed according to best evidence" and problematic polypharmacy where "multiple medications are prescribed inappropriately or the intended benefit of the medication is not realised" (Duerden 2013).

Table 2.4 Descriptive definitions of polypharmacy and associated terms (adapted from (Masnoon et al. 2017)

Term	Definition	References
Polypharmacy	• Patients visiting multiple pharmacies to obtain medications	(Gillette et al. 2015)
	• Co-prescribing multiple medications	(Filkova et al. 2014)
	• Simultaneous and long-term use of different drugs by the same individual	(Joaquim and Campos 2011)
	• Polypharmacy definition ranges from the use of a large number of medications, to the use of potentially inappropriate medications, medication underuse and medication duplication	(Maggiore et al. 2010)
	• Potentially inappropriate medications	(Bushardt et al. 2008)
	• Use of multiple medications concurrently and the use of additional medications to correct adverse effects	(Medeiros-Souza et al. 2007)
	• Use of medications which are not clinically indicated	(Fulton and Allen 2005)
	• More drugs being prescribed or taken than are clinically appropriate in the context of a patient's comorbidities	(Zarowitz et al. 2005)
Appropriate polypharmacy	Optimisation of medications for patients with complex and/or multiple conditions where medicine usage agrees with best evidence Rational	(Cadogan et al. 2015)
Rational polypharmacy and indiscriminate prescribing	Rational polypharmacy recognizes legitimate prescribing and indiscriminate prescribing suggests inappropriate prescribing (the terms "legitimate prescribing" and "inappropriate prescribing" were not explained)	(Ballentine 2008)
Pseudo-polypharmacy	Patients being recorded as taking more medications than they are actually taking	(Rollason and Vogt 2003)

This diverse range of definitions creates confusion for researchers and therefore Gillette et al. introduced a new term - 'extraordinary prescribing' (Gillette et al. 2015). The term is an attempt to dilute the contribution of the absolute number of medications prescribed (which may be appropriate in patients with multiple disease states) and rather focus on the consequences of prescribing. The authors indicate that 'extraordinary prescribing' defines "*patients who are taking medications that are either grossly excessive or not beneficial for that patient*"

(Gillette et al. 2015). To date, the term is yet to gain traction and polypharmacy remains the choice term. Although polypharmacy and inappropriate prescribing are sometimes used interchangeably, there are key differences. A patient might be described as subject to polypharmacy for example if they are taking more than five medications. However, the prescribing may be entirely appropriate given the patient's condition(s). Inappropriate prescribing therefore should be defined as "*the use of medicines whose potential harms outweigh their benefits or frequent omission of potentially beneficial medications or prescription of medications without clear indications*" (O'Connor et al. 2012).

2.1.5 Potentially inappropriate medications

Potentially inappropriate medications (PIM) are those medications in which the risk of adverse drug reactions outweighs any potential clinical benefits particularly when safer and more effective medicines are available. The risk associated with the prescribing of PIMs is the emergence of adverse drug reactions in patients. This has the potential to result in an unintended hospital admission, an A&E visit and increased mortality and morbidity (Bjerre et al. 2015). A variety of screening tools have been developed to assess the appropriateness of medications in older adults (see **Table 2.5**) and to make changes to medicines regimens as a consequence. The tools largely fall into two categories: (i) an implicit approach which is based entirely on the judgment of a clinician(s) after a review of a patient or (ii) an explicit approach where there is a categorical list of drugs that are considered as potentially inappropriate for individuals (Kashyap and Iqbal 2014).

Although the implicit approach is perhaps the preferred model as it is based on assessing the patient, their conditions and their medicines, it is a time-consuming approach and is dependent on the knowledge and skills of the clinician and their subsequent judgment according to each individual. While explicit criteria lack the person-centered approach, they provide a set of consistent standards (drug or disease oriented) that are approved by a

consensus panel, and enable the clinician reviewing an individual's medicines to make judgments on the current best evidence. They also provide for a desk-based review of a patient's medicines which is less resource intensive than implicit methods.

Beers criteria was chosen for this study because it is one of the most commonly used explicit criteria to identify the prevalence of PIMs. The criteria categorises medications into: (i) those that should be avoided in older adults aged 65 and over; (ii)medicines to be used with caution (independent of disease or condition) and (iii) medicines that should be avoided in particular disease states or conditions. Of note, as the researcher did not have access to the medical records of residents in care homes, Beers criteria provided a framework to identify PIMs independent of clinical diagnosis. Other tools e.g. STOPP/START are less valuable when clinical diagnosis is not available.

Table 2.5 Screening tools for the identification of potentially inappropriate medications in older adults (adapted from (Kashyap and Iqbal 2014).

Screening tools	Method used	Positive characteristics	Limitations
Explicit Methods			
Beer's criteria (Beers et al. 1991)	Derived from published reviews, expert opinions and consensus techniques without clinical judgement about the presenting patient.	Identifies and groups medications that may be inappropriate for older adults into three categories: (i) drugs that should be avoided in older adults; (ii) drugs that exceed the maximum recommended daily dose; (iii) drugs that should be avoided in combination with specific co-morbidity.	The criteria do not contain all causes of potentially inappropriate prescribing (e.g. drug interactions are not included). Controversy exists over some of the medications that are considered to be potentially inappropriate.
IPET Criteria (Naugler et al. 2000)	This is a revised version of Canadian McLeod criteria.	It includes 14 instances of inappropriate prescribing and identifies 38 agents as contraindicated or likely to cause drug-drug or drug-disease interactions based on risk-benefit ratio.	The criteria not based on physiological systems. The criteria is not comprehensive; there are only 14 cited situations to be avoided.
Zhan criteria (Zhan et al. 2001)	A variation of the 1997 version of the Beer's criteria	It has utility for identifying prescribing problems in retrospective review of older adult's medication lists.	It has limited applicability to geriatric clinical practice as it has low levels of inter-rater reliability and is focused only on those drugs which should be avoided in older adults without any consideration of drug dosage form, drug-disease interactions, or drug-drug combinations
Rancourt criteria (Rancourt et al. 2004)	Primarily based on Beer's and McLeod criteria. Updated and validated using modified Delphi method by local experts in long-term care setting of Quebec city, Canada.	Includes a wide range of potentially inappropriate medicines and is arranged according to drug classes along with their ATC code for ease of use and matches data on an international level.	The criteria is based on observations from one clinical setting in one region i.e. long term care settings in Quebec City. It is also more oriented towards assessment of psycholeptic drugs and there is a lack of evidence with respect to inter-rater reliability.
Health Plan Employer Data and Information Set (HEDIS) Criteria 2006 (National Committee on Quality Assurance 2018)	Provides a list of drugs which should always be avoided in elderly. It identifies rates of inappropriate prescribing in the elderly based on Beer's criteria.	It is currently being used in the 2006 Health Plan Employer Data and Information Set (HEDIS) in 2006 to assess quality of care for older Americans	The criteria does not include all the drugs listed in Beers criteria and the drugs are not classified according to severity. There is lack of convincing evidence showing the benefits of using HEDIS Criteria.

Screening tools	Method used	Positive characteristics	Limitations
STOPP criteria (Gallagher et al. 2008)	Part 1 of the STOPP/START criteria, this is a validated screening tool of older adult's medicines called STOPP (Screening Tool of Older People's potentially inappropriate Prescriptions). It incorporates commonly encountered instances of potentially inappropriate prescribing in older people including drug-drug and drug-disease interactions, drugs which adversely affect older adults at risk of falls and duplicate drug class prescriptions.	The criteria are easy to use as they are based on physiological systems similar to the pattern of most drug formularies. Each criterion is accompanied by a concise explanation as to why the prescription is potentially inappropriate.	The evaluation of this tool requires additional studies in different settings and different countries.
START criteria (Gallagher et al. 2008)	Part 2 of the STOPP/START criteria, this is a screening tool to alert prescribers to the right treatment. It was prepared and validated for identifying prescribing omissions in older adults.	It is a valid, reliable and comprehensive screening tools that enables the prescriber to appraise an older patient's prescription drugs in the context of his/her concurrent diagnoses	The international applicability of STOPP and START has not been established. Requires access to the patient and their records.
Winit-Watjana citeria (Winit-Watjana et al. 2008)	These explicit criteria list high-risk medications with potential adverse reactions, drug-disease interactions and drug-drug interactions. According to this list drugs acting on central nervous system, musculoskeletal system and cardiovascular system were high-risk medications in elderly.	This list has addressed different issue of inappropriate prescribing and most of identified inappropriate medications were similar among the different explicit criteria	This tool is not experienced in different clinical settings and also lack of inter-rater reliability
Implicit Methods			
Medication Appropriateness Index (MAI) (Hanlon et al. 1992)	An implicit criterion developed by Hanlon et al in 1992 and modified in 1997. It is intended to be a reliable, standardized method of addressing multiple elements of prescribing, applicable to a variety of medications, clinical conditions and settings.	Excellent intra-rater and inter-rater reliability associated with this tool which was tested in both the inpatient and ambulatory settings. It has numerous components to check the appropriateness of a medicine and can be applied to all type of medication in the context of patient-specific characteristics	A more time-consuming criteria as it takes 10 minutes to assess each drug.

2.1.5.1 National Prescribing Indicators (NPIs)

In addition to determining the appropriateness of medicines at the patient level, a variety of organisations have sought to establish national standards for the prescribing of a range of medicines called National Prescribing Indicators. These NPIs are used to promote therapeutic priorities and enable stakeholders to compare and contrast the prescribing of a medicine(s) by different prescribers or organisations. Ultimately, the NPIs serve to benchmark prescribers against a set of agreed and evidence-based standards. In Wales, the NPIs are 'owned' by the All Wales Medicines Strategy Group (AWMSG) (All Wales Medicines Strategy Group 2017) and feature three distinct categories: (i) safety indicators; (ii) antimicrobial stewardship indicators and (iii) efficiency indicators. Whilst not all the indicators are directly relevant to the care home setting, anticholinergic burden is a key indicator in this setting.

2.1.5.1.1 Anticholinergic Burden

Residents in care homes are widely prescribed drugs with anticholinergic properties (DAP) to treat a variety of disorders including gastrointestinal disturbances, motion sickness, sleep disorders and Parkinson' disease. These drugs exert their action through blockade of muscarinic receptors. However, the non-selective blockade of this receptor results in unwanted central and peripheral side effects leading to dry mouth, constipation, blurred vision, urinary retention, sedation, cognitive impairment and delirium (Tune 2001). In addition, older adults are more susceptible to the adverse effects of DAPs due to the age-related changes in pharmacokinetic and pharmacodynamics which may exacerbate their impact on this vulnerable population. Even when individual medicines have a low level of anticholinergic activity, where they are used cumulatively they have been associated with increased cognitive impairment and mortality (Fox et al. 2014). As a consequence, there is a drive to reduce the anticholinergic burden in individuals over 65 years of age.

2.2 Aims and objectives:

The aim of the present study is to explore the prescribing of medicines to resident in care homes.

The objectives are:

1. To identify the medicines prescribed to care home residents.
2. To assess the prevalence of polypharmacy and excessive polypharmacy in care homes residents.
3. To assess the prevalence of PIMs prescribed to care homes residents.

2.3 Methods

2.3.1 Ethical Approval

Prior to commencing this study ethical approval was obtained from the Cardiff School of Pharmacy and Pharmaceutical Sciences (SPPS) Research Ethics Committee (see Appendix 1). This study involved secondary analysis of anonymised patient data therefore consent from individual resident was not required.

2.3.2 Recruitment of care homes

This project formed part of a wider study funded by Welsh Government to explore the implementation of an electronic MAR system. The project was a collaboration between Cardiff University and a commercial partner, Invatech Health. Recruitment was led by Invatech Health although the inclusion/exclusion criteria and the recruitment methodology were developed in partnership. Ten care homes were recruited by purposive sampling from the Abertawe Bro Morgannwg University Health Board (ABMU) in Wales. To be eligible for the study, the nursing or residential home had to be located in the ABMU health board, primarily cater for older adults, be fully registered with the Care and Social Services Inspectorate Wales (CSSIW, now Care Inspectorate Wales) and currently use a paper-based MAR chart system. Identifying care homes in the health board was achieved in two parts. In Part 1, care homes in the three local

borough councils comprising the ABMU health board were identified from the Care and Social Service Inspectorate Wales (CSSIW) directory of care homes (http:/cssiw.org.uk/find-a-care-service/service-directory/? lang=en). The directory was filtered for adult residential services in the Swansea, Neath Port Talbot and Bridgend borough councils. In Part 2, the Lang Buisson commercial database of care homes was used to obtain telephone numbers, addresses and contact names for the care homes identified in Part 1.

An introductory letter was sent out from the ABMU Health Board to all care homes to invite them to a launch event to find out more about the project. All care homes were invited to express interest and volunteer to sign up for the project. The manager of each participating care home was approached to obtain written informed consent.

2.3.3 Data collection and extraction

Anonymised MAR charts were received from the ten participating care homes in October 2014 covering a 28-day medicines cycle that ran from September to October. An anonymisation process was carried out in the care homes such that any section of the MAR chart that could identify the resident was anonymised. This included the resident's name and room number, any information in relation to the pharmacy that supplied medication to the home and any further information that could link the MAR charts to any single person, organisation or service user other than the service provider themselves. A patient ID was assigned to each resident based on their date of birth.

The medicines prescribed for each resident was extracted directly from the MAR chart and classified according to therapeutic categories in the *British National Formulary* (BNF 2017). Information extracted from the MAR charts included: (i) date of birth; (ii) name of drug; (ii) strength of drug; (iii) type of formulation; (iv) dose of prescribed drug; (v) frequency of administration; (vi) quantity received; (vii) type of medication i.e. whether regular or 'when required' medications.

Dressings, nutritional supplements and related appliances were not included in the study.

2.3.4 Data analysis

Medication data for a 28-day period was collected and entered into Microsoft Excel for Mac version 15.33 (Microsoft Corporation; Seattle, USA). Descriptive statistics were generated to (i) categorise the prescribed medicines against BNF therapeutic class and (ii) to calculate the prevalence of polypharmacy (five or more medications prescribed) (Jiron et al. 2015) and excessive polypharmacy (ten or more medications prescribed) (Kann et al. 2015).

2.3.4.1 Calculating the prevalence of potentially inappropriate medicines

The fourth update of Beers criteria (Samuel 2015) was used to determine the prevalence of potentially inappropriate medicines use across the medication profiles of 260 residents in the ten care homes included in this study. The 2015 Beers criteria classifies 53 medication or medication classes into three classes: (i) 34 medications or medications classes that should be avoided (or deprescribed) for patients aged 65 years and older irrespective of their disease or condition; (ii) medications or medication classes that should be avoided in 19 specific disease or syndromes; and (iii) 14 medications that should be used with caution.

In the current study, the focus was on classes (i) and (iii) in Beers criteria i.e. those medications or classes of medication that should be avoided and those that should be used with caution; class (ii) was not applicable as the researcher did not have access to patient records that would have provided diagnostic criteria for prescribed medications. Only one modification to Beers criteria was made: Zopiclone was included in the list of (non-benzodiazepines hypnotics) replacing Eszopiclone because Zopiclone is commercially available in the UK (rather than eszopiclone). A description of the included medicines classes, the rationale for inclusion and the strength of evidence can be found in **Tables 2.6** and **2.7.** The final list of medications used in the analysis featuring 32 individual

medications that should be avoided in older adults and 12 individual medications that should be used with caution can be seen more conveniently in **Table 2.8**.

Beers criteria was applied to care home 10 (nursing home with specialised population having early onset dementia). In this home, some residents were < 65 which is outside of the scope of Beers criteria. However, analysis of the prescribing patterns in these residents showed similar levels for example of polypharmacy as those in other homes (residents > 65). As such, the researcher concluded that whilst the resident age profile may not have matched Beers, it remained valid given their prescribing to apply Beers criteria in this small number of residents. This is not without precedent. A study in Belfast applied STOPP / START criteria to a population of patients aged 40-65 (Moriarty et al. 2017) i.e. outside the normal framework.

Therapeutic class, *Drugs*	Rationale	Recommendation	Quality of Evidence	Strength of Recommendation	BNF category
Anticholinergics *Promethazine* *Hyroxyzine*	Highly anticholinergic; clearance reduced with advanced age, and tolerance develops when used as hypnotic; risk of confusion, dry mouth, constipation, and other anticholinergic effects or toxicity Use of diphenhydramine in situations such as acute treatment of severe allergic reaction may be appropriate	Avoid	Moderate	Strong	Antihistamine
Antispasmodics *Scopolamine*	Highly anticholinergic, uncertain effectiveness	Avoid	Moderate	Strong	Antispasmodics Hyoscine butyl bromide
Antithrombotic *Dipyridamole, oral short-acting (does not apply to the extended- release combination with aspirin)*	May cause orthostatic hypotension; more effective alternatives available; intravenous form acceptable for use in cardiac stress testing Safer,	Avoid	Moderate	Strong	Antiplatelet
Anti-infective **Nitrofurantoin*	Potential for pulmonary toxicity, hepatoxicity, and peripheral neuropathy, especially with long- term use; safer alternative available	Avoid in individuals with creatinine clearance <30 mL/min or for long-term suppression to bacteria	low	Strong	Urinary tract infections
Cardiovascular **Digoxin*	Use in atrial fibrillation: should not be used as a first-line agent in atrial fibrillation, because more-effective alternatives exist and it may be associated with increased mortality Use	Avoid as first-line therapy for atrial fibrillation	atrial fibrillation: moderate	atrial fibrillation: strong	Cardiac glycosides
Central nervous system Antidepressants, alone or in combination ** Amitriptyline* ** Paroxetine*	Recommendation Highly anticholinergic, sedating, and cause orthostatic hypotension; safety profile of low- dose doxepin (≤6 mg/d) comparable with that of placebo	Avoid	High	Strong	* Paroxetine-Selective serotonin reuptake inhibitors

Therapeutic class, *Drugs*	Rationale	Recommendation	Quality of Evidence	Strength of Recommendation	BNF category
Antipsychotics, first- (conventional) and second- (atypical) generation	Increased risk of cerebrovascular accident (stroke) and greater rate of cognitive decline and mortality in persons with dementia Avoid antipsychotics for behavioural problems of dementia or delirium unless nonpharmacological options (e.g., behavioural interventions) have failed or are not possible and the older adult is threatening substantial harm	Avoid, except for schizophrenia, bipolar disorder, or short-term use as antiemetic during chemotherapy	Moderate	Strong	Antipsychotics, first- and second-generation
Benzodiazepines Short- and intermediate- acting **Lorazepam* **Oxazepam* **Temazepam*	Older adults have increased sensitivity to benzodiazepines and decreased metabolism of long-acting agents; in general, all benzodiazepines increase risk of cognitive impairment, delirium, falls, fractures, and motor vehicle crashes in older adults	Avoid	Moderate	Strong	Anxiolytics Temazepam-Hpnotics
Benzodiazepines Long-acting **Diazepam* **Clonazepam*	May be appropriate for seizure disorders, rapid eye movement sleep disorders, benzodiazepine withdrawal, ethanol withdrawal, severe generalized anxiety disorder, and periprocedural anesthesia	Avoid	Moderate	Strong	Diazepam-Anxiolytics Clonazepam -Control of epilepsies
Nonbenzodiazepine, benzodiazepine receptor agonist hypnotics *Zolpidem* **Zopiclone*	Benzodiazepine-receptor agonists have adverse events similar to those of benzodiazepines in older adults (e.g., delirium, falls, fractures); increased emergency department visits and hospitalizations; motor vehicle crashes; minimal improvement in sleep latency and duration	Avoid	Moderate	Strong	Hypnotics *Zopiclone instead of Eszopiclone
Insulin, sliding scale	Higher risk of hypoglycemia without improvement in hyperglycemia management regardless of care setting; refers to sole use of short- or rapid-acting insulins to manage or avoid hyperglycemia in absence of basal or long-acting insulin; does not apply to titration of basal insulin or use of additional short- or rapid- acting insulin in conjunction with scheduled insulin (i.e. correction insulin)	Avoid	Moderate	Strong	Short and rapid-acting insulin in the absence of basal or long acting insulin

Therapeutic class, *Drugs*	Rationale	Recommendation	Quality of Evidence	Strength of Recommendation	BNF category
Proton-pump inhibitors	Risk of Clostridium difficile infection and bone loss and fractures	Avoid scheduled use for >8 weeks unless for high-risk patients (e.g., oral corticosteroids or chronic NSAID use), erosive esophagitis, Barrett's esophagitis, pathological hypersecretory condition, or demonstrated need for maintenance treatment (e.g., due to failure of drug discontinuation trial or H_2 blockers	High	strong	Proton-pump inhibitors
Non-cyclooxygenase-selective NSAIDs, oral: **Ibuprofen*	Increased risk of gastrointestinal bleeding or peptic ulcer disease in high-risk groups, including those aged >75 or taking oral or parenteral corticosteroids, anticoagulants, or antiplatelet agents; use of proton-pump inhibitor or misoprostol reduces but does not eliminate risk. Upper gastrointestinal ulcers, gross bleeding, or perforation caused by NSAIDs occur in approximately 1% of patients treated for 3–6 months and in ~2–4% of patients treated for 1 year; these trends continue with longer duration of use	Avoid chronic use, unless other alternatives are not effective, and patient can take gastro- protective agent (proton- pump inhibitor or misoprostol)	Moderate	Strong	Non-Steroidal Anti-inflammatory Drugs NSAIDs

Table 2.6 Drugs to be avoided in older adults (adapted from Samuel, 2015)

Therapeutic class, *Drugs*	**Rationale**	**Recommendation**	**Quality of Evidence**	**Strength of Recommendation**	**BNF category**
Aspirin for primary prevention of cardiac events	Lack of evidence of benefit versus risk in adults aged ≥80	Use with caution in adults aged ≥80	Low	Strong	Antiplatelet
Diuretics	May exacerbate or cause syndrome of inappropriate antidiuretic hormone secretion or hyponatremia; monitor sodium level closely when starting or changing dosages in older adults	Use with caution	Moderate	Strong	Diuretics
Carbamazepine					Control epilepsy
Mirtazapine					Other antidepressants
SNRIs					SNRIs
SSRIs					SSRIs
TCAs					TCAs

Table 2.7 Drugs to be used with caution in older adults (adapted from Samuel, 2015)

Table 2.8 Potentially inappropriate medicines used to characterise prescribing in this study

High risk medications	Therapeutic category according to Beers criteria	Therapeutic category according to BNF
Drugs that should be avoided		
1. Promethazine	Anticholinergics	Antihistamine
2. Hydroxyzine	Anticholinergics	Antihistamine
3. Dipyridamole	Antithrombotic	Antiplatelet
4. Aripiprazole	Antipsychotic	Antipsychotic
5. Pericyazine	Antipsychotic	Antipsychotic
6. Amisulpuride	Antipsychotic	Antipsychotic
7. Promazine	Antipsychotic	Antipsychotic
8. Prochlorperazine	Antipsychotic	Antipsychotic
9. Olanzapine	Antipsychotic	Antipsychotic
10. Haloperidol	Antipsychotic	Antipsychotic
11. Risperidone	Antipsychotic	Antipsychotic
12. Sulpiride	Antipsychotic	Antipsychotic
13. Quetiapine	Antipsychotic	Antipsychotic
14. Fluphenazine	Antipsychotic	Antipsychotic
15. Chlorpromazine	Antipsychotic	Antipsychotic
16. Trifluoperazine	Antipsychotic	Antipsychotic
17. Oxazepam	Benzodiazepines Short- and intermediate	Anxiolytic
18. Lorazepam	Benzodiazepines Short- and intermediate	Anxiolytic
19. Diazepam	Benzodiazepines Short- and intermediate	Anxiolytic
20. Digoxin >125mcg	Cardiovascular	Cardiac glycoside
21. Clonazepam	Benzodiazepines Long-acting	Control of epilepsies
22. Hyoscine Butyl bromide	Antispasmodics	Antispasmodics
23. Zolpidem	Hypnotic	Hypnotic
24. Zopiclone	Non-benzodiazepine, benzodiazepine receptor agonist hypnotics	Hypnotic
25. Temazepam	Benzodiazepines Short- and intermediate	Hypnotic
26. Nitrazepam	Hypnotic	Hypnotic
27. Ibuprofen	Non-cyclooxygenase-selective NSAIDs, oral	NSAIDs
28. Lansoprazole	PPIs	PPIs
29. Omeprazole	PPIs	PPIs
30. Amitriptyline	TCA	TCA
31. Paroxetine	Antidepressants, alone or in combination	SSRIs
32. Short and rapid-acting insulin	Insulin; in the absence of basal or long acting insulin	Insulin
Drugs that should be use with caution		
1. Aspirin	Aspirin for primary prevention of cardiac events	Antiplatelet
2. Furosemide	Diuretic	Diuretic
3. Bumetanide	Diuretic	Diuretic
4.Bendroflumethiazide	Diuretic	Diuretic
5. Spironolactone	Diuretic	Diuretic
6. Co-amilofruse	Diuretic	Diuretic
7. Citalopram	SSRIs	SSRIs
8. Sertraline	SSRIs	SSRIs
9. Venlafaxine	SNRIs	SNRIs
10. Duloxetine	SNRIs	SNRIs
11. Carbamazepine	Carbamazepine	Control of epilepsy
12. Mirtazapine	Mirtazapine	Other antidepressants

2.3.4.1.1 Anticholinergic burden

A retrospective review of the medicines data on the collected MAR charts was made to identify drugs with anticholinergic properties (DAPs). Those with anticholinergic properties were scored (scale 1 – 3) according to the Anticholinergic Effect on Cognition (AEC) criteria set out in the National Prescribing Indicators in Wales 2017-18 (All Wales Medicines Strategy Group 2017). A total AEC score was then calculated for each resident.

2.3.5 Statistical analysis

Univariate analysis (Pearson correlation) was performed to examine factors associated with PIMs including; (i) average age, (ii) prevalence of polypharmacy, (iii) average number of medications prescribed and (iv) number of residents per care home. The analysis was conducted using Graph Pad Prism version 7 (Graphpad Software; California, USA). $p < 0.05$ was considered statistically significant.

2.4 Results

2.4.1 Care Home Characteristics

Overall, some 260 residents residing in ten care homes were included in this study; the characteristics of the ten care homes are detailed in **Table 2.9.** The majority of residents (154; 59%) were 85 years of age or over whilst the average age of a resident was 83± 8.06 years (range 40-108 years). With the exception of care home 10, which specialized in care of patients with dementia (including early onset dementia), the care homes were broadly similar in characteristics i.e. the average age of the residents was broadly similar as was the average number of medicines prescribed per resident (8.3 [95% CI 8.3 to 7.8]). For the majority of residents, their medicines were primarily regular medicines (average number of regular medicines per resident ranged between 5 and 10 across the care homes) with “when required’ medications a smaller proportion of a resident’s prescribed regimen (average number of when required medicines per resident ranged between <1 and 2). The range in the number of medicines prescribed per

patient was quite dramatic. In care home 4 there were examples where residents were not prescribed any medications whilst in care home 10, a resident was prescribed 25 unique medicines.

Table 2.9 Care Home characteristics (n=10) with descriptive analysis of medications used by residents in each care home.

Care Home number	CH 1 Residential	CH 2 Nursing	CH 3 Nursing	CH 4 Nursing	CH 5 Nursing	CH 6 Nursing	CH 7 Nursing	CH 8 Residential	CH 9 Nursing	CH 10 Nursing*
Number of residents	19	21	25	26	53	20	17	24	14	41
Average age in years ±SD (range)	89±5(81-95)	75±4(79-102)	88±9(66-99)	86±6(72-95)	88±6(76-108)	88±4(79-95)	86±5(67-96)	87±8(62-99)	79±12(64-97)	64±12(40-98)
Number of meds prescribed	113	148	176	247	383	164	124	144	147	513
Mean number of meds per resident (95% CI)	6 (5.9%; 4.5-7.4)	7.0 (7%; 5.6-8.5)	7.0 (7%; 5.9-8.1)	9.5 (9.4%; 7.8-11.1)	7.2 (7.2%; 6.2-8.2)	8.2 (8.1%; 6.4-9.9)	7.2 (7.2%; 5.7-8.8)	6.0 (6%; 4.7-7.3)	10.6 (10.6%; 8.6-12.6)	12.5 (12.4%; 10.8-14.1)
Median number of meds per resident (range)	6(2-13)	7(2-15)	7(2-14)	9(0-19)	7(1-18)	7(2-16)	7(3-13)	6(1-14)	10.5(3-16)	12(3-25)
Mean N° of regular meds per resident	5	6	6	9	6	7	7	4	8	10
Mean N° of PRN meds per resident	1	<1	<1	1	<1	1.1	<1	2	2	2

**care home 10 specialised in the care of individuals with dementia*

2.4.2 General medicines patterns in care home residents

In total, 2,164 medicines were prescribed for the 260 residents studied. These medicines were categorised using the BNF according to the body system where they have their effect (see **Figure 2.2**). The system for which drugs were most commonly prescribed was the central nervous system which accounted for nearly 32% of the medicines prescribed. This was followed by cardiovascular system at 20% and gastro-intestinal system medications at 15%. Combined, these body systems accounted for more than 65% of all the drugs prescribed. Thereafter, the prescribing for other body systems did not represent more than 10% of the medicines prescribed. Of note, drugs to treat disorders of the immune system, malignant disease and drugs used as anesthetics represented less than 1% of all the drugs prescribed combined.

Table 2.10 provides an analysis of the prescribing patters at the individual care home level. The prescribing was found to be reasonably similar across the homes. Drugs that act on the gastro-intestinal system, cardiovascular system and nervous system were the top three therapeutic areas in all care homes (with the exception of care home 10) and accounted for greater than 59% of prescribed medicines in all homes. Care home 10, which specialises in the care of individuals with dementia, had a much higher prevalence of prescribing related to drugs that act on the nervous system (50.68%) and a lower prevalence of drugs that act on the cardiovascular system (6.82%). As shown in **Table 2.9**, the average age of residents in care home 10 (64 years) is much lower than other homes. Given that the incidence of cardiovascular disease increases with age, this finding is perhaps not surprising.

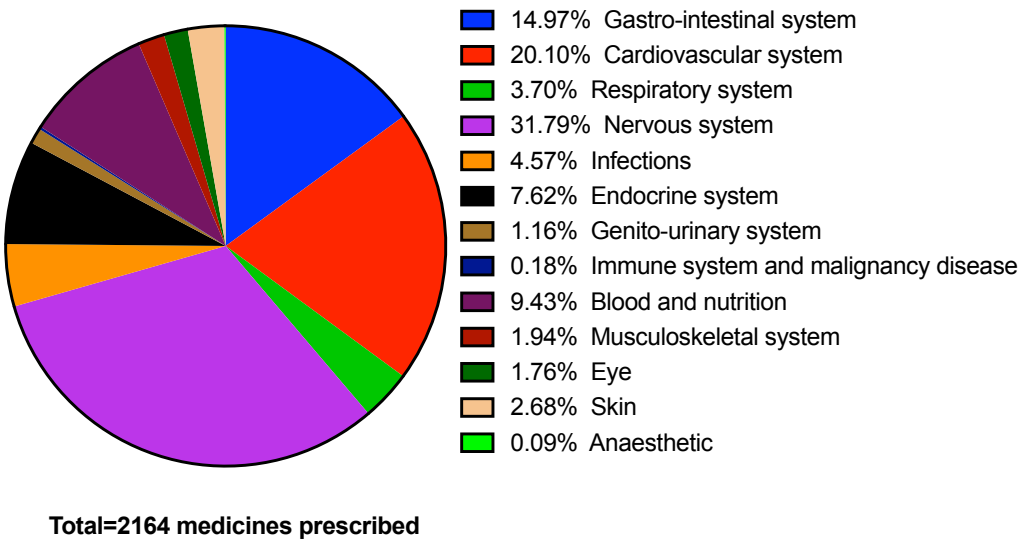

Figure 2.2 The percentage of medicines prescribed in the ten care homes examined in this study categorised by the body system in which they exert their therapeutic effect. Drugs acting on the nervous system (~32%), cardiovascular system (~20%) and gastro-intestinal system (~15%) accounted for over 65% of all the drugs prescribed.

Table 2.10 Breakdown of medicines prescribed to residents in each care home by body system. The prescribing patterns across the ten care homes was reasonably consistent with therapeutics acting on the gastro-intestinal system, cardiovascular system and nervous system accounting for ~60% or more of the medicines prescribed to residents.

	Medicines prescribed to residents categorised by body system (%)											
	CH1	**CH2**	**CH3**	**CH4**	**CH5**	**CH6**	**CH7**	**CH8**	**CH9**	**CH10**	**Mean**	**S.D**
Gastro-intestinal system	15.04	18.24	17.61	10.12	13.58	18.90	14.52	13.89	16.33	15.40	**15.36**	**2.59**
Cardiovascular system	26.55	25.00	21.59	21.05	29.77	17.07	33.06	28.47	12.93	6.82	**20.10**	**8.11**
Respiratory system	4.42	8.11	1.14	5.67	2.35	2.44	3.23	4.17	6.80	2.73	**3.70**	**2.19**
Nervous system	19.47	20.95	29.55	27.94	21.67	31.71	16.94	26.39	40.82	50.68	**31.79**	**10.43**
Infections	1.77	9.46	2.84	9.72	5.22	3.66	2.42	2.78	2.04	3.51	**4.57**	**2.93**
Endocrine system	12.39	6.08	8.52	7.69	9.40	6.10	8.06	7.64	4.08	5.85	**7.62**	**2.29**
Genito-urinary system	0.00	1.35	1.14	2.83	0.78	1.22	0.00	2.08	2.04	0.58	**1.16**	**0.92**
Immune system and malignant disease	0.88	0.00	0.00	0.00	0.26	0.00	0.81	0.69	0.00	0.00	**0.18**	**0.38**
Blood and nutrition	11.50	8.78	7.95	10.53	10.70	12.80	7.26	8.33	7.48	8.58	**9.43**	**1.87**
Musculoskeletal system	0.00	0.68	2.84	2.43	1.57	2.44	4.84	0.69	2.04	1.95	**1.94**	**1.36**
Eye	3.54	1.35	4.55	1.21	3.13	2.44	2.42	0.00	1.36	0.00	**1.76**	**1.49**
Skin	4.42	0.00	2.27	0.81	1.31	1.22	6.45	4.86	4.08	3.70	**2.68**	**2.09**
Anaesthetic	0.00	0.00	0.00	0.00	0.26	0.00	0.00	0.00	0.00	0.19	**0.09**	**0.10**
Total number of medicines prescribed	**113**	**148**	**176**	**247**	**383**	**164**	**124**	**144**	**147**	**513**		

A sub-analysis of the medicines prescribed within the categories of (i) gastrointestinal system; (ii) endocrine system; (iii) nervous system; (iv) respiratory system and (v) cardiovascular system is shown in **Figure 2.3.** For the medicines acting on the central nervous system, non-opioid analgesics, hypnotics and sedatives, antidepressant and antipsychotic drugs were the most commonly prescribed drugs in this category at 22%, 17% and 16% respectively. While for cardiovascular medications, antiplatelets, lipid modifying agents and diuretics were the most widely prescribed drugs at 23%, 17% and 15% respectively. In terms of medicines acting on the gastro-intestinal system, laxatives (57%) and PPIs (32%) accounted for almost 90% of medicines prescribed. Similarly, B2-agonist and antihistamines were the most widely prescribed medicines within the respiratory area at 40% and 30% respectively. Whilst in the endocrine system, both oral anti-diabetic drugs and drugs for treating disorders of bone metabolism were similarly prescribed at 23% each.

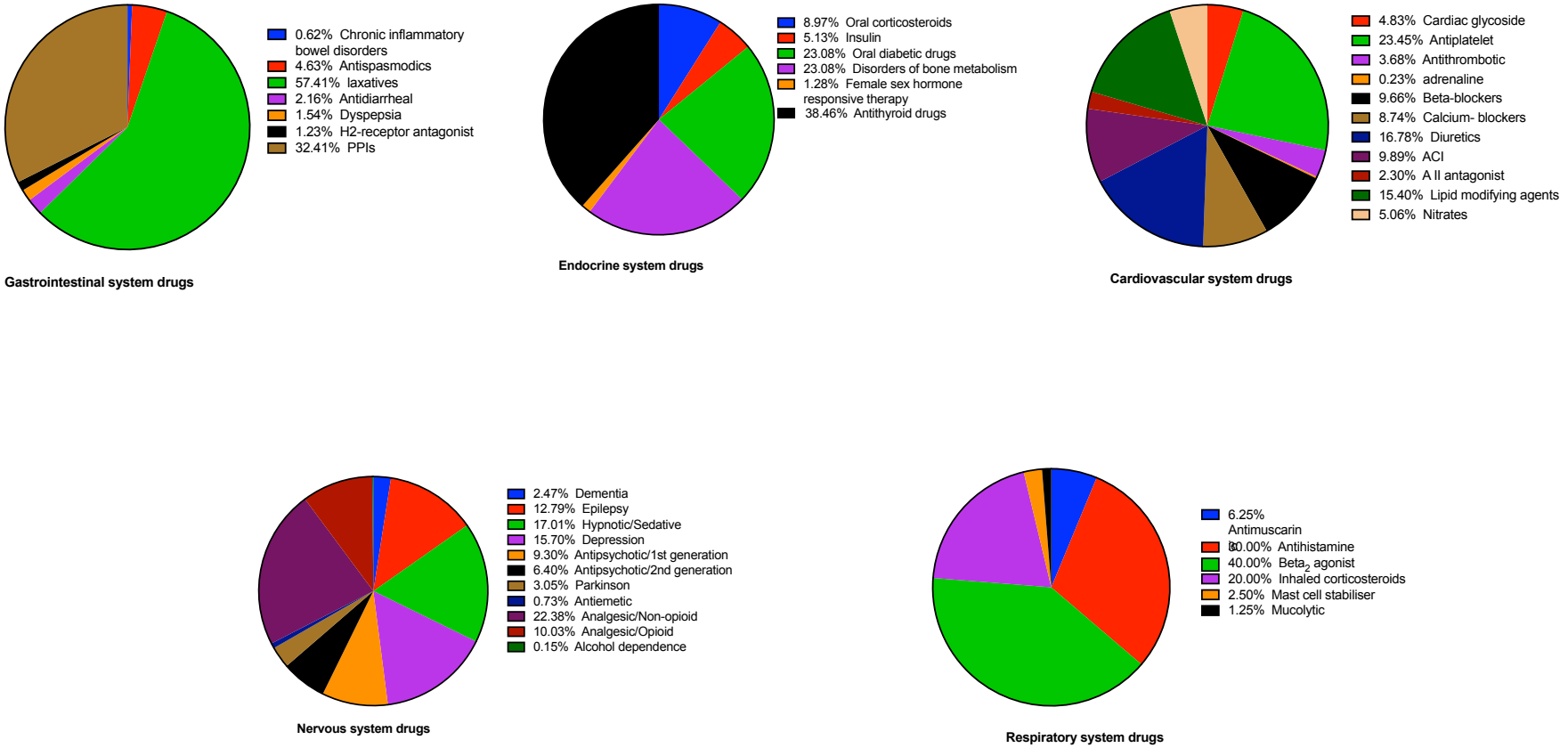

Figure 2.3 Breakdown of prescribing to care home residents by body system.

2.4.3 Prevalence of polypharmacy

The prevalence of polypharmacy (residents receiving ≥ 5 meds) and excessive polypharmacy (residents receiving ≥ 10 meds) in the ten care homes examined as part of this study is shown in **Table 2.11.** The average incidence of polypharmacy was 84% (range 68% to 96%) and excessive polypharmacy was 33% (range 11% to 76%). As can be seen, the variability between homes was much greater for excessive polypharmacy than for polypharmacy. Care homes 9 and 10 had the highest prevalence of excessive polypharmacy (71% and 76% respectively) and more than 90% of their residents experienced polypharmacy. Whilst the sample size is too small to draw any firm conclusions, it is worth noting that the two residential care homes featured residents with some of the lowest levels of polypharmacy.

Table 2.11 Percentage of care home residents exposed to polypharmacy and excessive polypharmacy.

Care Home	Percentage of residents with polypharmacy (≥ 5 meds)	Percentage of residents with excessive polypharmacy (≥ 10 meds)
1. Residential	68%	11%
2. Nursing	81%	14%
3. Nursing	88%	12%
4. Nursing	96%	46%
5. Nursing	77%	19%
6. Nursing	90%	30%
7. Nursing	76%	24%
8. Residential	75%	17%
9. Nursing	93%	71%
10. Nursing	95%	76%
Whole cohort	**84 %**	**33%**

2.4.4 Prevalence of potentially inappropriate prescribing

Beers criteria was applied to all the medications prescribed to the 260 residents included in this study. In total, 44 PIMs were seen to be prescribed across the 10 care homes. A total of 226 residents (87%) received at least one PIM and of these, nearly half were prescribed three or more PIMs (43%), 26% were prescribed two PIMs and 31% were prescribed one PIM (see **Table 2.12**). Of

note, the two residential homes in the study (care homes 1 & 8) had the lowest prevalence of residents receiving one or more PIM (63% and 71% respectively).

Table 2.12 The percentage of residents receiving potentially inappropriate medications. On average, 87% of residents were prescribed a potentially inappropriate medicine (range 63% to 100%).

Care Home	Number of residents (total = 261)	% of all residents receiving at least one PIM	% receiving 1 PIMs	% receiving 2 PIMs	% receiving ≥3 PIMs
1	19	63%	58%	-----	5%
2	21	86%	33%	33%	19%
3	25	76%	16%	28%	32%
4	26	92%	15%	27%	50%
5	53	87%	34%	26%	26%
6	20	95%	15%	35%	45%
7	17	94%	53%	24%	18%
8	24	71%	33%	29%	8%
9	14	100%	14%	14%	71%
10	41	100%	7 %	10%	83%
	Total	**87%**	**31%**	**26%**	**43%**

Out of all the medications prescribed (2,164 medications in total), 28% (615) were PIMs (range 12% to 37%) and this was divided into PIMs that should be avoided (17%) and PIMs that should be used with caution (11%) (see **Table 2.13**).

Table 2.13 Percentage of medicines prescribed in care homes that are PIMs sub-categorised as to whether they should be avoided or used with caution.

Care Home	N° of medications prescribed	% of medicines that are PIMs	% of medicines that should be avoided	% of medicines to be used with caution
1	113	12%	3%	9%
2	148	25%	11%	14%
3	176	28%	17%	11%
4	247	28%	15%	13%
5	383	27%	14%	13%
6	164	30%	15%	15%
7	124	22%	12%	10%
8	144	21%	8%	13%
9	147	37%	26%	11%
10	513	34%	27 %	7%
	Total	**28%**	**17%**	**11%**

As can be seen in **Table 2.13**, it is apparent that the prevalence of medicines to be avoided was lower in the residential homes than the nursing homes (care home 1 at 3% to be avoided and care home 8 at 8% to be avoided). The prevalence of PIMs was particularly high in homes 9 and 10 where PIMs to be avoided accounted for more than 25% of all medicines prescribed (26% and 27% respectively); in total PIMs accounted for more than a third of all medicines prescribed in care homes 9 and 10 (37% and 34% respectively).

A breakdown of the residents receiving either PIMs to be avoided or to be used with caution in each care home is provided in **Table 2.14**. There was no discernible pattern in the data, in five of the care homes patients receiving one or more PIMs to be avoided was more prevalent than those to be used with caution (care homes 4, 5, 7, 9 and 10), in three care homes the reverse was true (care homes 1, 2 and 8; of note 1 and 8 are residential homes) whilst in two care homes the prevalence was identical (care homes 3 and 6). Across the population studied, the prevalence of residents receiving at least one PIMs that should be avoided or used with caution was identical at 60%.

Table 2.14 percent of potential inappropriate medication based on two lists of Beers criteria received by resident in each care home

	% of residents receiving at least one PIMs		**% of residents receiving one PIMs**		**% of residents receiving 2 PIMs**		**% of residents receiving ≥3 PIMs**	
Care Home	**Avoid**	**Caution**	**Avoid**	**Caution**	**Avoid**	**Caution**	**Avoid**	**Caution**
1	16%	47%	11%	47%	5%	----	----	----
2	43%	71%	19%	52%	19%	19%	5%	----
3	56%	56%	20%	40%	16%	16%	20%	----
4	81%	73%	38%	42%	23%	19%	19%	12%
5	68%	58%	38%	38%	28%	17%	2%	4%
6	75%	75%	35%	45%	25%	20%	15%	10%
7	59%	53%	42%	41%	12%	6%	6%	6%
8	42%	50%	42%	33%	----	13%	----	4%
9	93%	71%	21%	36%	21%	29%	50%	7%
10	95%	56%	10 %	39%	17%	12%	68%	5%
Total	**60%**	**60%**	**28%**	**41%**	**18%**	**15%**	**20%**	**5%**

N.B. some residents may receive PIM(s) to be avoided and used with caution.

Table 2.15 provides a breakdown of the categories of PIMs prescribed to residents. The highest level of prescribing was for proton pump inhibitors (PPIs)

with 40% of all residents receiving a PPI followed by antipsychotics (32%), antiplatelets (26%), hypnotics (24%) and anxiolytics (22%); for all other therapeutic classes, the prevalence was less than 20%.

Table 2.15 Prevalence of residents receiving PIMs according to BNF therapeutic category. PPIs, antipsychotics, antiplatelets, hypnotics and anxiolytics were the most commonly observed PIMs each of which had a prescribing prevalence of more than 20% of the residents.

Therapeutic class	Number of residents receiving a medication (n = 260 residents)	Percentage of residents receiving a medication (rounded)
Antihistamine	2	< 1
Antiplatelet	68	26
Antipsychotic	83	32
Antispasmodic	6	2
Anxiolytic	58	22
Cardiac glycoside	2	< 1
Control of epilepsies	13	5
Hypnotic	62	24
Insulin	3	1
K sparing diuretic	5	2
Loop diuretic	43	17
NSAIDs	7	3
Other antidepressants	22	8
PPIs	105	40
SNRIs	9	3
SSRIs	38	15
TCA	6	2
Thiazide diuretic	6	2
Urinary tract infection	5	2

A statistical analysis using Pearson correlation was undertaken to identify if the prescribing of at least one PIM to a resident was associated with either age, number of residents in a care home, mean number of medicines prescribed per resident or the extent of polypharmacy. The analysis revealed a positive correlation between the prescribing of a PIM and the average number of medications taken by a resident ($p < 0.0051$) as well as the extent of polypharmacy ($p < 0.0184$). Conversely, no significant association was observed between the prescribing of PIMs and average age ($p < 0.2393$) or the number of residents in a home ($p< 0.7414$) (see **Table 2.16)**

Table 2.16 Pearson correlation between prevalence of PIMs and a range of parameters. Polypharmacy and the number of medicines prescribed showed a strong correlation with the potentially inappropriate prescribing.

% of residents receiving at least one PIM vs	Pearson r	95% CI	*P* value
Extent of polypharmacy	0.7218	(0.16-0.92)	0.0184*
Average age	-0.410	(-0.82-0.29)	0.2393
Mean number of meds	0.8038	(0.29-0.94)	0.0051**
Number of residents	0.1199	(-0.55-0.69)	0.7414

2.4.5 Anticholinergic burden in care home residents

Of the 260 residents included in this study, 52% (n=135) were prescribed at least one drug with anticholinergic properties (DAP). An 'anticholinergic effect on cognition' (AEC) score was applied to each drug and the total score calculated for each resident. Of all the DAPs prescribed 41% (n=107) attracted an AEC Score of 1, 12% (n=31) an AEC score of 2, and 10% (n=26) an AEC score 3 (data not shown). **Table 2.17** provides a breakdown of the number of residents with a total AEC score of 1, 2 or 3 or more by care home. In total, 45 residents (17%) were receiving DAPs that attracted a cumulative AEC score of three or more, 24 (9%) an AEC score of two and 66 (25%) an AEC score of one. There was quite considerable variability in the prevalence by care home. For example, in care home 1, just 2 residents of 19 (~1%) received a DAP whilst in care home 10 that rose to 34 residents of 41 (84%) receiving a DAP. Of note both care homes 9 and 10 had a significant percentage of residents (36% and 54% respectively) attracting an AEC score of three or more. As can be seen in **Figure 2.4**, 14 residents (5.4%) accumulated AEC scores that place them at risk of severe cognitive impairment whilst 31 residents (11.9%) accumulated scores that are likely to be clinically relevant (Pfistermeister et al. 2017). Although different scales have been developed to identify anticholinergic burden, the clinical consequences of the calculated burden has been shown to be broadly similar (Salahudeen et al. 2015) therefore, AEC score was applied in this current study given it was carried out in Wales where AEC is the preferred scale.

Table 2.17 number of residents prescribed medicines with a cumulative AEC Score of 1,2 or ≥ 3 per care home

Care home	N°. of residents	Residents with an AEC score of 1 (%)	Residents with an AEC score of 2 (%)	Residents with an AEC score of 3 or more (%)
1	19	1 (5%)	----	1 (5%)
2	24	7 (29%)	2 (8%)	-----
3	25	7 (28%)	1 (4%)	2 (8%)
4	26	14 (54%)	2 (8%)	3 (12%)
5	53	11 (21)	4 (8%)	5 (9%)
6	20	7 (35%)	4 (20%)	3 (15%)
7	17	2 (12%)	----	2 (12%)
8	24	6 (25%)	4 (17%)	2 (8%)
9	14	3 (21%)	3 (21%)	5 (36%)
10	41	8 (20%)	4 (10%)	22 (54%)
Total	**260**	**66 (25%)**	**24 (9%)**	**45 (17%)**

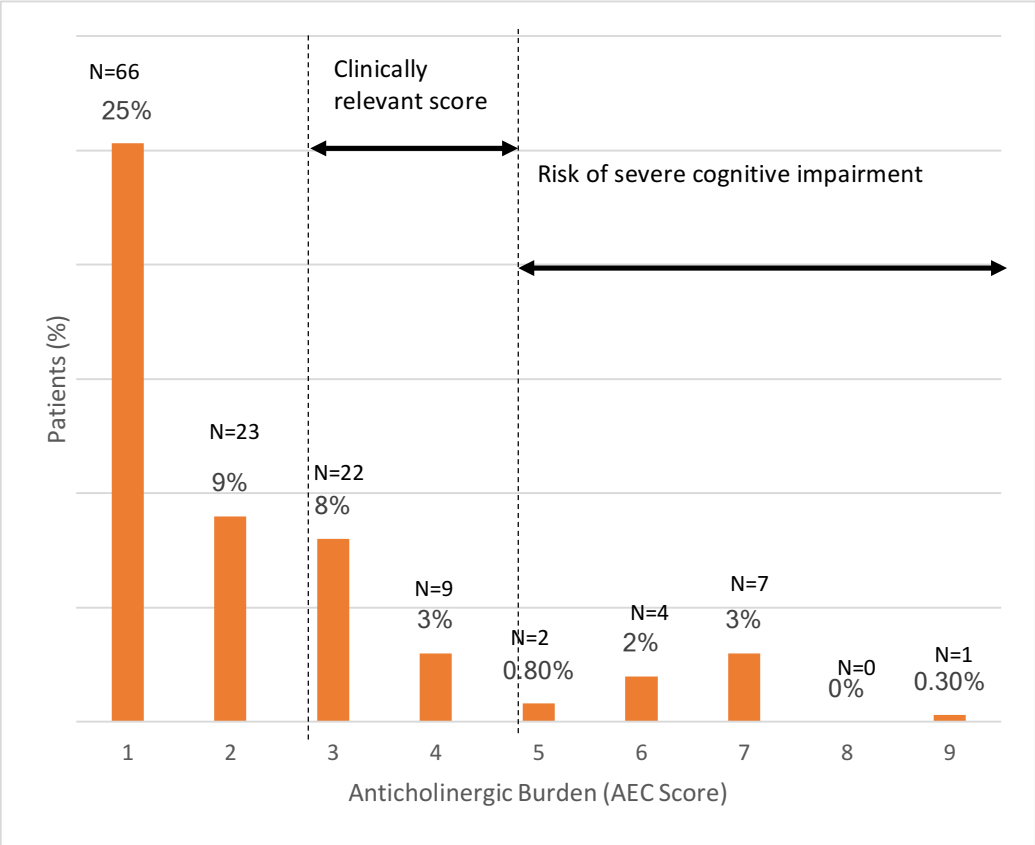

Figure 2.4 Anticholinergic effect on cognition scores in care home residents. Some 14 residents (5.4%) are likely to be at risk of significant cognitive impairment (AEC score of five or more) and 11 residents (4.2%) accumulated scores that are likely to be clinically relevant (AEC score of 3 or 4).

2.5 Discussion

There is evidence in the literature that residents of care homes are more likely to be exposed to inappropriate prescribing compared to patients in other settings (Loganathan et al. 2011; Shah et al. 2012). The incidence of polypharmacy in the older adult care home population is also thought to be more pronounced than other age matched populations (Bronskill et al. 2012). Combined with a continual decline in health status, this can have a number of consequences including the emergence of geriatric syndromes that include falls, functional and cognitive impairment and a reduced resistance to adverse drug events that can ultimately lead to unintended A&E visits, hospital admissions or in the worst case, death (Lau et al. 2005; Klarin et al. 2005; Hilmer et al. 2007). In this current study, the medications prescribed to 260 residents in 10 care homes in the Abertawe Bro Morgannwg University Health Board were examined through a retrospective analysis of paper-based MAR charts that covered a 28-day medicines cycle (September to October 2014); this provided a surrogate prescribing data set as currently there is no national data set that specifically details prescribing in care homes. A number of parameters were explored to assess the landscape of prescribing including (i) the prevalence of polypharmacy ($\geq$ 5 medicines prescribed) and excessive polypharmacy ($\geq$ 10 medicines prescribed); (ii) the prevalence of potentially inappropriate medicines as defined by Beers criteria for Potentially Inappropriate Medication Use in Older Adults and (iii) the anticholinergic burden placed on residents due to their medicines. All medicines were included in the analysis with the exception of borderline substances and appliances.

As has been demonstrated in the literature, the care home residents explored in this study were prescribed significantly higher number of medications than those in other health-care settings (Chen et al. 2001). For example, the average number of medicines taken by residents in this study was eight which compares to 2.03 for people aged 65-74 and 2.02 for those aged 75 and over in the later study. There is some evidence that entry into the care home has an impact on

the number of medicines a resident is prescribed. For example, Koopmans and colleagues explored the number of medicines an individual was prescribed immediately prior to entering a care home and then six weeks later. The authors found a small but significant increase in the mean number of medications prescribed to residents and the increase was most pronounced for medicines that act on the central nervous (Koopmans et al. 2003).

The residents in this current study were representative of the UK care home population in terms of age (Smith et al. 2015) with an average age of 83 years (range 40 – 108). The average number of medicines prescribed per resident was found to be eight (range from 0 to 25 medications). The findings in the literature in terms of the average number of medicines prescribed for care homes is fairly consistent. For example in the seminal CHUMS study, investigators reviewed MAR charts for 256 resident across 55 UK care homes (residential, nursing and mixed) and found that residents received an average of 8 medications (Alldred et al. 2009). Similarly, Gordon and colleagues reported an average of 8 medicines per resident in a cohort study conducted in 11 care homes in the UK (Gordon et al. 2014).

Similar findings have been demonstrated internationally. For example, Beers and colleagues investigated patterns of medication use in 12 care homes housing 850 residents in the US (Beers et al. 1988). They determined that residents were prescribed an average of eight medicines. Similarly, a cross-sectional study undertaken in all nursing homes in Helsinki, Finland with 1987 residents reported an average of eight medicines per residents (Hosia-Randell et al. 2008). Some studies however, have reported lower averages. For example, Furniss and colleagues investigated the impact of pharmacists undertaking medication reviews in 14 nursing homes in the UK. In their baseline data (330 patients) they reported that the average number of medications prescribed to each residents was five (Furniss 2002).

Despite some variability in the average number of medications prescribed to residents across these studies, all studies conclude that there is a high prevalence of polypharmacy in the older adult care home population. Polypharmacy has been described in a number of ways (see **section 2.1.4**) including absolute quantitative measures (normally five or more prescribed medicines) or using outcome-based measures (essentially the appropriateness of the prescribed medicines). In this current study, a quantitative definition was used because the researcher did not have access to residents' medical records and therefore a qualitative judgement on the appropriateness of the prescribed medicine(s) based on individual patient factors could not be made given the absence of a clinical diagnosis.

In this current study, the incidence of polypharmacy was determined to be 84% i.e. 84% of residents were prescribed five or more medicines. The literature is variable in this regard. For example in a European study (Czech Republic, England, Finland, France, Germany, Italy, and The Netherlands) in 57 nursing homes with 4,023 residents, 50% of the participants were prescribed five or more medicines (Onder et al. 2012). This was comparable with a study in the US that utilised a National Nursing Home Survey to survey 13,403 nursing homes residents and identified a prevalence of polypharmacy in 40% of the population studied (Dwyer et al. 2010). In contrast, a prevalence of 93% was reported for 302 residents in 8 nursing homes in Sweden (Inger et al. 2010). More recently, there has been a focus on excessive polypharmacy i.e. patients receiving ten or more medicines. In this study 33% of all residents received 10 or more medications. Again, there is variability in the literature. Elseviers and colleagues explored a stratified random sample of Belgian nursing homes and found that nearly 30% of residents received 10 medications or more (Elseviers et al. 2010). Similar findings were observed in the US through the National Nursing Home survey which reported a 40% prevalence rate (Dwyer et al. 2004) and a 37% prevalence rate was reported in 11 Veterans Affairs Medical Centers (Hajjar et al. 2005). However, in a cross-sectional study conducted with 68,939 Canadian

nursing home residents, the prevalence of excessive polypharmacy was roughly half that found in other studies at 15.5% (Bronskill et al. 2012). It is difficult to conclusively determine the reasons for this variability, however a number of hypotheses have been put forward in the literature (O'Sullivan et al. 2013; Garfield et al. 2009; Pierson et al. 2007) . These include a higher prevalence in nursing homes compared to residential (reflecting the complexity of patients in these settings) (Schuler et al. 2008) and the type of specialist care provided by some homes. Indeed, in this current study, residents of care home 10 which specialized in the care of individuals with dementia were found to have a higher prevalence of polypharmacy (95%) and excessive polypharmacy (66%) in comparison to other homes. Of the ten care homes included in this study, eight homes were nursing and two were residential. Whilst the sample size was relatively small and any conclusions should be made with caution, there were trends in the data. For example, residents in the two residential homes had the lowest prevalence of polypharmacy and were in the bottom half for excessive polypharmacy.

The clinical consequences of polypharmacy are well documented and are as a consequence of drug related problems related to drug-drug interactions, adverse drug reactions and in the older adult population the added risk of developing geriatric syndromes (Hughes et al. 2016). A variety of studies have highlighted these consequences. For example a study by Nguyen and colleagues in a 1200 bed nursing home in the USA found that there was a two-fold increase in the prevalence of adverse drug events in residents receiving nine medications or more (Nguyen et al. 2006). Similarly, Resnick and colleagues demonstrated that nearly 25% of the 242 residents residing in 26 assisted living facilities in the US were admitted to hospital or had an unintended accident and emergency visit due to polypharmacy (Resnick et al. 2018); of note, the authors found that rates of polypharmacy were higher than in other settings. Also, Delcher and colleagues found a direct relationship between the number of medications used and the prevalence of drug-drug interactions in newly admitted older adults

(65+) to a community-based hospital in Canada. In their study, the probability of drug-drug interactions was increased from 50% in patients taking 5-9 medications to 100% when the patients received 20 medications or more (Delcher et al. 2015). Of note in this current study three residents (from 260) were receiving 20 or more medications (data not shown). Jyrkka¨ and colleagues investigated the impact of polypharmacy on cognitive impairment in 294 older adults (75+) in Finland. In patients receiving 5 medicines or less, 20% were found to have some level of cognitive impairment. This increased to more than 50% in those patients receiving 10 or more medications (Jyrkkä et al. 2011). Kojima and colleagues focused on the impact of polypharmacy on the incidence of falls. The authors followed 172 older adults (average age 76 years) in an outpatient setting in Japan and found that 32 of these patients experienced a fall during the study period. Using a multiple logistic regression analysis, the absolute number of drugs prescribed was significantly associated with the incidence of falls and was independent of age, sex and extent of comorbidity (Kojima et al. 2012).

One of the factors partly responsible for polypharmacy is thought to be 'prescribing cascades'. A prescribing cascade is defined as a process where the adverse effects of one drug are misdiagnosed as a new symptom that results in a prescription to treat the new symptom rather than addressing the original adverse drug effect. This creates additional risk from the new drug and in some instances, increases the incidence of geriatric syndromes. For example, the use of anticholinergic drugs to treat the extrapyramidal effects of antipsychotics, has the potential to expose the resident to anticholinergic adverse effects such as orthostatic hypotension, urinary retention and blurred vision which in turn may adversely increase the risk of falls and cognitive impairment (Lavan and Gallagher 2016; Cahir et al. 2010).

Patient related factors such as female sex (Chen et al. 2001; Hosia-Randell et al 2008; Jyrkkä 2011), older adults residing in care homes (Chen et al. 2001; Haider et al. 2008) and socioeconomic characteristics such as low educational

attainment (Haider et al. 2008) have also been shown to be positively associated with the risk of polypharmacy. One factor where there is conflicting evidence is age. Some studies have shown that older adults aged 75 and over are more likely to be exposed to polypharmacy when compared to those aged 65-74 (Chen et al. 2001). While other studies have found that being 85 and over is strongly associated with polypharmacy (Linjakumpu et al. 2002) and excessive polypharmacy (Jyrkkä 2011). In contrast, other studies have reported that there is no significant correlation between age and polypharmacy (Chin et al. 1999; Junius-Walker et al. 2007; Vieira De Lima et al. 2013).

In addition, health related factors such as: (i) poor health status (Junius-Walker et al. 2007); (ii) multiple co-morbidity with at least three or more diagnosis (Vieira De Lima et al. 2013; Dwyer et al. 2010; Schuler et al. 2008), (iii) nutritional deficiencies (Hosia-Randell et al. 2008; Jyrkkä 2011); (iv) impairment in physical activity, and (v) progressive loss in cognitive capacity (Jyrkkä 2011) are positively associated with polypharmacy in older adults.

Beyond the clinical consequences to the resident, polypharmacy has been associated with increasing health care expenditure. For example, a study was undertaken in Sweden between 2005 and 2009 to determine the impact of increasing polypharmacy on prescribed drug expenditure (PDE). The prevalence of polypharmacy (≥5 prescribed drugs) increased by 8.3% over this period (from 11.1% to 12.0%) and the prevalence of excessive polypharmacy (≥10 prescribed drugs) increased by 9.9% over (from 2.4% to 2.6%). Overall, PDE increased by 4.8% and for patients with polypharmacy or excessive polypharmacy PDE increased by 6.2% and 7.3% respectively. Of note in a simulation that sought to neutralise increases in polypharmacy, no increase in total PDE was measured (Hovstadius and Petersson 2013). Similarly, the increased incidence of adverse drug events with polypharmacy has been shown to increase the risk of hospitalisation which increases health expenditure (Onder et al. 2002). In a study conducted with 6628 Japanese older adults (65+) using a health insurance claims

data, polypharmacy was a major predictor of potentially inappropriate prescribing, increased outpatient visits and risk for hospital admission that resulted in an increase of more than 30% in the healthcare expenditure (Akazawa et al. 2010). A small number of studies in the US have attempted to estimate the costs of medicines use and polypharmacy in the care home setting. A study by Kamboj and colleagues in Louisiana (US) nursing homes determined the average cost of medicines per resident per day to be $182 with an annual estimated cost of $2184 per resident. The authors found that older adults receiving multiple medications in nursing home were associated with higher expenditure (Kamboj et al. 1999). These costs appear to be rising with for example, Trygstad and colleagues reporting the cost of medicines had reached nearly $6000 per resident per year in 253 US nursing homes (Trygstad et al. 2005).

There have been a number of studies which have sought to examine a range of interventions, primarily pharmacist lead, to reduce the prevalence of polypharmacy in care home residents. A study by Zermansky and colleagues investigated the impact of pharmacists conducting clinical medication reviews on 661 elderly care home residents. The authors reported a substantial change in residents' medication regimens with a mean number of changes of 3.1 per resident, although no change in drug costs was observed (Zermansky et al. 2006). Furniss and colleagues reported a decrease in the mean number of prescribed medication from 5.4 to 4.2 during a pharmacist intervention in 14 nursing homes in the UK (Furniss et al. 2000). The clinical consequences of such interventions remains equivocal however with some studies reporting that medication reviews do not improve mortality rates or functional capacity (Zermansky and Silcock 2009) or reduce hospital admissions (Wallerstedt et al. 2014).

In this current study, there was an exploration of the general prescribing landscape in care homes. Medicines that act in the central nervous system

(31%), cardiovascular system (20%) and gastro-intestinal system (14%) were the most commonly prescribed medicines. This correlates with findings from studies in care homes in the UK (Furniss et al. 2000; Ryan et al. 2013) and internationally (Dwyer et al. 2010; Beloosesky et al. 2013; Pinto et al. 2013).

In the central nervous system, analgesics (22.4%), hypnotics & sedatives (17%) and antipsychotics (16.4%) were the most frequently prescribed medicines. This finding was similar to that reported in several studies within the same setting. For example, an earlier study by Avorn and colleagues in 12 care homes in the US reported that 29% of residents received an hynotic and 28% an antipsychotic (Avorn and Gurwitz 1995). For analgesics, Sandvik and colleagues investigated the trends in analgesic prescribing to care home residents in Norway for the period 2000 to 2011. Over those 11 years, the prescribing of paracetamol increased by 113% from 22.7% of residents to 48.4% of residents. Similarly, the prevalence of opioid prescribing increased from 1.9% to 17.9% (Sandvik et al. 2016).

In terms of analgesics, non-opioid analgesics were more commonly prescribed in comparison to other types. The incidence of mild to moderate pain in care home residents is known to be with up to 75% of residents suffering from pain (Mahoney and Peters 2008). As a consequence, the prescribing of non-opioid analgesics is high (Dwyer et al. 2010). Although serious adverse drug events are rarely associated with non-opioid analgesics, they are commonly prescribed in volume as 'when required' medications. The result is that they are responsible for increased medicines costs, and constitute a significant source of wasted medicines in care homes (see **Chapter 4**).

Consistent with other studies (Ruggiero et al. 2010; Sunil M Shah et al. 2012; Beers et al. 1988; B. Hagen et al. 2005; Vieira De Lima et al. 2013; Snowdon et al. 2005; Stevenson et al 2010), the prescribing of psychotropic medicines (hypnotics/anxiolytics and antipsychotics) was observed in more than half the residents in this current study. A population-based data-linkage study in the UK

by Maguire and co-workers on 250,617 individuals aged 65 and over found that the prescribing of psychotropic drug was significantly higher in care home residents (20.3%) compared with community dwelling older adults with only (1.1%). In addition, the prescribing of antipsychotics and hypnotics increased by more than 10% after admission to a care home (Maguire et al. 2013). Of note, more than quarter of antipsychotics prescribed in care homes are prescribed in the absence of a definitive diagnosis of severe mental health problems (Shah et al. 2011) and they are used for extended periods of time without review (Simoni-Wastila et al. 2014). Given that their efficacy in older adults is questionable (Wilfling et al. 2015), there has been much discussion in the popular press surrounding the use of antipsychotics in older adults in care homes and particularly in those with dementia where antipsychotics are used off-label (Briesacher et al. 2013). There is evidence in the literature that has highlighted serious safety issues around the use of antipsychotics with increased risk of falls (French et al. 2007), stroke, cognitive impairment and even death (Huybrechts et al. 2012; Schneider et al. 2006; Alldred et al. 2007; Schneider et al. 2005).

The same is true of hypnotics and anxiolytics, which have been associated with an increased risk of falls (Ray et al. 2000; Mcmahon et al. 2014; Berry et al. 2016), hip fractures (Wang et al. 2001; van der Hooft et al. 2008) and functional and cognitive impairments (Foy et al. 1995; Nazareth, Burkhardt 2008) especially when such medications are used for extended periods. Ultimately, the wide-spread use of psychotropic agents in older adults is a concern because of an acute susceptibility to the adverse effects of central nervous system medicines and their propensity to lead to the development or progression of a variety of geriatric syndromes.

Another area of prescribing in older adults that has seen intense scrutiny in recent years is the use of drugs with anticholinergic properties (DAPs) due to their propensity to adversely affect cognition and physical function. In this current study, more than 50% of the residents received at least one DAP. Using

the Anticholinergic Effect on Cognition scale, a score was calculated for any resident receiving one or more DAPs. Scores of 3 - 4 are considered to be clinically relevant and scores above five place residents at risk of severe cognitive impairment (Campbell et al. 2009; Fox et al. 2014; Pfistermeister et al. 2017). In this current study, 11.9% of all residents had a clinically significant score and 5% had a score that would indicate a significant risk of cognitive impairment. The highest incidence of anticholinergic burden was seen in care home 10 where more than half the residents had an AEC Sore of three or more. This is a concerning finding as dementia patients will have pre-existing cognitive decline which is likely to be exacerbated by the anticholinergic burden.

With regards to medicines that act in the gastro-intestinal system, the prescribing of laxatives was particularly prevalent with more than 50% of residents receiving one or more laxatives. This is consistent with a number of studies that have identified laxatives to be commonly prescribed in care homes (Snowdon et al. 2006; Jerry Avorn, Jerry H. Gurwitz 1995; Chen et al. 2014). The high prescribing rate has been attributed to a range of patient related factors in this cohort particularly related to age, lack of mobility, poor diet or the side effects of a number of medications commonly used in this population (Suominen et al. 2005; Ehrenberg and Ehnfors 1999). However, this may lead to chronic use of laxatives in some residents which may cause further drug related problems including electrolyte and mineral imbalances, severe dehydration, laxative dependence, chronic constipation, internal organ damage and increased colon cancer risk (International Longevity Centre-UK 2013).

Whilst the prevalence of polypharmacy and the general prescribing patterns in care home provides some insight into the risks of negative clinical consequences of medicines use in care home residents, it is less useful in determining the appropriateness of prescribed medicines. It is more useful to assess the prevalence of prescribing of potentially inappropriate medicines using standardised criteria.

To explore the prescribing of potentially inappropriate medicines, BEERs criteria (Samuel 2015) was used to assess the prevalence of PIMs using prescribing data captured from MAR charts; BEERs criteria has been used in a variety of studies to assess prescribing in care homes in the Europe and the USA (King and Roberts 2007; Niwata et al. 2006; Varallo et al. 2012; Storms et al. 2017; Stafford et al. 2011; Perri 2005; Mamun et al. 2004; Vieira De Lima et al. 2013; Ruggiero et al. 2010; Pinto et al. 2013). Some 87% of the residents in this current study were prescribed at least one PIM and 43% were prescribed three or more PIMs. The PIMs were sub-categorised into those that should be avoided and those that should be used with caution. Some 60% of residents received at least one PIM that should be avoided and 20% received three or more PIMs that should be avoided. Similarly, 60% of residents received at least one PIM that should be used with caution but only 5% received three or more PIMs that should be used with caution. Some residents received a combination of PIMs to be avoided and used with caution (data not shown). Irrespective of this, the prevalence of inappropriate prescribing (at least against BEERs criteria) was significant. A number of studies including those in Brazil (Vieira De Lima et al. 2013), Belgium (Anrys et al. 2018), Finland (Hosia-Randell et al. 2008) and Japan (Niwata et al. 2006) have sought to estimate the prevalence of PIMs prescribing for care home residents. The reported prevalence shows a high degree of variability with studies reporting a prevalence of at least one PIM anywhere between 20% to 80% (King and Roberts 2007; Niwata et al. 2006; Varallo et al. 2012; (Hosia-Randell et al. 2008; Barnett et al. 2011; Hwang et al. 2015; O'Sullivan et al. 2013; Vieira de Lima et al. 2013; Verrue et al. 2012; Ryan et al. 2013). In the UK and Ireland, the landscape is similar, for example O'Sullivan and colleagues explored prescribing to 732 residents in 14 nursing homes and long stay community hospitals. They found that 50% of the residents were receiving at least one PIM (O'Sullivan et al. 2013), not too dissimilar to this current study. However, in a cross-sectional study of 10,387 care home residents, 33% were prescribed a PIM compared to 21% in the community setting (Shah et al. 2012). Whilst this

heterogeneity in the literature might be influenced by the unavailability of certain medications in different countries or due to differences in study design and duration, it is clear that there is a substantial level of potentially inappropriate prescribing to care home residents both nationally and internationally.

In agreement with findings related to polypharmacy, the prevalence of PIMs was lower in the two residential care homes included in this study. Although the numbers are small, this finding might suggest that residents in residential homes are less likely to have complex clinical conditions requiring prescribing interventions compared to those in nursing home. Care home 1 had a particularly interesting pattern of PIMs where the prevalence of medicines to be used with caution (46%) dramatically outweighed those to be avoided (16%). While in nursing home 10 (nursing with specialist dementia care), the inverse was true i.e. 65% of residents received medicines that should be avoided and only 5% received medicines that should be used with caution.

It should be noted that the study design utilised here did not allow for a determination of the reasons why residents were prescribed PIMs i.e. whether it is related to poor prescribing habits, non-evidence-based indications, complex health conditions associated with the residents, or the prescribing cascade phenomenon. Therefore, further studies should seek to address this gap in the knowledge base using a resident' medical records to make a comprehensive judgment with regards to the appropriateness of medications used according to each clinical condition.

In this study, a moderate negative correlation was identified between the prevalence of PIMs and advancing age which is in agreement with other studies (O'Sullivan et al. 2013; Vieira De Lima et al. 2013). It is unclear why this is the case but may be associated with deprescribing protocols in end of life care (Holmes et al. 2006; Liu 2014).

In contrast, a higher number of prescribed medications and the presence of polypharmacy was a strong predictor of PIMs prevalence. This finding has been corroborated in a variety of studies both in the UK (O'Sullivan et al. 2013) and internationally (Fiss et al. 2011; Ryan et al. 2013; Pinto et al. 2013; Vieira De Lima et al. 2013; Niwata et al. 2006; Tommelein et al. 2015; Chen et al. 2012) in care homes and in other health care settings (Maio et al. 2006; Gallagher et al. 2011; Fialová et al. 2005; Frazier 2005).

Other factors have also been identified to have a positive association with the prescribing of PIMs. For example, a number of studies have found that females are more likely to be prescribed PIMs (Pinto et al. 2013; Rigler et al. 2004; Bierman et al. 2007). Other studies have found that poor health status (Fu et al. 2004) and multiple co-morbidities are risk factors for the prescribing of PIMs (Chin et al. 1999; Klarin et al. 2005; Vieira de Lima et al. 2013; Elseviers et al. 2014). Of note, length of stay in a care home is associated with significant increase in the likelihood of being prescribed a PIM (Chen et al. 2012; Rancourt et al. 2004).

Although the prescribing of a PIM does not necessarily result in patient harm, the use of inappropriate medicines has been associated with increased negative health outcomes (Lund et al. 2010; Hedna et al. 2015; Donna 2008; Heider et al. 2017). For example, the use of anxiolytics, sedatives or hypnotics may increase the incidence of falls and fractures among older adults. This finding was reported in a case control study in the USA with 17,198 patients aged 65 and over receiving benzodiazepines and related drugs. The authors reported that benzodiazepine use was associated with an increase in the relative risk of hip fracture and this increased with dose, interacting drugs and the risk was highest at the point of initiation of the benzodiazepine (Zint et al. 2010). Of note, some 22% and 24% of residents in this current study were prescribed an anxiolytic or hypnotic respectively.

More broadly, a link has been established between Beers criteria and the incidence of drug related problems in care home residents leading to drug-drug interactions (Hosia-Randell et al. 2008) and unintended hospital admission (Fick et al. 2001; Klarin et al. 2005; Lau et al. 2005; Jano and Aparasu 2007; Budnitz et al. 2007). As Gallagher and O'Mahony noted, nearly half of 715 older adults receiving Beers criteria PIMs were subjected to acute hospital admission due to their related adverse drug events in the UK (Gallagher and O'Mahony 2008). This was confirmed by a prospective study conducted in six European teaching hospitals (Switzerland, Spain, Belgium, Italy, and the UK) on 900 older adults which revealed a significant association between Beers criteria PIMs and recent hospitalisation ($p < 0.01$) (Gallagher et al. 2011).

Furthermore, exposure to PIMs has been shown to increase health care cost. In an earlier study by Fick and colleagues in the USA on 2,336 Medicare managed care patients aged 65 and over, a significant association was demonstrated between high prevalence of PIMs use and total cost paid ($p < 0.0001$) (Fick et al. 2001). Similarly, a study by Donna and colleagues in a community dwelling population with 17,971 individual aged 65 and over in the USA, reported a two-fold increase in the utilisation of health care services with a significant correlation between the number of PIMs used and overall cost (Donna 2008) This was in agreement with a study using a retrospective observational approach in Germany with 521,644 out-patients aged 65 and over. This study reported an increase in mean total health care cost by €2321 due to PIMs related adverse drug events (Heider et al. 2017).

Several studies have sought to investigate the effect of interventions that are designed to reduce the prescribing of PIMs in care homes. A range of interventions were examined including: medication reviews, case conferencing, clinical decision support systems, educational interventions and some of these have been tested in care homes (Alldred et al. 2013). For example several studies have evaluated the effect of training on the rate of prescribing / use of

psychotropic drugs versus behavioral management techniques (Fossey et al. 2006; B. F. Hagen et al. 2005; Meador et al. 1997). These studies have found a decrease in the number of residents using such medications or reductions in their dosages with training. Other studies have emphasised the role of the pharmacist or the multidisciplinary team in reducing inappropriate prescribing through medication reviews or the use of screening tools. These interventional approaches generally focus on deprescribing. Deprescribing is defined as 'a process of withdrawing, changing or even reducing the dose of the current medications of older adults' (Woodward 2003). Deprescribing approaches are suggested to decrease both adverse drug events and medicines costs (Garfinkel et al. 2010). However, the clinical impacts of these interventions in reducing the risk of harm to the patients associated with PIMs is still equivocal (Furniss et al. 2000; Zermansky et al. 2006; Roberts et al. 2001; Koria et al. 2018; Patterson et al. 2014; Cooper et al. 2015).

In conclusion, this chapter has described the prescribing patters for 260 older adults in ten care homes in the South Wales region. The prevalence of polypharmacy (5+ medicines), excessive polypharmacy (10+ medicines) and the use of potentially inappropriate medicines was significant but in line with studies in the literature. A significant number of residents were also exposed to a significant anticholinergic burden. Together, this is likely to place some residents at risk of cognitive impairment, geriatric syndromes and increased morbidity and mortality. In an already vulnerable population, careful consideration of prescribing practice is needed and efforts should be made to reduce the medicines burden on such individuals.

References:

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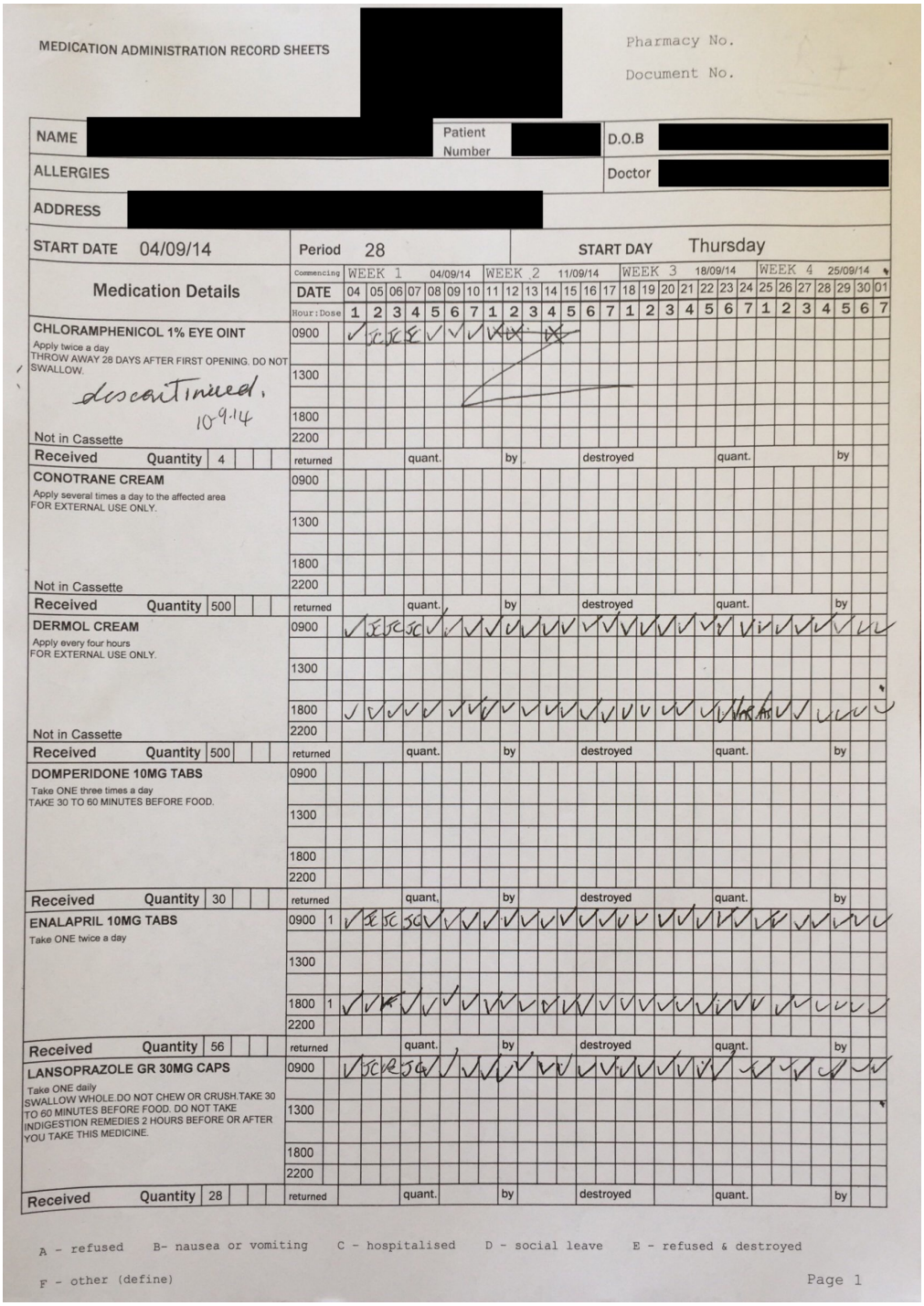
Chapter 3. Medicines administration errors in care homes

3.1 Introduction

3.1.1 Medication administration record charts

When medicines are administered to residents in care homes, the administration must be documented on Medicines Administration Record (MAR) charts. MAR charts represent the core documentary record of medicines administration to residents. Each resident should have a separate MAR chart that provides details about the resident including their name, date of birth and allergy status, contains a list of all the medicines to be administered to the resident with associated dosage instructions, any special instructions or precautions associated with the medicines, and provides a grid in which administrations are recorded; where an administration is not made the reason for the omission should be noted using defined codes (NICE 2015).

There is no single defined format for a MAR chart, however the contents will be broadly similar allowing for effective administration to the resident and subsequent recording of such an administration. In general, the majority of care homes operate a 28-day medicines cycle and therefore MAR charts normally have a 28-day duration. MAR charts are typically generated by the Pharmacy that supplies the care home with the resident's medication. MAR charts may be printed or may be handwritten. Printed MAR charts are preferable to most care homes because they are more legible and avoid clerical errors that may occur during the transcribing of information from one document to another (Centre for Policy on Aging 2011). For an example of a MAR chart see **Figure 3.1**.



MEDICATION ADMINISTRATION RECORD SHEETS [redacted]

Pharmacy No.

Document No.

NAME [redacted] Patient Number [redacted] D.O.B [redacted]

ALLERGIES Doctor [redacted]

ADDRESS [redacted]

START DATE 04/09/14 Period 28 START DAY Thursday

Medication Details

Commencing WEEK 1 04/09/14 WEEK 2 11/09/14 WEEK 3 18/09/14 WEEK 4 25/09/14

DATE 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 01

Hour:Dose 1 2 3 4 5 6 7 1 2 3 4 5 6 7 1 2 3 4 5 6 7 1 2 3 4 5 6 7

CHLORAMPHENICOL 1% EYE OINT
Apply twice a day
THROW AWAY 28 DAYS AFTER FIRST OPENING. DO NOT SWALLOW.
discontinued. 10.9.14
Not in Cassette
Received Quantity 4 returned quant. by destroyed quant. by

CONOTRANE CREAM
Apply several times a day to the affected area
FOR EXTERNAL USE ONLY.
Not in Cassette
Received Quantity 500 returned quant. by destroyed quant. by

DERMOL CREAM
Apply every four hours
FOR EXTERNAL USE ONLY.
Not in Cassette
Received Quantity 500 returned quant. by destroyed quant. by

DOMPERIDONE 10MG TABS
Take ONE three times a day
TAKE 30 TO 60 MINUTES BEFORE FOOD.
Received Quantity 30 returned quant. by destroyed quant. by

ENALAPRIL 10MG TABS
Take ONE twice a day
Received Quantity 56 returned quant. by destroyed quant. by

LANSOPRAZOLE GR 30MG CAPS
Take ONE daily
SWALLOW WHOLE.DO NOT CHEW OR CRUSH.TAKE 30 TO 60 MINUTES BEFORE FOOD. DO NOT TAKE INDIGESTION REMEDIES 2 HOURS BEFORE OR AFTER YOU TAKE THIS MEDICINE.
Received Quantity 28 returned quant. by destroyed quant. by

A - refused B- nausea or vomiting C - hospitalised D - social leave E - refused & destroyed

F - other (define)

Page 1

Figure 3.1 Exemplar Medication Administration Record (MAR) chart. This MAR chart covers a 28-day medicines cycle. Resident and prescriber information (redacted) is in the top left-hand corner. The left-hand column features the medicines to be administered to this resident along with associated dosing instructions. The grids to the right of the medicines information allows those administering to record the administration or provide a code to indicate why an administration has not been made.

Sometimes, medicines may be changed during the monthly cycle either through addition of 'interim' medicines for example for acute conditions or a resident's existing medication may change for example due to changes in the dose. For interim medications, a separate MAR chart is provided. For changes to existing medicines, a responsible staff member will hand amend the existing MAR chart(s) to reflect the changes in a clear and legible way; the prescriber instigating these changes should be documented and all amendments should be signed and witnessed.

The act of recording medicines administrations is an important regulatory requirement. For example, under the Care Homes (Wales) Regulations 2002, each care home must have a 'registered person' who retains overall responsibility for ensuring the effective recording, handling, safe keeping, safe administration and disposal of medicines. In England, the Care Quality Commission has issued quality and safety guidelines highlighting the provider's responsibility to comply with the regulations of the Health and Social Care Act 2008. The guidelines emphasise the importance of embedding effective procedures with regards to medicines management and documentation of medicines administration.

In Wales, completed MAR charts are inspected by the Care Inspectorate Wales (CIW) in order to determine the quality of medicines management and to measure compliance against the National Minimum Standards (Care Inspectorate Wales 2014). These National Minimum Standards address seven main themes: (i) choice of home; (ii) health and personal care; (iii) daily life and social activities; (iv) complaints and protection (v) environmental standards (vi) staffing (vii) management and administration; for a detailed explanation of the standards see **Chapter 1**.

3.1.1.1 Documentation process

Ensuring that all of the information on the MAR chart is accurate, up-to-date and

compliant with regulatory requirements remains the responsibility of the care home (NICE 2014). In practice however, this task is generally undertaken by the pharmacist when the MAR chart is generated at the pharmacy as the medications are being assembled (Alldred et al. 2009).

Once the medication has been administered to the resident according to the date and time indicated on the MAR chart, the MAR charts should be annotated to indicate an administration has been made. This annotation should be completed as soon as possible and certainly should not be left blank. If a prescribed medicine is not administered to the resident, there are normally 'codes' specified on the MAR chart that should be used to define the reason that the administration has been omitted (see **Table 3.1**). On completion, MAR charts must be retained for 3 years after which they can be destroyed. (NICE 2014).

Table 3.1 Examples of codes used on MAR charts to denote records of administration

Code	Definition
A	Absent
N	Nausea or vomiting
H	Hospitalised
D	Destroyed
R	Refused
NT	Not Taken
C	Carer's Notes (overleaf)
L	On Leave
D/C	Discontinued
O	Other*
S	Asleep
M	Made Available
Q	Offered but not required

* where a reason of 'other' is used, this needs to be defined.

Of note, the codes are not standardized across the sector and as a consequence there may be some differences in care homes with regards to the number and range of codes used to cover all the possible reasons for not giving the medicine. Somewhat confusingly, care homes may use different letters with the same definition.

3.1.2 The medicines administration process

There are normally four administration rounds per day which are commonly

labelled either as: (i) 8am, 12pm, 4pm and 8pm rounds or (ii) morning, afternoon, teatime and bed rounds. Medicines are stored on a trolley along with the MAR charts. In the majority of care homes the trolley contains three different categories of medicines. Regular medications in the form of tablets and capsules that are packed in a Monitored Dosage System (MDS). This system was introduced in 1990s to facilitate medicines administrations through pre-packaged medications in compartments that correspond to the day and time that they are to be given (Alldred et al. 2011). MDS 'trays' are usually assembled in the pharmacy and can be useful in the administration process as it does not require the individual administering the medicines to 'pot up' the resident's medicines from original packs. 'When required' medicines are stored on the trolley in their original packs and are only administered should the patient require them. Formulations that cannot be included in the MDS system but are regular items such as liquids, topical medicines, inhalers etc. are also stored in their original containers. Estimates suggest that 40% of medicines administered to residents are contained in MDS systems (Alldred et al. 2009). On commencing an administration round, the medicines trolley is wheeled to the resident by the staff member undertaking the round.

Before administering the medicines, the 'five rights' should be considered to ensure safe administration of medicines i.e. right patient, right drug, right dose, right route and right time (Federico 2015; Denham 2007). To do so, the member of staff administering medicines will confirm the identity of the resident matches the MAR chart and will then use the MAR chart to guide the administration. They should ensure that the doses in the MDS system are consistent with the MAR chart i.e. the correct strength, dosage form, route of administration and number of dosage units to administer. Similarly, the MAR chart should be used to identify any medicines to be administered that are not in the MDS tray and perform the same checks. Finally, they should identify any when required medicines on the MAR chart, ascertain whether the patient needs the medicines (against a defined protocol) and if so administer them.

Having administered the medicines, it is important to document the administration. This should be completed immediately following administration of each individual dose to the resident (NICE, 2014) and administration boxes should not be left blank (National Institute for Health Research 2016). If left blank, this could result for example in extra doses being given as there is a possibility that another individual will assume that the resident didn't receive the medication. This failure to document an administration has been shown to directly result in medication errors (Haw et al. 2007; Dickens 2007). In practice, there is anecdotal evidence that administrations are actually signed for once the round has been completed rather than immediately following administration to a resident.

3.1.3 Impact of documentary errors on the administration process

The MAR chart is used as a guide by the member of staff administering medicines. Therefore, any documentary errors on the MAR chart may lead to errors in administration. Whilst there are only a limited number of studies that have highlighted documentary problems with MAR charts, issues that have been identified in the literature include (i) discontinued medications that continue to be administered because they have not been removed from the MAR chart; (ii) newly prescribed medicines that are not added to the original MAR chart and are therefore not administered; (iii) discrepancies between the MAR chart administration instructions and the label on the medication; (iv) alterations to dose and frequency of existing medicines by a prescriber that are not updated on the MAR chart; (v) new prescriptions issued during the monthly cycle that may result in a resident having several MAR charts with different starting dates (Smith 2004). A key study in the field is the Care Homes Use of Medicines Study (CHUMS) (Alldred et al. 2009) which evaluated medicines management in 55 care homes within 3 different areas of England. The authors concluded that 22.3% of the 256 residents studied were subject to at least one administration error. Whilst the study didn't specifically focus on errors in the MAR charts, it was reported that improper documentation was one of the contributing factors

that lead to medication errors. This was in addition to poor communication among health care providers, distractions, lack of adequate policies and environmental factors (Alldred et al. 2009). The problem of documentary errors is not unique to the UK. In a study in the US, 58 handwritten MAR charts were reviewed revealing 24% had missing information and 19% had missing directions for use of the medicines (Gray et al. 2006). In an earlier study conducted in a US nursing home, charts were reviewed by a clinical pharmacist consultant and 'charting and transcription' errors were among the leading causes of administration issues (Vlasses et al. 1977). In a study in Australia by Qian and colleagues, this time in the residential care home setting, a review of MAR charts revealed a variety of errors including duplicate signatures for some medicines administrations and a failure to report the time of administration due to lack of space on the documentation (Qian et al. 2015). Human factors that have been shown to contribute to documentary errors include inadequate staff training and an absence of a protocol for completing MAR chart documentation (Alldred and Standage 2011). It is worth highlighting that documentary errors are not a unique feature of care homes, indeed in a systematic review by Keers et al. in the secondary care setting, documentary errors were similarly a contributory factor that lead to administration errors. (Keers et al. 2013b).

In the same way that inappropriate prescribing can result in harm to residents, administration errors such as dose omissions, extra doses, wrong drug administered, wrong strength administered etc. can lead to significant harm. In this study then, MAR charts were retrospectively analysed to identify errors in administration.

3.2 Aims and Objectives

The aim of this current study was to identify the types and prevalence of medicines management errors in care homes through a retrospective analysis of MAR charts.

The objectives were:

1. To characterise the types of errors that may be identified through MAR charts
2. To develop a protocol to identify errors on MAR charts
3. To undertake a retrospective analysis of MAR charts to quantify the errors identified.
4. To identify the prevalence of errors associated with potentially inappropriate medications (PIMs).

3.3 Methods

3.3.1 Overview of study design

This study featured a retrospective study of medication errors in care homes using MAR charts. Ten care homes were recruited for the study and MAR charts were collected over a 28-day medicines cycle in September 2014. All the records of medicines administration on the MAR charts were assumed to be accurate representations of the administrations that took place in the care home. An outline of the study design is shown in **Figure 3.2**.

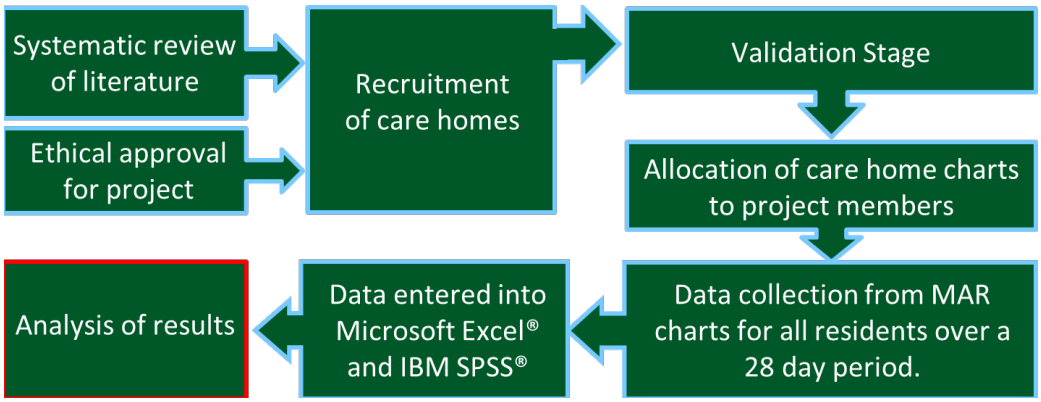


Figure 3.2 Schematic of the study design

3.3.2 Ethical approval

Prior to commencing this study ethical approval was obtained from the Cardiff School of Pharmacy and Pharmaceutical Sciences (SPPS) Research Ethics Committee (see **Appendix 1**).

3.3.3 Recruitment of care homes

Ten care homes were recruited by purposive sampling from the Abertawe Bro Morgannwg University Health Board (ABMU) in Wales. A full description of the recruitment process is described in **Chapter 2 section 2.3.2**. Briefly, the inclusion criteria was that the home was located in the ABMU health board, primarily catered for older adults, was registered with the Care Inspectorate Wales (CIW) and that they used a paper-based MAR chart.

3.3.4 MAR chart collection

Anonymised MAR charts were received from the ten participating care homes in October 2014 covering a 28-day medicines cycle that ran from September to October. A full description is provided in **Chapter 2 section 2.3.3**.

3.3.5 Development of MAR chart evaluation protocol

3.3.5.1 Categorisation of medication errors

In this study, the definition of a medication error was adopted from the US National Coordinating Council for Medication Error Reporting and Prevention: '*Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of health professional, patient or consumer*.' This definition was chosen as it provides the broadest description of a medication error.

Errors were assessed and categorised based on The National Institute for Health and Care Excellence (NICE 2014) guidance for Medicines Management in Care Homes. These guidelines outline a series of best practices related to the safe and effective use of medicines in care homes. The areas of the guidance that were used to inform the development of a protocol to identify errors were: (i) 1.4

Ensuring that records are accurate and up to date; (ii) 1.7 Accurately listing a resident's medicines (medicines reconciliation); (iii) 1.12 Receiving, storing and disposing of medicines; (iv) 1.14 Care home staff administering to residents. A table of the sub-categories of the guidance used to develop the protocol can be found in **Appendix 2**. This resulted in the production of an initial set of criteria by which MAR charts could be assessed (see **Table 3.2**).

Table 3.2 Initial criteria for identifying medicines related errors on MAR charts.

Criteria	Notes for assessing MAR chart
MAR charts should record the Date of Birth (DoB) and allergy status of the resident	Check for allergy status, DoB
MAR charts should indicate any reason for not giving medicine(s) using a defined code	Check for empty administration boxes, undefined codes
Medication administration times should be consistent with stated medicines rounds	Check for timing of administration against time indicated on MAR chart
All hand-written changes on the MAR charts should be signed by a witness	Identify any hand amendment and check for second signature
Medicines must have clear instructions for administration	Identify any medicines listed with as directed instructions or with no administration instructions
Controlled Drug administrations should be witnessed and signed	Identify Controlled Drugs on MAR chart and check to see if witness signature is present
MAR charts should record the maximum frequency of PRN medications	Identify PRN medicines and check to see maximum frequency listed; for paracetamol containing products ensure instructions indicate minimum of 4-hour period between administrations
MAR charts should record complete information for each medication	Check for name, strength and formulation
MAR charts should record the quantity of each medicine for the current medicines cycle received	Check for quantity discrepancy between the received medication and quantity carried over from previous cycles

A batch of MAR charts from a single care home (care home 0; comprising 19 residents for the June/July 2010 medicines cycle) was then analysed to identify any discrepancies against the criteria listed in **Table 3.2**; this was undertaken by members of the research team (n = 10), lead by the researcher, reviewing each MAR chart independently. The research team then met to discuss the identified

errors and any identified errors that were not listed in the initial criteria in order to develop a refined protocol and error categorisation. This was achieved through a series of face-to-face discussions until consensus was reached within the team. After each meeting the MAR chart analysis rulebook was updated and the MAR charts from Care Home 0 were re-analysed. *N.B. results from Care Home 0 were not included in the final analysis.*

Once the protocol was finalised (see **Appendix 3**) a validation step was undertaken. In this step, members of the research team (n = 10) analysed Care Home 1 (comprising 19 residents for September/October 2014) independently using the rulebook. A face-to-face team meeting confirmed that errors extracted by individual team members were consistent across the research team. A schematic of the methodological approach is shown in **Figure 3.3**.

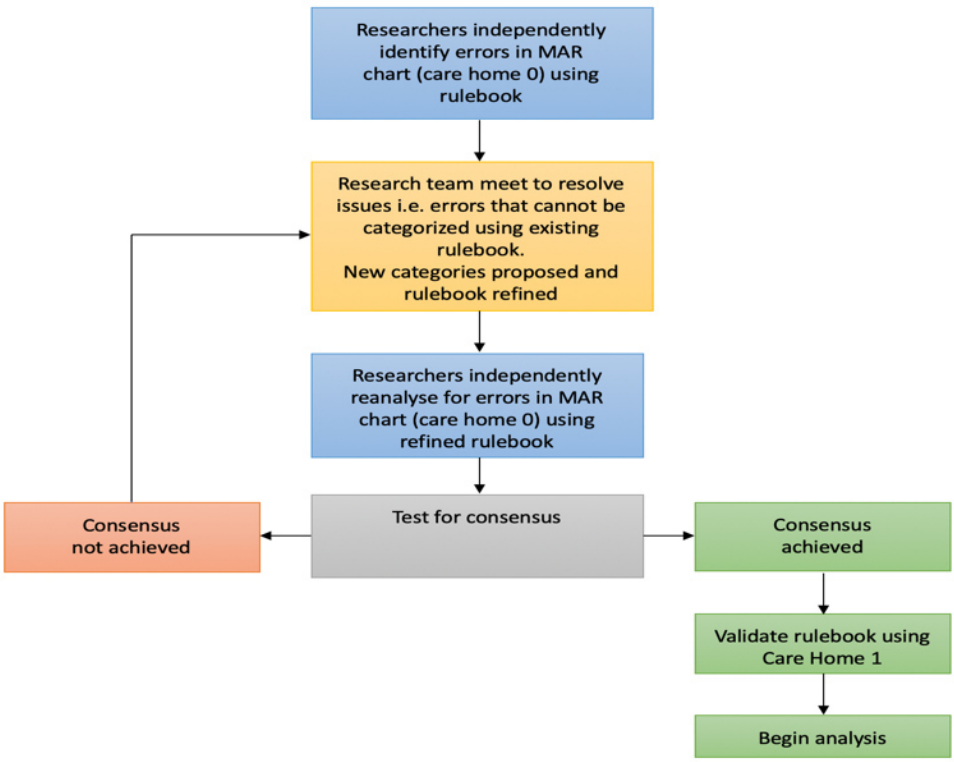


Figure 3.3 Schematic of how the research team validated the protocol (rulebook) to ensure consistency of data extraction from MAR charts.

The final categories used for assessment of medication errors are shown in **Table 3.3.**

The remaining nine care homes were assigned to a separate member of the research team (n = 9) and analysed using the rule book. This process was co-ordinated and overseen by the author of this PhD; in total for the ten care homes examined in this study, 720 MAR charts were reviewed. Two pragmatic assumptions were made when analysing the MAR charts and these were:

- The documentation of administrations was an accurate reflection of the administrations that took place
- Anything that was not written on the MAR charts did not occur unless otherwise stated by the service provider.

The study design was discussed with a statistician who indicated that a Kappa coefficient for inter-rater reliability was not needed given the overall management of the research team by the researcher.

Table 3.3 Finalised categories *of MAR chart errors.*

Category	Subcategory	Origin of the error	Example
Regulatory Errors			
	1) 'As directed' instruction	Prescriber, Pharmacy and CH Staff	As directed is written on the label
	2) Undefined code used	CH Staff	A code used is not defined on MAR chart, e.g. (O) was written without clear definition
	3) Incorrect number of signature	CH Staff	Hand amendment with insufficient signatures, e.g. changes in the daily doses was hand amended with one signature.
	4) Drug name misspelt	Pharmacy and CH Staff	Incorrect spelling of product name
	5) No maximum PRN dose	Prescriber, Pharmacy	A maximum dose PRN does not stated on label
	6) Missing chart information	Pharmacy, CH Staff	Information not related to medication is missing from the chart, e.g. date of birth, start date of chart, allergies etc.
Administration Errors			
	1) Missed medication cycle	Care home staff	No dose is administered for all 28 days, e.g. no entry on chart for Furosemide.
	2) Omission		An administration box is empty. (Each empty box is a separate error)
	3) Deviation from stated dose		The instructions on the administration label are not followed. (Each deviation is a separate error), e.g. two doses was given for Complan sachets once daily instead of one dose twice a day.
	4) Extra dose		An administration of an additional dose of a prescribed medication, e.g. Carbamazepine was given twice daily instead of once daily.
	5) Wrong time		A dose administered at different time from the prescribed time (±1 hr) e.g. Mirtazapine was administered at tea time instead of night.
	6) Deviation from PRN protocol		Administrations of when required medication that does not follow the PRN protocol.
	7) Unexplained crossing out of an administration		A cancelled / crossed out administration with no explanation.
MAR chart Errors			
	1) Dose Absent	Prescriber and Pharmacy and CH Staff for all sub-categories	The dose is completely absent from the label, e.g. no dose was written for Warfarin but instead (dose according to INR was written).
	2) Strength Absent		The strength is completely absent from the label, e.g. no strength was written for Hyoscine s/c injections.
	3) Formulation Absent		The formulation is completely absent from label, e.g. no formulation was written for Mirtazpine.
	4) Duplicate Entry		There is more than one entry for the same product, e.g. a duplicate entry was observed with Carbamazepine.
	5) Missing Time		The time section of chart for administered doses is not filled in, e.g. time was missing for administration of Risperidone.

	6) Incomplete Dosage Information		There are incomplete dosage instructions, e.g. no site of application for a cream, or no frequency stated.
Stock Errors			
	1) Quantity Discrepancy	CH Staff	The amount administered exceeds the amount recorded in stock.
	2) No Date Recorded		No date is recorded for received stock
	3) No Quantity Recorded		No quantity is recorded for received stock
	4) No Signature		No signature is present for received stock.
Errors that cannot be categorised			
	1) Miscellaneous*	N/A	Include any error that could not be categorised from the available data, e.g. Controlled drugs were administered without second signature.

3.3.6 Data extraction and analysis

MAR charts were received from ten care homes comprising 260 unique residents. The MAR charts were reviewed against the validated protocol (rulebook) and errors extracted and recorded using a data collection form in Microsoft Excel for Mac version 15.33 (Microsoft Corporation; Seattle, USA). The data collection form **(see Appendix 4)** had fields for: care home number, resident date of birth, age in years, resident id number, total number of medications administered to resident, chart number (if more than 1 per resident), number of medications on chart, name of medication, controlled drug classification, BNF section, BNF category, presence of an error (Yes/No), date of error, drug round during which error took place (wherever possible), whether a PRN protocol is needed for the drug and was available, the main category of the error, the sub-category, and a brief description of the error.

The type and frequency of medication errors from the MAR charts of the 260 residents were recorded and data entered into an Excel spreadsheet designed for this purpose. Descriptive statistics were produced in Microsoft Excel. Administration errors and MAR chart errors were isolated for further analysis as these errors were deemed to be more likely to cause harm to residents than other categories.

3.3.6.1 *Quality Assurance*

Once data entry was complete, a quality assurance process was carried out. The researcher extracting the errors from the MAR charts read through their Microsoft Excel Spreadsheet to identify any obvious mistakes. Finally, a sample of 10% of resident's data across the ten care homes was randomly selected by the PhD author and checked for errors. If any mistakes were identified they were corrected and another sample of 10% was selected and checked, repeating until no mistakes were found. Residents were selected by resident number using a random number generator (Randomness and Integrity Services Ltd).

3.3.7 Calculating error rate

Error rate per resident was calculated using total number of opportunities for errors (TOE) as a denominator and number of errors identified as the numerator (see **Equation 1**). Total opportunities for errors comprises the total number of doses scheduled to be administered in accordance with the prescriber's orders plus any extra doses given i.e. it is the total number of doses administered to a resident, whether appropriate or not, plus any omitted doses (Tissot et al. 1999; Flynn et al. 2002). The numerator was total number of errors (TNE, i.e., more than 1 error per dose could be counted) (Keers et al. 2013a).

Equation 1:

$$Error\ rate = \frac{Number\ of\ errors\ identified}{Total\ opportunities\ for\ errors} \times 100$$

Although, there are several different denominators used to estimate the rate of medication errors (Lewis et al. 2009; James et al. 2009), the total opportunities for errors is a well-established parameter (Alldred 2009; Keers et al. 2013a; Berdot et al. 2012). In this current study TOE was used based on CHUMS study, the seminal study in this field. The numerator can be either the number of dose administrations with one or more errors (OME; i.e. each dose is binary either correct or incorrect), or the total number of errors (TNE; i.e. a dose can be associated with more than one error) (Keers et al. 2013a). TNE has the tendency to inflate error rate and indeed can result in error rates that are greater than 100%. Conversely OME may not capture the extent of the error because a resident may receive the wrong drug, at the wrong strength and at the wrong time but this would only be counted as one error in the calculation of the error rate. In this study, the TNE was used as the best compromise of the two methods.

3.3.8 Counting the total number of opportunities for error in each care homes

The total opportunities for errors was calculated directly from MAR charts by the researcher. A protocol (see **Appendix 5**) was created for this process to include all the scheduled medications on the MAR charts plus any deviations from the scheduled medicines as described in MAR chart annotations. In most cases this information could be gathered from the dosing instructions however, there were a number of caveats where 'workarounds' were needed. These included:

- Commonly, for paracetamol and paracetamol related products, although the products were prescribed as a regular medication, they were administered as when required medications (PRN). A decision was taken to only include actual administrations in the count of opportunities for error not the scheduled administrations in this case.
- Where dosing instructions were ambiguous (e.g. apply as often as you like!!) administrations were counted.
- There were cases where two MAR charts were found for the same medication(s). It was clear that some individuals administered from the one chart and other individuals from the second chart. None of the administrations for these duplicate medicines overlapped and therefore only one scheduled administration was counted.
- The letters used by some staff as a signature to denote an administration in some cases overlapped with defined MAR chart codes for example one staff member used the initial N to mark an administration but that was also the home's code for nausea and vomiting. In this case, the researcher used her own judgement in counting medicines.
- Hand-made amendments to dosing schedules were not followed by some staff i.e. the original dosing schedule was followed. In this case the opportunities for error was based on actual administrations and not the new schedule.
- PRN medications were excluded from the counting process because,

there was no distinct protocol or policy for their administration within the recruited care homes. This made any interpretation of the prescribers' intention against the administration practice flawed.

3.3.9 Identifying errors with potentially inappropriate medications

Administration related errors associated with potentially inappropriate medications were extracted from MAR charts. Beers criteria was used to classify medicines as potentially inappropriate. For a description of Beers criteria see **Chapter 2**; a list of Beers criteria medications and medication classes can be found in **Table 2.8**.

3.4 Results

3.4.1 Frequency of errors identified

MAR charts for all residents (260) from each of ten care homes were analysed over a 28-day medicines cycle with the exception of care home 2, from which the analysis was for 17 days only. The errors identified were recorded, analysed and categorised according to five distinct categories: (i) administration errors; (ii) regulatory errors; (iii) stock errors, (iv) MAR chart errors and (v) miscellaneous errors. **Table 3.4** details the absolute number of errors identified in each care home across all error categories and those related to administration errors alone i.e. those errors that are most immediately patient facing.

Table 3.4 Total number of errors identified for 10 care homes

Care Home	N° of residents	Total number of errors identified (all categories)	Number of administration errors identified
1	19	648	419
2*	21	1369	460
3	25	1593	707
4	26	1533	731
5	53	2947	1613
6	20	1335	401
7	17	1086	584
8	24	360	96
9	14	1571	697
10	41	3820	1062

*17 days of administration data was available; for all other homes it was 28 days.

3.4.2 Average number of errors residents are exposed to each week

Given the variability in resident occupancy in each care home, the absolute number of errors is less informative than the potential resident exposure to an error. Therefore, the number of errors per resident per week was calculated in terms of the total number of errors identified in each home and the administration errors (see **Table 3.5**). As can be seen, even in the best performing care homes, a resident was likely to be exposed to four errors per week and in the poorest performing homes that rate rises to 28 errors per week. Not all the categories of errors pose an immediate risk to patient-safety, however, administration errors are more likely do so as they are directly patient facing and therefore an 'error' rate per resident per week for administration errors was also calculated. The best performing care home was care home 8 which had the lowest number of administration errors per resident per week at one error and the highest number of errors was 12 administration-related errors per resident per week in care home 9. Given the small sample size, the relative efficiencies of nursing homes versus residential care homes could not be elucidated in this study.

Table 3.5 Number of errors per resident per week (total for all error categories and administration errors)

Care Home	Number of errors per resident per week	Number of administration errors per resident per week
1	9	6
2	14	5
3	16	7
4	15	7
5	14	8
6	17	5
7	16	9
8	4	1
9	28	12
10	23	6
Average ±SD	**17±10**	**6±3**

3.4.3 The error rate as a function of the opportunities for errors

In addition to calculating the error rate as a function of the number of errors a resident was likely to be exposed to each week, the error rate was also calculated as a function of the total opportunities for error (see **section 3.3.7**). The error rate for administration errors is shown in **Table 3.6**. The overall error rate across the ten care homes was 19.1% i.e. for all the opportunities for error, 19.1% were associated with an administration error. Across the ten care homes, the error rate ranged from 2.9% (care home 8) to 12.3% (care home 5). The mean error rate was 8.6% with a narrow standard deviation of 0.03% demonstrating limited variability across the homes.

Table 3.6 Medicines administration error rate in each care home as a function of the total opportunities for errors. In the best performing care home (number 8), 2.9% of all opportunities for an error were associated with an administration error whilst in the worst performing home (number 7) this increased to 12.3%.

Care home	Total opportunities for errors	Error rate for administration errors
1	4062	10.3%
2	4333	10.6%
3	7100	9.9%
4	8288	8.8%
5	13744	11.7%
6	6053	6.6%
7	4751	12.3%
8	3224	2.9%
9	8948	7.8%
10	22314	4.8%
Total	**82,817**	**19.1%**
	Mean ± S.D.	**8.6 ± 0.03**

3.4.4 Errors by care home

The absolute number of errors identified in each care home for each of the error categories used in this study is shown in **Table 3.7**.

Table 3.7 The absolute number of medicines related errors identified in the ten care homes examined in this study.

	Number of errors					
	Administration	**Regulatory**	**MAR chart**	**Stock**	**Misc.**	**Total**
Care Home						
1	419	79	20	126	4	**648**
2	460	149	56	593	111	**1369**
3	707	124	85	286	391	**1593**
4	731	143	53	339	267	**1533**
5	1613	424	164	417	329	**2947**
6	401	155	51	620	108	**1335**
7	584	129	37	313	23	**1086**
8	96	89	44	93	38	**360**
9	697	206	79	362	227	**1571**
10	1062	246	141	588	1783	**3820**

In order to better compare homes, the percentage of each error type was calculated from the total number of errors identified in each care home (see **Table 3.8** and **Figure 3.4)**. Whilst there is evidence of inter-home variability, some patterns do emerge. For seven of the ten homes (1, 3, 4, 5, 7, 8 and 9),

administration errors were the most frequently encountered errors (range 27% - 65%). For the remaining three homes, stock was the most frequently encountered error in two homes (homes 2 and 6) and miscellaneous errors was the most common error category in care home 10. In the majority of homes (8/10), MAR chart errors (errors associated with incomplete or absent information on the MAR chart) were the least commonly encountered errors.

Table 3.8 Percentage breakdown of each error type for each care home. In seven of the ten care homes, administration errors represented the most frequently encountered error type. In the remaining three homes, for two homes stock errors were the most commonly encountered error whilst for the final home it was miscellaneous errors.

	Care Home Number									
Errors (% of total)	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
1. Regulatory	12	11	8	9	14	12	12	25	13	6
2. Administration	65	34	44	48	55	30	54	27	44	28
3. MAR chart	3	4	5	3	6	4	3	12	5	4
4. Stock	19	43	18	22	14	46	29	26	23	15
5. Miscellaneous	1	8	25	17	11	8	2	11	14	47

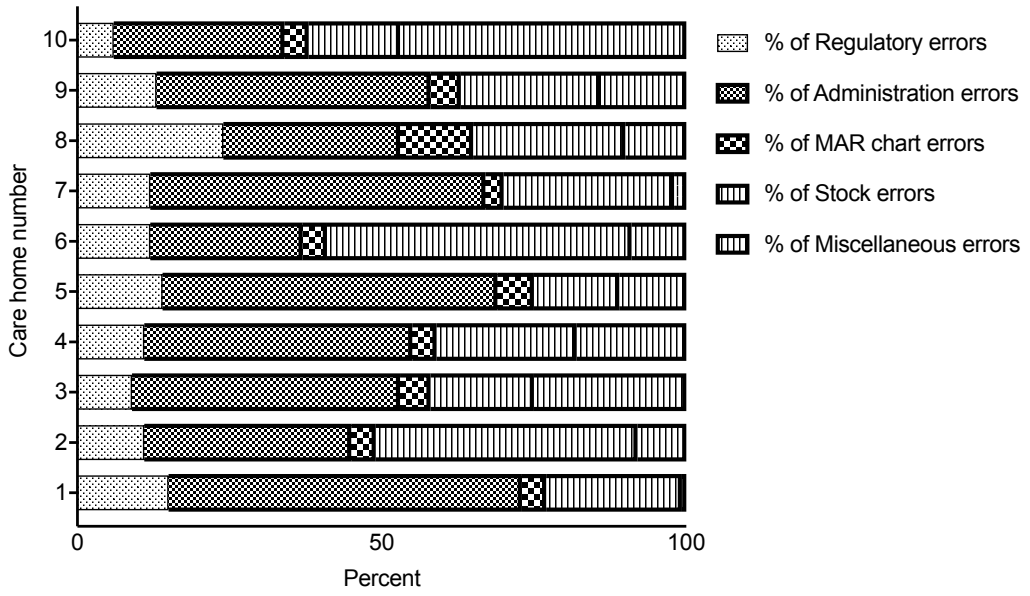


Figure 3.4 Percentage breakdown of each error type for each care home. In seven of the ten care homes, administration errors represented the most frequently encountered error type. In the remaining three homes, for two homes stock errors were the most commonly encountered error whilst for the final home it was miscellaneous errors.

3.4.5 Prevalence of errors in each of the primary error categories

A breakdown of the frequency of errors by sub-category for the primary error categories of (i) administration errors; (ii) MAR chart errors; (iii) regulatory errors and (iv) stock errors was calculated and is presented here.

3.4.5.1 Administration errors

Administration errors were broken down into six subcategories: (i) deviation from the stated dose; (ii) a missed medicines cycle; (iii) an omitted dose; (iv) an extra dose; (v) dose administered at the wrong time and (vi) an administration has been crossed out without explanation. A breakdown of the frequency of errors in each care home under these six categories is depicted in **Table 3.9** and **Figure 3.5**. Omitted doses were found to be the most common error type within the administration error category in all care homes with the exception of care home 6 where incorrect timing of an administration was the most common. The range in the percentage of administration errors accounted for by omitted doses was 5% (in care home 6) up to 99% (in care home 9). A number of the subcategories were not associated with high levels of error in any of the care homes studied. Deviation from the stated dose (range 0 – 3%) and an unexplained crossing out of an administration (range 0.4% to 2%) were particularly uncommon both in terms of the absolute number of errors identified (data not shown) and their contribution to the administration error category within each home as a whole. An unexplained missed medication cycle (i.e. a resident did not receive one or more medicines for the entirety of a 28-day cycle) displayed some variability (range 0% up to 13%). Whilst there were four care homes (3, 6, 9 and 10) where no resident missed a medicine(s) for the duration of a medicines cycle, in the remaining care home at least one resident did not receive one or more of their medicine(s) for the entirety of the cycle.

Table 3.9 Breakdown of administration errors (percentage) by subcategory. Data is presented as percentage of the total number of administration errors identified. In all care homes (with the exception of care home 6) omitted doses was the most frequent error type identified.

	Care Home Number									
Administration Errors %	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Deviation from stated dose	1	0	0	0	0.1	0.5	0	0	0	3
Missed medication cycle	6	2	0	2	2.9	0	5	13	0	0
Omitted dose	45	86	91	64	82	5	84	84	99	94
Extra dose	40	5	2	17	11	29	10	1	0.1	2
Wrong time	7	5	6	15	3	64	0.1	0	0	0.6
Crossing out	1	2	1	2	1	1.5	0.9	2	0.9	0.4
Absolute N° of errors	419	460	707	731	1613	401	584	96	697	1062

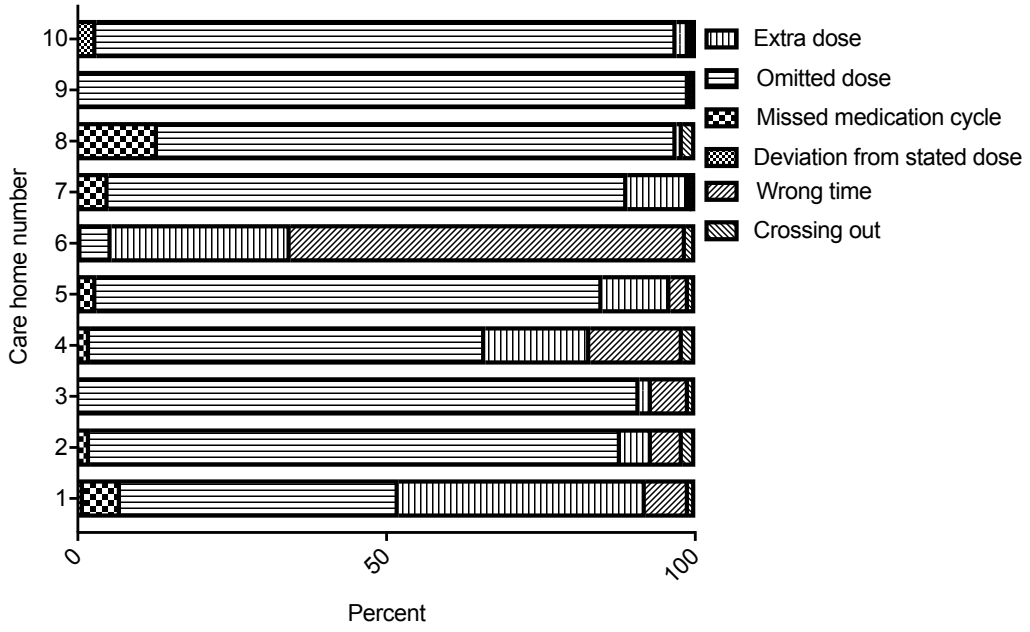


Figure 3.5 The frequency of administration errors (percentage) broken down into subcategories. In all care homes with the exception of care home 6, omitted doses were the most frequent error type identified.

3.4.5.2 MAR chart errors

The MAR chart error category was comprised of six sub-categories related to either missing information about the drug or a duplicate entry for a drug on the MAR chart. Specifically, the sub-categories were (i) the dose of the drug was absent; (ii) the formulation of the drug was absent; (iii) the strength of the drug

was absent; (iv) the required time of the administration was absent; (v) the dosing information was absent or (vi) the MAR chart(s) for the resident contained a duplicated medication. Whilst the absolute number of MAR chart errors identified in the care homes was relatively small (20 – 164 errors; range 3 – 12% of all errors identified in each home; see **Table 3.10** and **Figure 3.6**) nevertheless such errors are associated with risk to the patient. With the exception of care home 1, there were examples in all care homes where the dosage instructions were incomplete on the MAR chart. Indeed, in care home 6 some 43 of the 51 MAR chart errors (84%) were associated with incomplete information. Similarly, with the exception of care homes 4 and 7, there were examples in all care homes of MAR charts where the dose was absent. This would prevent the individual administering the drug cross-referencing with the MDS tray or the medicines pack to ensure the dose is correct if it was on the label. In eight out of the ten homes, the scheduled time for the administration was absent from the MAR chart. Where the medicine was packaged in an MDS tray, the person administering the medicine would be guided to administer the medicine according to the schedule on the tray. However, for medicines that are not packaged in an MDS tray (liquids, inhalers etc) then the person administering would have to use their judgement as to when the medicine should be administered. Of note, in seven care homes there were examples of medicines being duplicated like-for-like on a resident's MAR chart(s) increasing the risk that a resident will receive duplicate therapy unnecessarily.

Table 3.10 Breakdown of MAR chart errors (percentage) by subcategory. Data is presented as percentage of the total number of MAR chart errors identified.

	Care Home Number									
MAR chart Errors (%)	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Dose absent	75	11	2	0	18	8	0	36	2	50
Formulation absent	0	9	2	40	26	0	19	36	0	0
Strength absent	5	4	4	3	10	8	0	8	0	3
Missing time	15	18	29	21	2	0	30	0	54	23
Duplicate medication	5	13	19	6	16	0	5	0	0	1
Incomplete dosage information	0	45	44	30	28	84	46	20	44	23
Absolute N° of errors	**20**	**56**	**85**	**53**	**164**	**51**	**37**	**44**	**79**	**141**

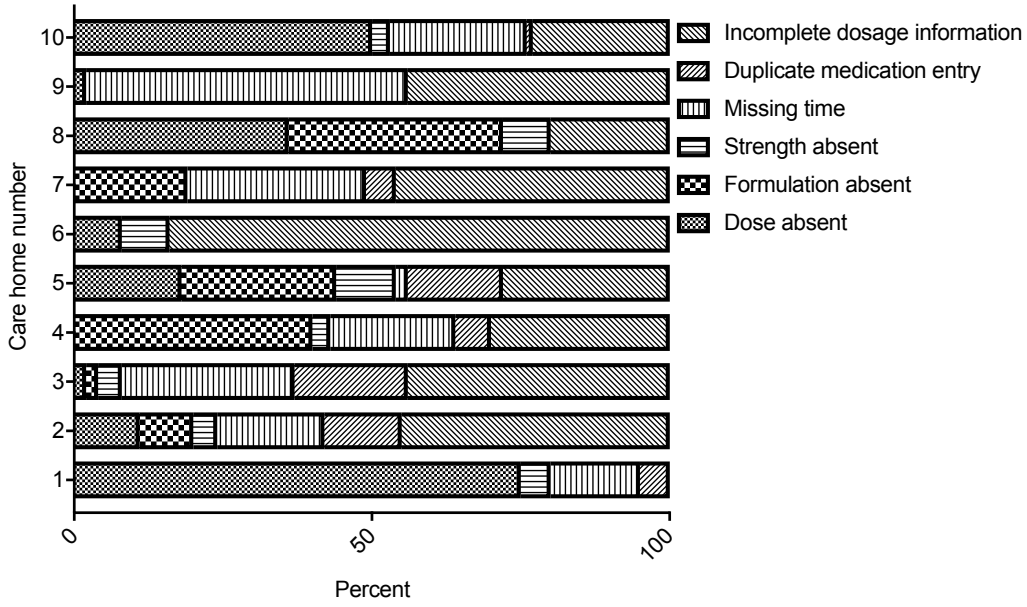


Figure 3.6 The frequency of MAR chart errors (percentage) broken down into subcategories.

3.4.5.3 Regulatory errors

Regulatory errors are errors related to contraventions of regulatory standards or guidance. In this case, the regulatory errors category was comprised of six sub-categories: (i) medicines written up with 'as directed' directions; (ii) missing chart information (e.g. DOB, allergy status); (iii) no maximum dose stated for when required (prn) drugs; (iv) the drug name was spelt incorrectly; (v) a signature is missing (for example when a dose is changed mid-cycle) and (vi) an undefined code is used on the MAR chart to detail some piece of information about an administration. The breakdown of regulatory errors by subcategory are shown in **Table 3.11** and **Figure 3.7**. The absolute number of instances where drug name was misspelt was very small and indeed in the majority of homes (6/10) there were no examples of this error. In the homes where this error was identified, it was primarily associated with hand written charts rather than those that were printed. In all care homes there were MAR charts where medicines were written up with 'as directed' dosing instructions. In the case of medicines packed in MDS trays the decision on the appropriate dosing would have been

made by the pharmacy team when assembling the tray. However, for medicines that are not assembled in MDS trays, this would require somebody in the care home making a clinical decision on how and when it the medicine be administered. Similarly, in 8/10 homes, there were examples where '*when required*' medicines did not have a maximum dose stated. This relies on those administering the medicines to have the requisite clinical knowledge to understand when the maximum number of administrations has been achieved in any 24-hour period.

Table 3.11 Breakdown of MAR chart errors (percentage) by subcategory. Data is presented as percentage of the total number of regulatory errors identified.

	Care Home Number									
Regulatory errors	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
As directed	32	8	18	3	10	14	7	7	5	29
Missing chart information	20	23	9	23	36	7	14	30	3	5
No maximum prn dose	0	11	11	8	1	3	0	1	4	6
Drug name misspelt	0	0	0	2	1	2	0	2	0	0
Missing signature	28	30	35	54	36	43	74	34	32	22
Undefined code	20	28	27	10	16	31	5	26	56	38
Absolute number of errors	**79**	**149**	**124**	**143**	**424**	**155**	**129**	**89**	**206**	**246**

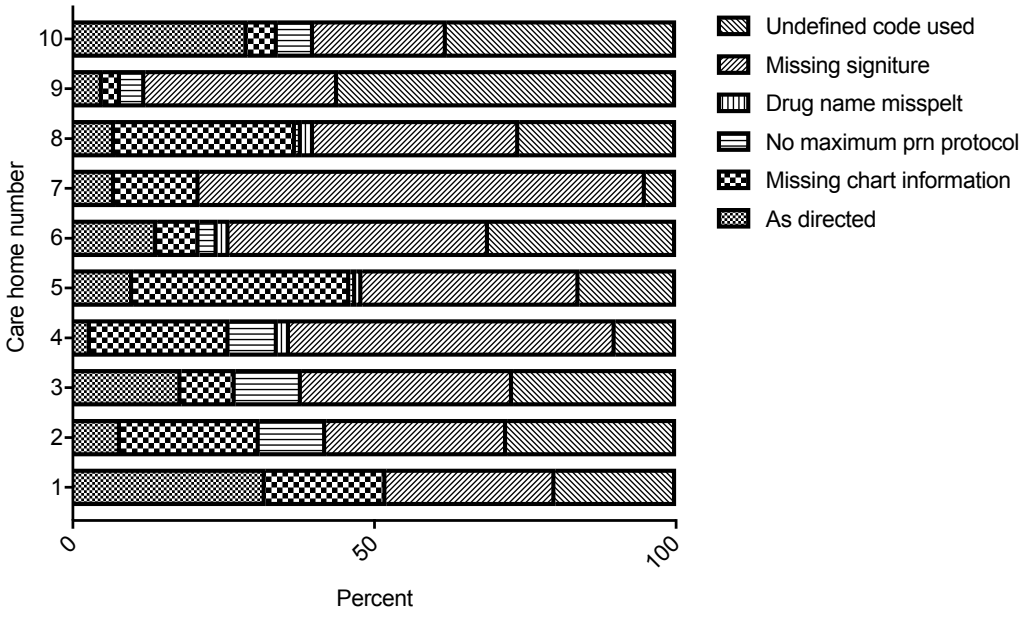


Figure 3.7 The frequency of regulatory errors (percentage) broken down into subcategories.

It is a regulatory guidance that the hand amendment related to changes in dosing or any instruction of medications should be signed by two members of staff on the MAR chart. However, in all care homes there was a significant number of medicines administrations where a witness signature was missing (range 22% - 74% of MAR chart errors identified).

In all care homes, there were MAR charts that did not contain resident related information such as the DOB (which is used for identification purposes) or allergy status (which is used to ensure a resident does not receive a medication which they are allergic to). **Table 3.12** shows the number of residents in each home that had MAR charts that did not contain sufficient information.

Table 3.12 Number of residents in each home with a MAR chart that had missing information (DOB or allergy status)

Care Home	Number of residents	Number of residents with missing information on their MAR chart (%)
1	19	58%
2	21	71%
3	25	32%
4	26	42%
5	53	91%
6	20	45%
7	17	65%
8	24	88%
9	14	36%
10	41	27%

In many cases, individuals that made an administration used a code to make some comment about the administration. However, these codes were ad hoc and did not conform to those defined on the MAR chart. There were instances of the use of such undefined codes in all homes. Examples of such codes are O or S which may have related to out of stock or stock issue but there was no definition on the chart.

3.4.5.4 Stock errors

Whilst stock errors may not lead to immediate resident harm, where stock is not accounted for appropriately, it may for example run out prematurely which

could lead to delays in resident treatment. In this study, stock errors were broken down into four sub-categories: (i) no date of receipt of stock is recorded; (ii) the quantity of stock received was not recorded; (iii) no signature is made to acknowledge receipt of stock and (iv) there are quantity discrepancies where the amount administered exceeds the recorded stock. A breakdown of these errors can be seen **Table 3.13** and **Figure 3.8**. The majority of errors in this category were associated with the date of the arrival of stock not been recorded and nobody in the home signing to indicate receipt of such stock. These categories were fairly consistent across the homes in terms of the frequency of the errors identified. Whilst in some homes, records of the quantity of medicines received was almost entirely complete (care homes 1, 7, 9 and 10), in other homes there were a fairly significant number of instances where the quantity of stock received was not recorded. For example, in care home 6, there were 217 instances where the stock received was not recorded. This accounted for 34% of all the stock errors identified in this care home. Discrepancies in the quantity of medicines received was fairly variable across the homes. For example, in care home 7 there were no discrepancies between the stock recorded and the medicines administered whilst in care home 10 there were 105 instances where the amount administered exceeded the recorded stock; this accounted for 18% of all stock errors in care home 10.

Table 3.13 Breakdown of stock errors (percentage) by subcategory. Data is presented as percentage of the total number of stock errors identified.

	Care Home Number									
Stock errors	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
No date recorded	41	31	32	74	31	33	49	37	49	44
No quantity recorded	2	31	26	10	29	34	2	22	0.3	2
No signature recorded	40	31	34	14	31	33	49	36	42	36
Quantity discrepancy	17	7	8	2	9	0.3	0	5	9	18
Absolute number of errors	**126**	**593**	**286**	**399**	**417**	**620**	**313**	**93**	**362**	**588**

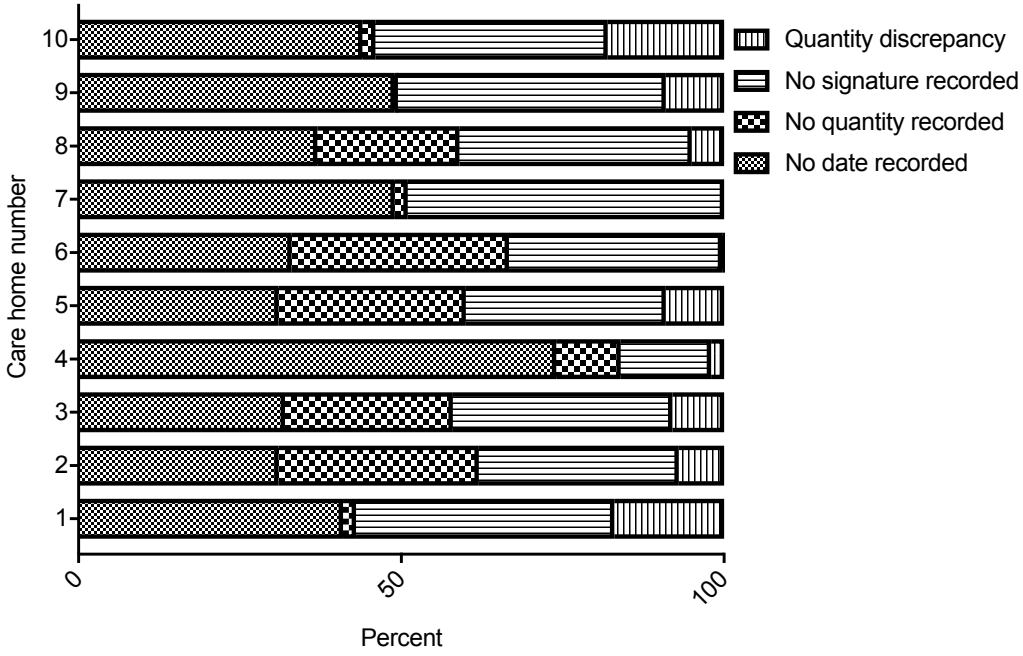


Figure 3.8 The frequency of stock errors (percentage) broken down into subcategories.

3.4.6 Relationship between the number of medicines administered and the frequency of errors

There is some evidence in the literature that the frequency of medicines related errors in care homes is associated with the total number of medicines administered (Barber et al. 2009b). A Pearson correlation co-efficient was therefore calculated for the total number of medicines administered versus the frequency of (i) administration errors; (ii) MAR chart errors; (iii) regulatory errors and (iv) stock errors. **Table 3.14** shows the output of the Pearson correlation calculation.

Table 3.14 Assessment of the correlation between the total number of medicines administered and the frequency of medicines related errors identified.

	Pearson correlation coefficient	P value	Strength of correlation	Direction of correlation
Administration errors	0.7452	0.0134	Strong	Positive
MAR chart errors	0.848	0.0019	Strong	Positive
Regulatory errors	0.6962	0.0253	Moderate	Positive
Stock errors	0.4755	0.1649	*Not significant*	

The analysis revealed a statistically significant strong positive relationship between the total number of medicines administered and the number of administration errors (ρ = 0.7452; p = 0.0134) and MAR chart errors (ρ = 0.848; p = 0.0019). A statistically significant moderate positive correlation was also observed between total number of medicines administered and the number of regulatory errors identified (ρ = 0.6962; p = 0.0253). However, for stock errors, there was no statistically significant correlation between total number of medicines administered and the number of stock errors identified.

3.4.7 Medication errors associated with potentially inappropriate medicines

Given the high prevalence of prescribing of PIMs identified in this study (see **Chapter 2**) an analysis of the administration and MAR chart errors associated with such medicines was undertaken. **Table 3.15** shows the number of residents across the ten care homes that were exposed to an administration error associated with their PIM and the number of residents that had a MAR chart error associated with their PIM; some residents may have had both an administration error and a MAR chart error associated with their PIM. As can be seen, with the exception of the cardiac glycosides, there were residents with administration errors in all categories of PIMs. In terms of MAR chart errors, the number of residents with a MAR chart error associated with their PIM was significantly lower and indeed, no MAR chart errors were identified for hypnotics, potassium sparing diuretics, NSAIDs, SNRIs, SSRIs, thiazide diuretics or drugs used to treat urinary tract infections. A substantial number of residents were exposed to administration errors associated with their PIM. This was particularly prevalent for antiplatelets (23 residents, 33.8%), antipsychotics (37 residents, 44.6%) drugs for the control of epilepsy (7 residents 53.8%), and other antidepressants (11 residents, 50%); the prevalence was high for other categories but the analysis is not robust given the low number of residents receiving such medicines.

Table 3.15 Prevalence of administration errors and MAR chart errors associated with PIMs. Data is presented as the total number of residents identified with errors.

PIM	Number of residents receiving a PIM	Number of residents with one or more administration errors related to a PIM	Number of residents where the PIM had a MAR chart error
Antihistamine	2	0 (0.00%)	0 (0.00%)
Antiplatelet	68	23 (33.8%)	2 (2.9%)
Antipsychotic	83	37 (44.6%)	4 (4.8%)
Antispasmodic	6	2 (33.3%)	1 (16.7%)
Anxiolytic	58	16 (27.6%)	1 (1.7%)
Cardiac glycoside	2	0 (0.00%)	2 (100%)
Control of epilepsy	13	7 (53.8%)	2 (15.4%)
Hypnotic	62	12 (19.4%)	0 (0%)
Insulin	3	1 (33.35)	2 (66.7%)
K sparing diuretic	5	1 (20.0%)	0 (0%)
Loop diuretic	43	10 (23.3%)	5 (11.6%)
NSAIDs	7	2 (28.6%)	0 (0%)
Other antidepressants	22	11 (50.0%)	1 (4.5%)
PPIs	105	23 (21.9%)	2 (1.9%)
SNRIs	9	4 (44.4%)	0 (0%)
SSRIs	38	8 (21.1%)	0 (0%)
TCA	6	2 (33.3%)	1 (16.7%)
Thiazide diuretic	6	1 (16.7%)	0 (0%)
Urinary tract infection	5	3 (60.0)	0 (0%)

A breakdown of the administration errors associated with PIMs categories is provided in **Table 3.16**. Dose omission was the most frequent error identified in almost all class of PIMs and the prevalence was particularly high for antiplatelets (47 omissions), antipsychotics (147 omissions), anxiolytics (119 omissions), hypnotics (49 omissions) and PPIs (64 omissions). Of note, although the absolute number of extra doses administered was low, there were nine instances of an extra dose of an antipsychotic being administered and 29 instances of an extra dose of a PPI being administered. Similarly, there were 28 instances where a hypnotic was administered too early i.e. not as a night time dose. The clinical impact of such errors remains to be elucidated.

Table 3.16 Breakdown of administration errors by subcategory for PIMs. Data is presented as the number of errors per subcategory.

PIM	Deviation from stated dose	Missed medication cycle	Omitted dose	Extra dose	Wrong time	Crossing out
Antihistamine	0	0	0	0	0	0
Antiplatelet	0	1	47	1	22	1
Antipsychotic	0	0	147	9	0	3
Antispasmodic	2	0	26	0	1	0
Anxiolytic	0	0	119	3	31	1
Cardiac glycoside	0	0	0	0	0	0
Control of epilepsies	0	0	13	1	27	0
Hypnotic	0	0	49	0	28	0
Insulin	0	0	1	0	0	0
K sparing diuretic	0	1	0	0	0	0
Loop diuretic	0	1	21	2	28	1
NSAIDs	0	0	15	0	0	0
Other antidepressants	0	0	15	0	28	1
PPIs	0	1	64	29	2	0
SNRIs	0	0	23	1	26	0
SSRIs	0	0	14	0	0	1
TCA	0	0	2	0	0	0
Thiazide diuretic	0	0	1	0	0	0
Urinary tract infection	0	0	5	0	0	1

3.4 Discussion

A retrospective analysis of paper-based medication administration records (MAR charts) was undertaken in ten care homes in the South Wales region to explore the nature and extent of errors related to medicines management. Medicines management was used here in the broadest context from the receipt of stock through to the administration of medicines to residents. A total of 25 distinct errors types were identified that were categorised into five main categories: (i) administration errors; (ii) MAR charts errors; (iii) regulatory errors; (iv) stock errors and (v) miscellaneous errors that could not be assessed without further information. The error categories that were used in this study were informed by The National Institute for health and Care Excellence (NICE 2014) guidance for Medicines Management in Care Homes. An initial set of criteria for identifying medicines related errors on MAR charts was devised and this was used to analyse a batch of MAR charts from a 'test' care home. Through an iterative process, the criteria were refined until consensus was achieved within the research team. An analysis 'rule book' was then used to analyse the MAR charts of 260 residents over a 28-day medicines cycle.

There are a variety of methodologies that can be used to identify medicines errors in health and social care settings including patient monitoring, chart review, analysis of computer records, observation, error reporting, and claims data (Montesi and Lechi 2009). Each of these methodologies have their own advantages and disadvantages. For example, the direct observation of patient care is accurate and effective in capturing active errors. However, it is time consuming, difficult to scale, requires significant training of the observer who must normally belong to the same professional group that are administering care (Flynn et al. 2002; Michel 2004) and is liable to the Hawthorne effect i.e. the observer modifies their behavior/actions as a consequence of being observed (McCarney et al. 2007). Chart review on the other hand is a commonly used method to retrospectively analyse data sources such as medical charts,

prescription data and laboratory data against standardised criteria. The challenges in using this data is that it can be difficult to train assessors, it is time-consuming and laborious to analyse such records at scale and the results depend on the quality of documentation and record keeping. Despite such limitations, chart review is a commonly used methodology for detecting medicines errors (Morimoto et al. 2004; de Vries et al. 2008; Hogan et al. 2008; Tam et al. 2008). However, the identification of medicines errors using any methodology must be treated with caution as there is evidence in the literature that indicates that the different methodologies often pick up different types of errors with sometimes limited overlap. For example, Hogan and colleagues reviewed seven sources of hospital data to identify harm: (i) Clinical Incident database; (ii) Health and Safety Incident database (iii) Complaints database (iv) Claims database; (v) Inquest database; (vi) the Patient Administration System and (vii) case notes. Case notes (which share some similarities with MAR charts) were found to identify the largest number of incidents but there was little overlap with errors identified in the other sources investigated. Along with other factors such as differences in sample size, period of study, local systems and policies, this can make it difficult to compare studies (Keers et al. 2013b). To summarise, whilst any one methodology will capture a particular range of errors it will not capture all errors in the setting and wherever possible a range of methodologies should be employed.

In this study, MAR charts represented an accessible data source for the identification of medicines related errors in care homes. The researcher could find only one other study in the literature that used MAR charts to identify medication errors in nursing home. The study, published in the US in 1979 aimed to identify documentary issues with MAR charts. The process involved four members of staff reviewing 15 MAR charts over a four-month period to identify any errors in the documentation using a protocol that was developed in house. The study revealed 15 types of errors related to the documentation some of which were similar to this current study (Krikorian 1979).

In this current study, a total of 16,262 unique errors were identified in the MAR charts across the five main error categories. This corresponded to an average of 17 (±3) errors per resident per week. This however does not reflect the errors that patients are exposed to because errors such as stock errors are not usually immediately resident facing. In contrast, administration errors (omitted doses, missed medication cycles, deviations from the stated does, extra doses, doses administered at the wrong time and deviations from the prn protocol) are directly patient facing and have the greatest potential to cause patient harm. As such, administration errors were examined in some detail and were found to be the most common error type identified in seven of the ten care homes investigated. This finding is consistent with other studies that have reported medication administration errors as the main source of errors in care homes (Alldred et al. 2009; Crespin et al. 2010; Greene et al. 2010; Lane et al. 2014; Pierson et al. 2007) and indeed other health care settings (Ghaleb et al. 2010; Haw et al. 2007; Kelly et al. 2011; Keers et al. 2013a; McLeod et al. 2015; Härkänen et al. 2017; Härkänen et al. 2015). Indeed, a recent report on the '*Prevalence and economic burden of medication errors in the NHS in England*' found that, more than half of the 237.4 million medication errors reported in the NHS over a one year period were related to administration errors, although the majority of these errors were said to have minor or no potential for clinical harm (Elliott et al. 2018).

In order to explore the patient exposure to administration errors, the number of administration errors per resident per week was calculated. On average, residents were exposed to 6 (±3) administration errors per week and the prevalence of administration errors by opportunity was 8.6% (±0.03). In the seminal CHUMs study (Alldred et al. 2009), 256 residents had two of their medicines rounds observed to identify administration errors. The prevalence of administration errors by total opportunities was 8.4% which is remarkably similar to the findings in this current study. Whilst the approach of reviewing MAR charts to identify administration errors in this study showed good

alignment with the CHUMs study, Richard and colleagues reported an administration error rate of 0.2% using chart review compared to 10% with an observational approach in 30 long term care facilities. The authors suggested that this underestimation of medication errors may be attributed to the fact that many medication errors were unreported or could not be identified using MAR chart review as this process didn't actually reflect the administration process. Also, only 10% of the MAR charts were reviewed in detailed leaving 90% with a cursory review which might lead to underestimation of errors that could be identified through MAR charts. (Shannon and De Muth 1987).

In common with the CHUMS study (and that of others (Pierson et al 2007; Greene et al. 2010), omitted doses were the most frequently encountered administration error in this current study accounting for an average of 73.4% (data not shown) of the administration errors across the ten homes compared for example to 49.1% in the CHUMS study. The reason for dose omissions is multifactorial. There are human factors for example interruptions during the administration rounds and medicines related factors for example the unavailability of medications at the time of administration.

In a number of homes, and particularly in care home 6, there was evidence of doses that were administered at the wrong time. This was shown to be a significant issue in a US study in nursing homes which reported that nearly half of the administration errors identified were administrations made at the wrong time (Scott and Volgesmier 2006). In care home 6 in this study, this was largely attributable to the administration of stimulant laxatives at 4pm instead of 8pm as prescribed. Whilst this makes sense from a clinical perspective and is unlikely to cause resident harm, ultimately it contravenes the prescriber's intentions. There is a paucity of literature exploring the reason for such changes to the scheduled administration time and it is likely to be multifactorial however possible reasons might include: (i) the prescriber has changed the administration schedule but the chart has not been updated, (ii) somebody in the home has

taken the decision based on experience, (iii) it is a genuine error, (iv) a dose was missed and then administered at the next medication round, (v) limited staffing levels at particular times (particularly for the night time and morning rounds) may mean that it is more expedient to change the administration schedule.

Whilst this close alignment of results in a similar study population provided some confidence that MAR chart review is accurate in estimating medication administration errors, not all studies have reported similar findings. Indeed, the prevalence of administration errors reported across a number of studies in the US in care homes varies between 10%-69% of all administered doses (Barker et al. 2002; Zimmerman et al. 2011; Desai et al. 2011; Desai et al. 2013; Lane et al. 2014).

The number of care homes within the study was too low to make any firm conclusions on whether errors were higher in nursing homes compared to residential homes. In terms of exposure of patients to administration errors, care home 8 (a residential home) was the best performing home with just one administration error per resident per week. The other residential home, care home 1, sat at the average with six administration errors per week. It might have been expected that nursing homes deliver better quality of medicines administration because of the higher standard of professional training received by nurses (c.f. carers in residential homes) however there is evidence in the literature to suggest that this is not the case (Scott-Cawiezell et al. 2007) with residential homes having a lower prevalence of medication errors. This is partly attributed to residential care home residents having less complex medical conditions and lower rates of polypharmacy (Szczepura et al. 2008). Indeed, in this current study the prevalence of polypharmacy was the lowest for the two residential care homes (see **Chapter 2**). The Care Quality Commission (2014) has identified similar differences between people in residential care homes and those in nursing homes in respect to the quality of health care. They highlighted an improved trend in the performance of residential homes against quality

standards compared to nursing homes particularly with respect to suitability of staff, safeguarding and safety, care and welfare and quality of monitoring (CQC 2014)

From the total 6770 administration errors identified in this study, 816 (12%) were related to PIMs, while only 39 (5%) of the MAR chart errors were associated with PIMs from a total of 730 errors. The prevalence of administration errors associated with PIMs was particularly high for drugs that act in the CNS system (antipsychotics, drugs for the control of epilepsy, other antidepressants) and antiplatelets. In the main, these administration errors were associated with omitted doses which can lead to preventable adverse drug reactions and serious patient safety issues (Handler et al. 2006). To the best of the author's knowledge, there is no literature related to errors in PIMs administration in care homes. However, some studies have examined the classes of medications that are most commonly involved with medication errors in care homes. A study by Hughes and co-workers in North Carolina for example found that antipsychotics were among the top 10 classes of medications associated with medication errors (Hughes et al. 2016). Similarly, an earlier study by Gurwitz and colleagues in 18 nursing homes found that 546 adverse drug events were associated with the use of antipsychotics and anxiolytics medications. Of note, 85% of these preventable adverse events were related to medication errors (Gurwitz et al. 2000). The same authors in another study in two care homes found just less than half of the adverse drug events were related to medication errors, from which, antipsychotics were among the most common medications involved in the occurrence of these errors (Gurwitz et al. 2005)

The reasons that administration errors occur is likely to be multifactorial and may be as a consequence of 'follow through errors' arising from errors made by the prescriber or at the pharmacy, they may be due to the individual administering the medicine or may be influenced by the patient / resident. Hughes and Ortiz have suggested four lines of defence in preventing medication

errors; the prescriber, the dispenser, the administrator (most often nurses), and the patient themselves (Hughes and Ortiz 2005). The responsibility to deliver effective care to residents therefore does not fall solely to care home staff, but all individuals involved in resident care. As a consequence, the administration process is exposed to both human errors and system errors (Reason 1991).

A number of studies have explored the reasons for medication errors in care home and have highlighted particular issues that are prevalent in the care home setting (Dilles et al. 2011; Vogelsmeier et al. 2007; Crespin et al. 2010). In order of prevalence these studies have shown the reasons to be (i) human error; (ii) transcription errors; (iii) distractions; (iv) not following procedures / processes; (v) a lack of communication between relevant parties; (vi) incorrect medication received from the pharmacy or the medication is unavailable and (vii) documentation contains inadequate or inaccurate information. Dilles and colleagues sought to codify the barriers to effective medicines management in nursing homes, focusing particularly on the experience of nurses, and identified four domains (i) nurses; (ii) interdisciplinary co-operation; (iii) organisational structure and culture and (iv) patient and family (Dilles et al. 2011). The nurse related factors included a lack of knowledge of therapeutics, attitudinal problems and a sense of not understanding how far their responsibility for administrations reaches (this was particularly true for the monitoring phase following administration). In terms of interdisciplinary cooperation, lack of communication between staff in the home, poor accessibility to prescribers and pharmacists, problems in the legibility and completeness of documentary information and poor definition of the tasks to be completed were cited as barriers to effective medicines management. The organizational issues were similar to those seen in other industries, high workload, staff shortages (particularly nurses), interruption during the administration round, lack of standardisation of processes across and within care homes and processes that were not seen to be effective. Nurses also felt that administering all medicines at the same time was a barrier to effective administration. Finally, the patient

related factors were related to capacity and consent, the intellect of the patient and their family and the emergence of new and more complex disease states in residents that demanded higher levels of care.

Interruptions and distractions during the administration round are commonly cited as a major challenge in the effective administration of medicines in care homes (Lee et al. 2015; Alldred et al. 2009; Dilles et al. 2011). In the secondary care setting, they have been shown to lead to a loss of attention, concentration and focus on the patient and in observational studies in both the secondary care and nursing home setting they have been shown to increase the number of administration errors (Scott-Cawiezell et al. 2007; Biron 2009; Westbrook et al. 2010) . There are essentially two sources of interruptions which might lead to a medication errors, either individuals administering the medicines are interrupted directly (e.g. by other staff, other residents, phone calls etc.) or there is a technical interruption (e.g. missing equipment, inability to find medications) (O'Shea 1999; Alldred et al. 2009). NICE have recommended that interruptions and distractions should be kept to a minimum during administration rounds (NICE 2014). Whilst to date there have been no observational studies that have sought to determine the impact of interventions to minimise interruptions, a number of studies have suggested that training to enable nurses/carers to prioritise multiple requests and specifically targeting avoidable interruptions would be beneficial (Colligan and Bass 2012; Buchini and Quattrin 2012).

The risks of errors arising from interruptions is compounded when staff with less training or lower levels of competency are permitted to administer medicines in care homes (Hinchliffe A. 2010; Dilles et al. 2011). These staffs are usually inexperienced, have a lack of knowledge and thus are more likely to make mistakes during the administration process. NICE Guidelines recommend that skilled and trained staffs should be put on duty and planned staff breaks should be avoided during medicines administration round (NICE 2015). Indeed, Care Inspectorate Wales (Care Inspectorate Wales 2014), has a national minimum

standard that requires at least 50% of the staff in a care home to hold an NVQ level 2 (or higher) qualification.

One issue here is the high turnover rate and shortage of staff within the care home sector which the CQC reported on in October 2014 (CQC 2014). Similar issues were raised by Care Inspectorate Wales (CIW) in their annual report (Care Inspectorate Wales 2014). Adequate staffing is required to ensure medicines administration is carried out properly and to provide good care to the resident. Studies do suggest that shortages of personnel are likely to increase the number of administration errors in care homes. For example in a report by the UK Department of Health '*Building a safer NHS for patients: improving medication safety*' and in a study by Vaismoradi and colleagues to qualitatively evaluate the perceptions of nursing students on medication errors, staff shortages and poor training were said to contribute to the high prevalence of medication errors (Smith 2004; Vaismoradi et al. 2014).

In the care home setting, monitored dosage systems (MDS) are commonly employed to help manage the administration process and indeed, in this study, all the recruited care homes used MDS trays. However, MDS trays have their own limitations. They can only be used for solid oral medicines and they lack flexibility when medicines or their doses are changed mid-cycle (Alldred and Standage 2011). Of note, there is little evidence to suggest MDS is a safer method of administration compared to using original packs (Alldred et al. 2009). It does however increase the workload demands on the pharmacy and in order to repackage medicines at scale, MDS pharmacy hubs are created which can decrease the interdisciplinary collaboration with the home as the hub is often more remote that the local pharmacy (Alldred et al. 2009). In addition, even where MDS systems are in place, medications such as oral liquid, inhalers, eye/ear drops and powders cannot be put in the MDS compartments and therefore arrive at the home in their original packing. This requires two

medication administration processes to be in place increasing complexity and the risk of making an error (Morrison 2014).

The second error category that was investigated in this study and which has the potential to cause resident harm was MAR charts errors. These are instances where the MAR chart does not contain all the necessary information to make a safe administration. For example, the dose, strength, formulation or timing of the administration may be missing or the directions for use are simply written up as “as directed”. It is a regulatory requirement that MAR charts contain all the necessary information related to the medicine. Ultimately where this information is incomplete, it relies on an individual in the home (nurse or carer) making a judgement. If the medicines are assembled in the MDS tray, then the likelihood of error is reduced. However, for medicines that cannot be put in an MDS tray then the potential for an error with the administration increases. There may also be variation in administration because medicines are not administered by the same member of staff all the time and different staff members may make a different judgement call. Therefore, it is important to make sure that all the instructions are present on the MAR chart and that those individuals administering the medicines fully understand the instructions. There were occasions where a resident was potentially put at risk due to insufficient dosage information. The MAR charts where this occurred were therefore not compatible with recent NICE guidelines that are definitive about the importance of clear and complete information concerning drug administration (NICE 2014).

In this current study, the prevalence of MAR chart errors was relatively small, accounting for 3 – 12% of all errors identified (range of absolute errors 20 – 164). In the main, the errors were associated with either the absence of a dose, incomplete dosage information or there was no scheduled time for the administration; missing formulation details and absence of a strength for the medicine(s) was less common. It is worth reiterating that the MAR charts are generated in the pharmacy based on the resident’s prescription and therefore

the source of the error is at the pharmacy. Nevertheless, from a regulatory perspective it is the responsibility of the home to ensure the MAR chart is accurate and complete. Ultimately, these MAR chart errors betray a failure in the systems and processes from the prescriber through to the home. The prescriber should ensure the prescription is complete, where it is not, the pharmacist should liaise with the prescriber to rectify any missing information and if that slips through on the MAR chart the home should engage with the pharmacist and/or prescriber to update the MAR chart. Such errors are not unique to the care home setting. In the Institution of Medicine's (IOM) report, 'Preventing Medication Errors' (Bates 2007), inappropriate labelling has been cited as a cause of medication errors that may contribute to the occurrence of adverse events. In a study by Jeetu and Girish, the authors highlighted that nearly a quarter to one third of medication errors were attributed to improper labeling (Jeetu and Girish 2010).

Another type of MAR chart error that was identified in this study was where a medicine was duplicated on the MAR chart. Examples of duplicated medicines were found in seven of the care homes; in most cases the duplicate medicine was on a second chart making it harder to spot. To the best of the researcher's knowledge, none of the duplicated medicines were administered to residents. However, such errors have the potential, if left unspotted, to cause unwarranted duplication of therapy which may lead to patient harm.

A surprising finding was that the number of MAR chart errors strongly correlated with the total number of medicines administered ($\rho = 0.848$; $P = 0.0019$). In fact, the correlation was stronger than for the number of administration errors. With the current data it is not possible to determine if there is a causal relationship.

There is an opportunity for pharmacists to play a greater role here. Beyond ensuring that MAR charts are complete and accurate, pharmacists can play a role in education and training and medicines reviews at the care home. In 2006, Zermansky and colleagues suggested that pharmacists can play an important

role in minimising the occurrence of medication errors in care homes but they are not routinely involved in medicines management in care homes to the extent they are in hospitals (Zermansky et al. 2006). Whilst there has been a rise in the number of care home based pharmacists, research into their effectiveness is currently lacking.

In this study, the prevalence of regulatory errors was also explored. Regulatory errors comprised six subcategories: (i) as directed instructions; (ii) an undefined code was used on the MAR chart; (iii) where an amendment was made to the MAR chart a confirmatory signature was not made; (iv) the drug name was misspelt; (iv) no maximum PRN dose was indicated when one was required and (vi) there was missing chart information such as DOB or allergy status. Similar to MAR chart errors, as directed instructions and maximum PRN doses should be resolved at the pharmacy before the MAR chart arrives at the home. Nevertheless, the home should seek to rectify such errors with the prescriber or pharmacist as soon as it is identified. In contrast errors in the remaining subcategories should be resolved at the care home. The absolute number of regulatory errors was fairly low (at least in comparison to other categories) and the instances of a drug being misspelt were almost non-existent. The majority of errors in this category were associated with undefined codes being used to make some comment about an administration and mid-cycle changes to medicines not being signed. From a governance perspective, the latter is particularly serious as it does not allow for an audit trail to fully understand the nature of the change. It was clear from the review of MAR charts that there were a lot of hand amendments to the charts and these did not always have signature or the name of prescriber who instigated or authorised the changes. The use of undefined codes contravenes regulatory guidance (NICE 2015) but is perhaps a consequence of local practices that are established due to incomplete and non-standardised processes within the sector (Dilles et al. 2011).

Effective stock management appeared to be a significant issue in all care homes within this study. The absence of adequate stock has been shown for example to be a contributor to medicines administration errors (omission and wrong time) in the secondary care setting (Dean et al. 1995; Ho et al. 1997; Taxis et al. 1999). Many of the medications received had no indication of 'booked in' quantities, the date received or a signature to indicate who receipted them. Together these can lead to errors in stock management that may result in a medication being unavailable for a resident at the point of administration. Where this is associated with an MDS tray it may be that the entirety of the resident's medicines is missing. In addition, there were discrepancies in the quantity received compared to the actual number of administration events indicated on the MAR chart. Again, this may increase the risk of a medicine running out leading to an avoidable delay in administration to the resident. Another issue that may arise out of poor stock control is waste medicines. A medicine may be reordered unnecessarily due to discrepancies between actual stock and recorded stock.

In the study presented in this chapter, errors associated with stock, regulatory requirements and information on the MAR chart were examined in addition to administration errors. However, a search of the literature revealed a paucity of literature examining for similar issues. This is probably as a consequence of most studies focusing on either detecting medication administration errors alone, (Flynn et al. 2002; Dickens 2007; van den Bemt et al. 2009; Kim and Bates 2013) or investigating errors in other elements of the medication management process including dispensing, ordering and monitoring. (Carayon et al. 2014; Pierson et al. 2007; Barber et al. 2009a; Latif et al. 2013). These areas were outside the scope of this thesis and indeed could not be addressed through MAR chart analysis.

In summary, this study has explored the nature and prevalence of medicines management errors in care homes through a retrospective analysis of MAR charts. The number of errors identified was significant and in line with those identified in the seminal CHUMS study (Alldred et al. 2009). Medicines administration errors were particularly prevalent and this was primarily related to dose omissions. Whilst it was beyond the scope of this study, the clinical consequences of such medication errors should be explored as a matter of urgency.

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Chapter 4. An Exploration of Medicines Waste in Care Homes

4.1.1 Medicines use in the UK

Medicines play an important role in improving the health and wellbeing of patients and remain one of the most common health interventions. As a consequence, the volume of medicines prescribed in the UK continues to grow year on year. In England, NHS spending on medicines has grown from £13 billion in 2010/11 to 17.4 billion in 2016/17 representing an average increase of 5% per annum. The majority of this increase in spending is accounted for by secondary care where medicines spend has increased by approximately 12% per annum (Ewbank et al. 2018). In the primary care setting, spend has grown more steadily even though the number of items prescribed has almost doubled to 1.1 billion in the decade leading up to 2016. This increase in the prescribing of medicines was partly mitigated against by a reduction of approximately 25% in the cost per prescribed item to £8.34 over the same period. In Wales, data on prescription spend is available for the community setting (Welsh Government 2017). In 2017, 80.4 million items were dispensed (up 0.2% from 2016) representing a spend of approximately £580 million. Of note, the number of medicines prescribed per head of population in 2017 was higher than all the other UK territories (25.8 items compared to 22.3 in Northern Ireland, 20.0 in England and 19.2 in Scotland). Omeprazole was the most commonly prescribed item in Wales in 2017 (2.6 million items).

Clearly, the extent of expenditure on medicines in the UK is significant. However, where prescribing is appropriate and administration is effective, the therapeutic benefits derived from medicines are likely to relieve the economic pressure on the NHS by preventing the use of alternative interventions (for example an unintended A&E visit or hospital admission) which are more costly than medicines (NICE 2015). However, as has been described in **Chapters 2 & 3**, medicines are not always prescribed appropriately nor are they always administered or taken effectively and as a consequence resources are wasted. These wasted resources may include medicines waste, unwarranted bed days in secondary care or unnecessary A&E visits and GP consultations (Hyttinen et al.

2016; Hyttinen et al. 2018; Hudhra et al. 2016; Heider et al. 2018). The World Health Organisation uses an umbrella term for this: “irrational use of medicines” that encompass inappropriate prescribing, dispensing or patients failing to take them properly which results in waste of healthcare resources (World Health Organisation 2016). The scale of the problem is significant with WHO estimating that greater than 50% of all medicines are prescribed, dispensed or sold inappropriately, and 50% of patients do not take their medicines correctly.

4.1.2 Medicines waste

The issue of medicines waste has been well established nationally (Hazell and Robson 2015). Whilst there is no standardised definition of waste and different authors use similar but subtly different definitions (White 2010; Abou-Auda 2003; York Health Economics Consort and The School of Pharmacy 2010), medicines waste is categorised by the supply of prescription medicines to patients that are ultimately discarded. In the seminal ‘York Study’ titled “Evaluation of the scale, causes and costs of waste medicines” by the York Health Economics Consortium and the School of Pharmacy, UCL medicine waste was defined as “drugs that are dispensed but are ultimately physically discarded. That is, they are put into domestic waste or the drains, or returned to pharmacists or dispensing doctors for incineration.” This definition was developed out of the European Waste Framework Directive (2008) that defines waste as ‘any substance or object the holder discards, intends to discard or is required to discard’. Waste medicines therefore are medicines that have been supplied to patients but not consumed or are partly consumed and ultimately are disposed of. This can be because there is no longer a therapeutic need or because they have exceeded their expiry date. At some stage, the medicines are then disposed of either in household waste or returned to a pharmacy or other appropriate medicines disposal service.

In the UK, there have been a small number of robust studies evaluating the scale of medicines supplied by the NHS that are wasted. In May 1995, the Office of

Populations and Census Surveys (OPCS) published their Omnibus Survey (Office of Population Censuses and Surveys 1997) which included an evaluation of medicines waste. Officers visited 2000 homes in England to identify medicines that were not currently being used. Remaining medicines were either those that were intended to be used at some later date or the individual had no intention of using them at any point in the future. The authors classified waste as those medicines that were not intended for future use. By extrapolation, the report concluded that 11 percent of homes in the UK had at least one medicine that would eventually be disposed of.

The York study in 2010 expanded the definition of waste medicines to medicines that are not currently in use i.e. they included medicines for which there was no intention to use them again at any point in the future and those that are being retained for future use (or just in case). The authors justified this on the basis that retaining medicines may risk patient harm on two counts. Firstly, the individual has to make a judgement on self-medicating and there is a risk that the expiry date on the medicine has been achieved. The authors used a different methodological approach to that of the OPCS. They developed a telephone survey with a target (arbitrary) of 1000 responses (1185 actual) and audited medicines returned to 114 community pharmacies across five primary care trusts in England; the audit also included medicines returned from care homes. From the data collected, the authors estimated that some £300 million worth of medicines are wasted annually in England. This could be divided into £90 million of medicines retained in an individuals home, £110 million of medicines returned to the pharmacy and £50 million returned by care homes (York Health Economics Consort and The School of Pharmacy 2010). Put another way, these wasted medicines account for £1 of in every £25 spent on prescribed medicines or 0.3% of overall NHS spend. The authors concluded that the scale of medicines waste is likely to be underestimated as a consequence of the survey methodology employed, disposal in household waste or via other disposal routes such as returning medicines to dispensing GPs.

It is worth noting that the issue of medicines waste is not unique to the UK. In Canada in a study to quantify the value of returned medicines to 58 pharmacies over a two month period, the cost of discarded medication was estimated to be $60,350 (Cameron 1996). Similarly, in Spain, the estimated cost of returned medicines to 38 community pharmacies over 7 working days was €8539.9 (Coma et al. 2008), while in the USA, wasted medicines are said to accounted for US$1 billion annually in older adults aged 65 and over (Morgan 2001).

There are several key consequences of medicines waste for patients, practitioners, healthcare organisations and society. Such wastage imposes an economic burdens in terms of direct expenses as a consequence of the cost of unused medicines and their disposal and indirect costs for the time spent on prescribing and dispensing process (Langley et al. 2005b; James et al. 2009).

4.1.3 The cause of medicines waste

Waste can happen at any stage in the medication management process from the time of issuing the prescription until the medications are in the hands of the patient. The causes of medicines waste are outlined in **Table 4.1** below. As can be seen, the causes of waste can be categorized into those instances where the waste is unavoidable (patient death, patient recovery, an appropriate change of medication) and those that are avoidable (repeat dispensing, stock piling and over ordering, the duration of the prescription, inappropriate disposal in care homes, non-adherence). It is also clear that patients and healthcare professionals (prescribers, pharmacists, care home personnel) all contribute to the generation of medicines waste. Indeed, in a recent report in Bristol exploring some of the main causes of medicines waste, lack of clinical knowledge of care home staff was said to be a contributory factor. In their report, the authors stated that some staff were not confident with the administration of some medications (particularly 'when required' medicines) or familiar with the clinical condition of residents. As a consequence, they ordered all the prescribed medicines irrespective of whether they were being taken regularly by the resident. Similarly,

suboptimal working processes were said to contribute to medicines waste. Such processes included: (i) lack of space to store medications for example one carer claimed that that she had disposed of unused sachets of laxatives due to lack of storage space; (ii) inappropriate storage conditions such as the temperature of the refrigerator was not regularly monitored and went out of range leading to the disposal of some medicines; (iii) receiving the wrong medication due to errors in prescribing or dispensing of medicines (Bristol Clinical Commissioning Group 2016).

Whilst, patient non-adherence is commonly cited as the major contributory factor leading to medicines waste, the *'Evaluation of the Scale, Causes and Costs of Medicine Waste'* report in 2010 concluded that, most medicines wastage is as a consequence of issues related to repeat prescribing and dispensing processes. For example, in a study that sought to audit the appropriateness of medicines prescribed by GPs in Bristol, of the 3,693 medicines dispensed during the last 3 months of the financial year 2014-2015, approximately 590 (16%) were unnecessary (Bristol Clinical Commissioning Group 2016).

Table 4.1 The causes of medicines waste (adapted from (Hazell and Robson 2015))

Cause of waste	Notes	References
Repeat dispensing	Medicines that have been prescribed to patients are dispensed irrespective of whether they are needed.	(Petty 2017)
Stock piling and over ordering	Patients or care homes will order all repeat medication irrespective of whether it is required; for patients this can be driven by a fear that if they do not order all their medicines they will be deprescribed.	(Abahussain et al. 2006)
Change of medication	In instances where a patient's condition changes or where are adverse drug reactions to their existing therapies, a change in medication may be necessitated. The remaining stock of the existing medicine is then wasted.	(Braund et al. 2008)
Patient recovery	A patient may recover from a condition before the stock of the medicine treating the condition is fully consumed. Any remaining medicines stock is waste.	(Coma et al. 2008)
Patient death	A patient death may lead to waste medicines where anticipatory medications are prescribed or where a patient's regular medicines are not used	(Langley et al. 2005a)
The duration of the prescription	Where the prescribing duration is extended (e.g. three month's worth of a medicine are prescribed and dispensed) there is an increased risk that the patient will recover or change medications before the original prescribing duration is exceeded.	(Hawksworth 1996)
Inappropriate disposal	Some care homes dispose of all remaining medication at the end of a 28-day medicines cycle even if the shelf-life of the product has not been reached.	(Bristol Clinical Commissioning Group 2016)
Non-adherence	Patient may either intentionally or non-intentionally fail to adhere to their prescribed therapy.	(Ryan and Wagner 2003)

In 2014, West and colleagues conducted a systematic review of the literature related to medicine waste (West et al. 2014). The authors retrieved 14,157 papers related to waste and screened this down to 42 papers. The authors noted that there was a discrepancy in what constituted medicines waste between papers which made comparison difficult. However, the most commonly cited reasons for medicines waste were: (i) medication changed (Morgan 2001)(Mackridge and Marriott 2007); (ii) patient's death (Cook 1996); (iii) resolution of the patient's condition (Coma et al. 2008); (iv) expired medicines (Braund et al. 2009); (v) excessive stock at home (Abahussain et al. 2006) and (vii) discontinuation by the patient (Abahussain et al. 2006). In another study, West and colleagues used the Delphi technique to define medicines waste and explore it's contributory factors. Using an expert panel of academics, practitioners, government officials, representatives from professional organisations and patients situated in Malta, the authors identified four main contributory factors: (i) physical and environmental factors; (ii) social and psychological patient factors; (iii) cultural factors and (iv) practitioner factors. Each of these factors was associated with one or more conceptual themes that the panel perceived to contribute to medicines waste (**see Table 4.2**).

Table 4.2 Factors contributing to medicines waste (adapted from (West et al. 2015)

Contributory factors	Conceptual themes
Physical and environmental factors	Expiry dates reached before stock used Providing large quantities of medicines to patient
Social and psychological patient factors	Non-adherence as a consequence of limited patient education Medicines ordered by relative or carer when they are not required Communication issues – medicines ordered when not needed Patient death
Cultural factors	Free healthcare system
Practitioner factors	Inappropriate or unnecessary medicines prescribed Medication reviews not undertaken to rationalise therapy

The York study (York Health Economics Consort and The School of Pharmacy 2010) attempted to link medicines wastage with loss of therapeutic value from medicines. The use of medicines was categorised then as either optimal (i.e. medicines are fully consumed, and therapeutic benefits maximised) or therapeutic loss (therapeutic benefits reduced or lost completely). They then developed a schematic indicating the link between waste and loss of therapeutic outcomes (see **Figure 4.1**). Clearly, some of the causes of waste medicines can be prevented (e.g. preventing over supply, encouraging adherence through patient education and counselling) whilst some are non-preventable (e.g. patient death) with estimates suggesting that the split between preventable and non-preventable waste is roughly 50:50 (York Health Economics Consort and The School of Pharmacy 2010). The authors suggested that reducing the avoidable waste burden would result in some extra costs associated with implementing better waste control measures. Even factoring this in, they estimated that on average each primary care trust in England could realise up to £0.5 million in savings per annum or put another way £1 - £2 per head of population. Whilst such savings would be financially and politically desirable, the authors argue that it is the greater returns that could be achieved from maximising medicines use to improve health outcomes is more effective than a reduction in medicines waste. For example, the authors suggest that the therapeutic loss due to non-adherence in five therapeutic domains is likely to be more than £500 million (York Health Economics Consort and The School of Pharmacy 2010). The authors therefore suggest that tackling inappropriate medicines use by patients (which may lead to reductions in medicine waste as a by-product) should be a priority.

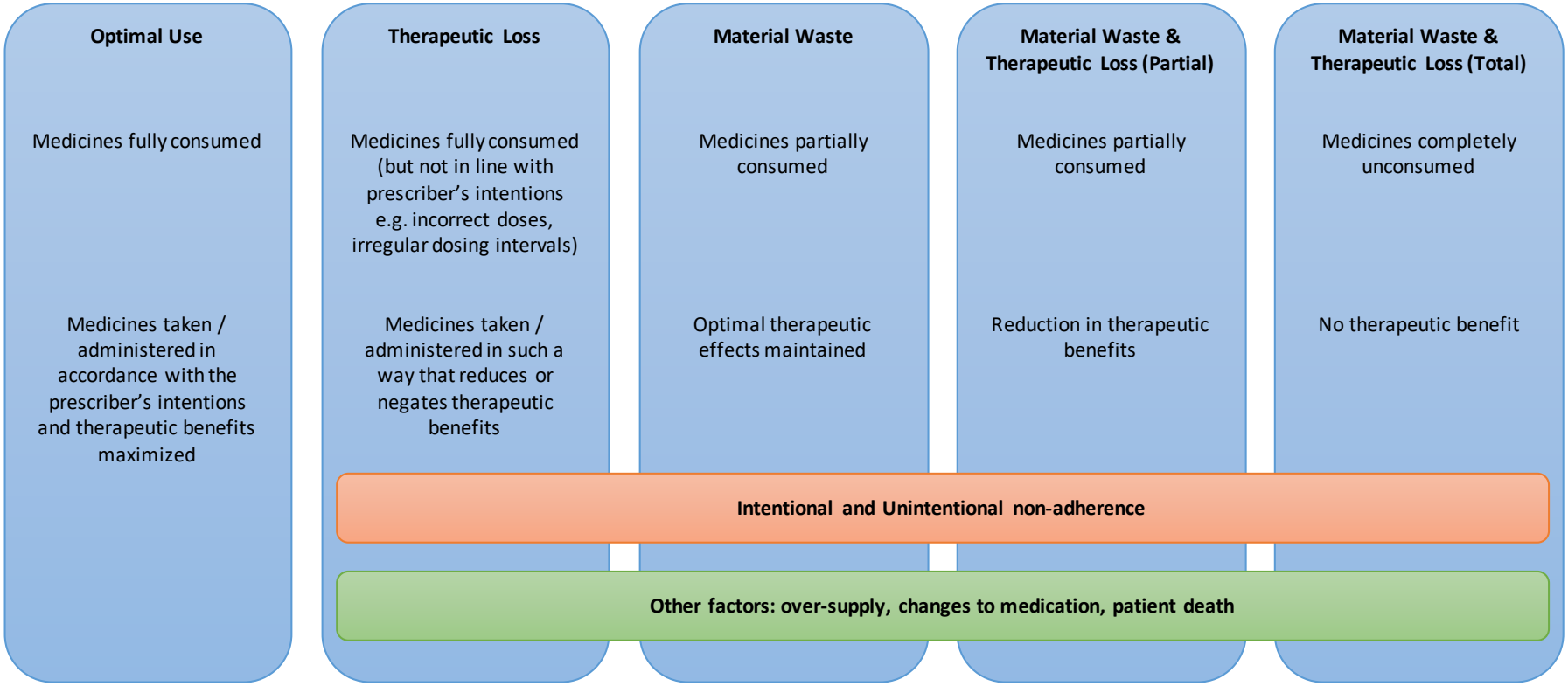

Figure 4.1 Medicines waste and therapeutic loss adapted from Hazell and Robson 2015)

4.1.4 Non-adherence

Non-adherence to a medication is defined as a patient failing or choosing not to take medicines in a way agreed with the prescriber. Non-adherence can arise as a result of a patient deliberately not taking their medicine(s) as agreed with the prescriber i.e. intentional non-adherence. For example, they may hold particular beliefs or concerns, they may not agree with their diagnosis or they may adjust their dose. Non-adherence can also be unintentional for example when a patient forgets to take their medicine. It is worth highlighting that patients may be non-adherent to a number of medicines at the same time but for different reasons. The World Health Organisation has highlighted five factors that contribute to non-adherence (World Health Organization 2003)(see **Table 4.3**). Allemann and colleagues suggested that these factors could be divided into modifiable and non-modifiable determinants of non-adherence (Allemann et al. 2016). For example, a patient's knowledge and beliefs about their medicines may be modifiable through an educational intervention whilst their educational attainment may be non-modifiable (at least in the short term). The authors suggested that in the main interventions should be directly targeted at the modifiable determinants although there may be opportunities to tailor an intervention towards addressing non-modifiable determinants.

Table 4.3 Factors that contribute to non-adherence to medicines.

Contributing Factor	Examples
Socioeconomic factors	Poor educational attainment, unemployment, low socioeconomic status
Healthcare systems and team factors	Ineffective medication distributions services, overworked healthcare professionals
Therapy related factors	The duration of treatment, how immediate the beneficial effects are seen, past success with other treatments
Conditions related factors	Symptom severity, effective treatments availability, the individual's level of disability as a consequence of their therapy
Patient related factors	Forgetfulness, poor motivation, non-agreement with the diagnosis

4.1.4.1 Non-adherence in care homes

There is a general perception that because residents are being 'administered' medicines, non-adherence is not a significant issue. Indeed, Hughes and Goldie interviewed eight GPs, 17 residents and conducted two focus groups with nurses (total 9 participants) to explore adherence and shared decision making in the nursing home environment. The authors concluded that the major theme to emerge was 'control'. GPs and nurses respectively felt it was necessary to retain control of prescribing and administration to ensure the safety and efficacy of medicines. Residents apparently accepted this control without question, reported that they were adherent to their medicines and were not involved in share decision making (Hughes and Goldie 2009). Although adherence to medicines in the care home setting could be described as optimal due to the regimented administration of medicines, there is evidence in the literature of enforced adherence (compliance) whereby a resident continues to receive their medicines for extended durations without review. This may exacerbate any adverse reactions to such medicines (Hughes 2008). Barnes and colleagues used a qualitative approach to explore medicines administration use in care

homes and found that the priority for nursing staff was to ensure all medicines prescribed for a patient were administered. The authors suggested that there would be times where a resident was not able to exercise any form of "intelligent non-compliance" for example where they had cognitive impairment or were unable to communicate (Barnes et al. 2006). This issue can be exacerbated where covert administration occurs i.e. administrations are concealed in food or drink. Whilst this may be justified on medical grounds, there are instances in the literature where covert administration has occurred but is inappropriate (Kirkevold and Engedal 2005). A second issue is one of erratic adherence i.e. residents may be administered all their medicines but at the wrong times (for example if it is inconvenient for staff) or where any special instructions are not followed (for example taking a medicine on an empty stomach). Ultimately, the issues of adherence in care home residents is unexplored but may lead to therapeutic loss and / or waste medicines.

4.1.5 Medicines waste in care homes

Much of the research on medicines waste in care homes is quite historic with the first reported study by Mathieson and Rawlings (1971) who estimated that 15% of all medicines wasted were from nursing homes (Mathieson and Rawlings 1971). Then, in 1978, Howard and Strong studied medicines return books for a 100-bed nursing home over a 4 year-period in the US and estimated $6,420.24 worth of discarded medicines over the study period. The authors estimated the cost for 374 items including solid dosage form (tablets, capsules), topical preparation, suppositories and parenteral preparation (Howard et al. 1978). Much of the research then focussed on exploring reductions in medicines waste that could be achieved through monitored dosage systems. For example, Parrot (1980) in a 120-bed nursing home, compared the cost of discarded medicines arising from a 30-day card dispensing system with a monitored unit dose system. The author showed that nearly $18 extra medicines waste was generated per resident per month as a consequence of the traditional card system in comparison with that of a monitored unit dose system (Parrott 1980). Similarly,

Brown and Kirk reported that the annual cost of discarded medicines using unit dose systems was 17% less than generated by traditional systems in a study conducted in 17 care homes in Indiana, USA (Brown and Kirk 1984). This was followed by another study in 1985, to estimate the cost of discarded medicines in 12 nursing homes over a two-year period. This study found that $64.08 of medicines was wasted per resident per year and this was largely as a consequence of either a change in the resident's medicine regimen or death of a resident (Farmer et al. 1985).

The landmark study on medicines waste in care homes in the UK was conducted by the York Health Economics Consortium in partnership with The School of Pharmacy, London (York Health Economics Consort and The School of Pharmacy 2010). They studied the medicines returned to 114 community pharmacies over a one-month period. The medicines returned from care homes accounted for 16% of the total wastage at a value of £50 million. In Wales, medicines waste in care homes is under-explored although from a total of £98 million spent on prescribed medications in 2016, £650,000 were associated with unused medicines in care homes in the Abertawe Bro Morgannwg University Health Board (ABMU) area (The Welsh NHS Confederation 2017). Ultimately, medicines waste from care homes remains underexplored.

4.2 Aims and Objectives

The aim of this study was to explore the types and quantity of medicines wasted in a sample of care homes in the South Wales area.

The objectives were to:

1. Quantify the value of wasted medicines from medicines returns books
2. Quantify the value of medicines stockpiled or overstocked
3. Explore the types of medicines wasted in this sample of care homes.

4.3 Methodology

4.3.1 Study design overview

This study sought to explore medicines waste in care homes. To the best of the researcher's knowledge, there is no established protocol for the measurement of medicines waste in care homes in the literature. As such a methodology was developed. The developed methodology was in two parts: (i) medicines returns books were requested from participating care homes (it is a CQC requirement that returns books are completed each month) (CQC 2016); (ii) medicines in the home were physically counted and then reconciled against the current MAR chart to identify the stockpiling or overstock of medicines. The value of the returned medicines and the overstocked medicines was then calculated using the British National Formulary (BNF 68) to estimate the scale of medicines waste. The reader might ask whether it was necessary to count stock in the home and instead rely solely on the returns books. However, there is anecdotal evidence that medicines are stockpiled and the returns book does not accurately capture the totality of medicines that have been or need to be returned. Indeed, during visits to care homes, the researcher noted a number of practices that suggest direct stock counts are more appropriate and valid. For example, medicines were found in the home that had been stopped i.e. they were not on the resident's MAR chart, storage areas that were labeled with one resident's name contained the medicines of other residents and there were medicines for residents who no longer reside in the home. As such, it was necessary to account for unnecessary medicines stock that is held at the home but that has not been or will never be returned. In reconciling the stock required on the MAR chart against the stock held, excess stock could be assessed.

4.3.2 Recruitment of care homes

The recruitment of care homes to this phase of the study was similar to that described in **section 2.3.2** but with some modifications. Briefly, care homes were recruited by purposive sampling from the ABMU health board in Wales with

recruitment lead by Invatech Health; inclusion/exclusion criteria and the recruitment methodology were developed in partnership with the researcher. To be eligible for the study, the nursing or residential home had to be located in the ABMU health board, primarily cater for older adults, be fully registered with the Social Inspectorate Wales (SIW) and currently use a paper-based MAR chart system. The mechanism by which care homes were identified is detailed in **section 2.3.2**. Care homes that participated in the studies detailed in Chapters 2 and 3 were asked if they would like to continue their participation in this study; some care homes chose to do so whilst others did not. As a consequence, further care homes were recruited (care homes 11 and 14), this was the same coding used for a larger study (homes 12 and 13 did not take part in this phase of the study). The managers of participating care homes were asked if they would be willing to submit returns books for evaluation (the least intrusive option), allow the research team to conduct stock counts in the home or both (preferred). In total, seven care homes consented to stock counts of which, four also provided returns books.

4.3.3 Data Collection

4.3.3.1 Overstock

Overstock refers to any stock remaining at the end of a medicines cycle i.e. if a resident's medicines are not administered in line with the prescriber's intentions, there will be stock leftover. These should be returned at the end of the medicines cycle but where it is not, it would create an unnecessary stockpile. Medicines may also accumulate for 'when required' medicines if these are not required by the resident during the medicines cycle and are not returned. To calculate overstock, seven care homes were visited during 2015 on the following days: (i) 17 March-care home 3; (ii) 20 March-care home 4; (iii) 10 March-care home 6; (iv) 19 February-care home 8; (v) 18 February-care home 9; (vi) 18 February-care home

11; and (vii) 18 February-care home 14. Ideally, each home would have been visited with the same number of days remaining in the medicines cycle. However, this was not possible as the research team had to work around the care home's schedule. In addition, it became clear during stock counts that the remaining stock in some cases was greater than the total monthly supply on a MAR chart indicating that waste had been accumulating for some time and not just over the period of the medicines cycle.

A copy of the MAR chart(s) for each of the residents was obtained and the quantity of medicine(s) that should be remaining for each resident to the end of the medicines cycle was calculated using the dosage instructions on the MAR chart(s). This was then followed by a physical count of the medicines in the home. A stepwise process of counting was followed:

1. Number of doses in the resident's MDS tray;
2. Number of PRN medications;
3. Volume of liquid formulations (visual estimation);
4. Amount of creams and ointments (visual estimation);
5. Any medicines in the refrigerator (e.g. insulins, eye drops);
6. Number of dressings;
7. Number of nutritional supplements;

These items were primarily located on the medicines administration trolley or stored in cabinets or on shelves in a dedicated room. Controlled Drugs (CDs) and any medicines that were not prescribed on a named patient basis were excluded from the study.

Discrepancies in stock were determined by comparing the quantity required by each patient until the next medication cycle started with the actual quantity determined from the stock count. Any discrepancy that amounted to an overstock of < 10 dosage units was ignored. This was a pragmatic approach given

the volume of medicines to be counted in a narrow window of opportunity. All counts were entered directly into Microsoft Excel for Mac version 15.33 (Microsoft Corporation; Seattle, USA).

The development of the protocol for counting medicines was led by the researcher. Stock counts in care home 4 were made by the researcher and were used to train two Erasmus students who completed the counts in the remaining six homes. All data analysis was by the researcher.

4.3.3.2 Returned medicines

Returned medicines data was obtained from the returns record book. This is a record of the medicines that are returned to the supplying pharmacy (in the case of residential care homes) or to a clinical waste supplier (in the case of nursing homes) following completion of a medicines cycle. Data was extracted from the returns books for four care homes. The data in the returns books corresponded to the end of a monthly medicines cycle. The information extracted and entered into Microsoft Excel for Mac version 15.33 (Microsoft Corporation; Seattle, USA) was: (i) the date of the return; (ii) id of the resident; (iii) name and strength of the medication; (iv) quantity returned; (v) pack size; (vi) reason for disposal; and (vii) signature of the person responsible for entering the medicines returns information. Where data from the returns book was incomplete, a number of assumptions were made. Where the pack size was missing, it was assumed the smallest pack size had been prescribed to be consistent and where the strength of the formulation was missing the lowest available strength of the medicine was used. In two of the homes, the stock in the returns bins was cross-referenced with the stock entered in the returns book and was found to be the same, validating the data entry in the returns book.

A summary of the data collection period is shown in **Table 4.4** below.

Table 4.4 Summary of when waste data was collected.

Care Home	Returns book analysed	Stock counts made	Number of days remaining in medicines cycle
3	January meds cycle	17/3/2015	8 days
4	April meds cycle	20/3/2015	3 days
6	*Not available*	10/3/2015	15 days
8	*Not available*	18/2/2015	5 days
9	January meds cycle	18/2/2015	5 days
11	January meds cycle	18/2/2015	5 days
14	*Not available*	18/2/2015	5 days

4.3.4 Data analysis

The value of returned and overstock medicines was calculated from the generated spreadsheets based on the cost of each medicine as listed in the British National Formulary (BNF 68). To do this, the BNF price for the smallest packet was divided by the pack size to generate the cost per dosage unit. This was then multiplied by the number of dosage units that were either returned or overstocked i.e.

Cost of the unused medicines = Cost per unit x Quantity unused

(Ciullo and Shepherd. 1977).

If the medicine was not listed in the BNF or there was no price associated with it (e.g. Magnesium Hydroxide, Olive Oil) the medicine was excluded.

4.4 Results

4.4.1 Quantifying the value of medicines waste from overstock

There is evidence in the literature that medicines are stockpiled 'just in case' and therefore returns books may not provide a full picture of the level of waste in care homes. In order to better capture the extent of medicines waste in care homes, the value of medicines stockpiled (overstock) was estimated. To do this,

a copy of the MAR charts for all residents in seven care homes was obtained. At 'optimal efficiency', there would be no overstock and the stock of each medicine would be exactly sufficient to last the patient until the next medication cycle. Using the resident' MAR charts, the stock needed to take the resident to the next medicines cycle was determined. The stock of each of the resident's medicines was then counted and any excess was deemed to be overstock.

Table 4.5 represents the value of overstock in the seven participating care homes. As can be seen, the total value of overstock was £3119.95 which equates to £20.25 of overstock per resident based on 154 residents. The range in the value of overstock per care home was fairly large with care home 14 overstocking just £4.74 of medicines and care home 11 overstocking £774.05. Of course, not all the care homes housed the same number of residents and therefore the value of overstock was normalised to resident number. Care home 14 still had the lowest value of overstock (£0.68 per resident) but care home 9 had the most with £44.29 0f overstock per resident.

Table 4.5 The value of overstocked medicines in each of the seven care homes studied. The total value of the medicines stockpiled was £3119.95. This equates to £20.25 of overstocked medicines per resident per month (based on 154 residents).

Care home number	Type of home	Number of residents	Value of waste from overstock	Average value of overstock per resident
3	Nursing	25	£451.25	£18.05
4	Nursing	29	£130.68	£4.50
6	Nursing	27	£746.41	£27.64
8	Residential	24	£304.25	£12.65
9	Nursing	16	£708.57	£44.29
11	Nursing	26	£774.05	£29.77
14	Residential	7	£4.74	£0.68
	Total	**154**	**£3119.95 (£20.25/resident)**	

4.4.2 Value of medicines wasted by BNF category

In order to understand the nature of the medicines waste generated, the medicines were categorised according to BNF chapter which essentially represents the body system in which the medicine acts. As can be seen in **Table 4.6**, medicines acting in the nervous system was the category that generated the most waste (£832.34) representing ~ 27% of the waste generated. Four of the 13 categories examined each contributed more than 10% of the value of the waste generated and combined they accounted for more than 70% of the value of the waste generated. These represented medicines that act on the GI system (£605.19; 19.40%), the cardiovascular system (£411.11; 13.18%), the nervous system (£832.34; 26.68%) and medicines used in infections (£365.61; 11.72%). Very little waste in terms of value (less than 5% of the total) was generated by medicines acting on the genito-urinary system, medicines used for blood disorders or nutritional issues, medicines used for musculo-skeletal problems or used to treat eye conditions. No waste was identified for medicines used to treat immune and malignant disease, skin conditions or ear, nose and throat problems.

Table 4.6 Medicines waste identified in seven care homes through stock counts, categorised by BNF chapter. Drugs acting on the nervous system represented the therapeutic area in which the most waste was generated (£832.34) representing 27% of all the waste generated. Medicines acting on the GI system, cardiovascular system nervous system and medicines used in infection represented almost 71% of the waste generated.

BNF chapter	Value of medicines overstocked	Percentage of total waste
1 Gastro-intestinal system	£605.19	19.40
2 Cardiovascular system	£411.11	13.18
3 Respiratory system	£264.22	8.47
4 Nervous system	£832.34	26.68
5 Infections	£365.61	11.72
6 Endocrine system	£172.84	5.54
7 Genito-urinary system	£3.25	0.10
8 Immune system and malignant disease	---	---
9 Blood and nutrition	£119.60	3.83
10 Musculoskeletal system	£40.50	1.30
11 Eye	£58.71	1.88
12 Ear, nose and oropharynx	---	---
13 Skin	---	---
Other (e.g. nutritional supplements, nebules etc)	246.58	7.90
Total	**£3,119.95**	

A breakdown of the individual medicines that were wasted in the four therapeutic areas where waste was highest (i.e. GI system, cardiovascular system, nervous system and medicines used to treat infections) is shown in **Table 4.7**. As can be seen laxatives (£572.70) and paracetamol containing products (£253.67) are the largest contributors to the total value of waste accumulated followed closely by memantine and furosemide. Unlike memantine which has a relatively high price (unit pack cost of £12.71), paracetamol, laxatives and furosemide are all inexpensive (unit pack costs less than £10) indicating that the volume of waste associated with these drugs is high. Rifaximin has a particularly high unit pack cost (£259.23) which explains why it contributes significantly in terms of waste even though the quantity wasted was small (39 tablets)

Table 4.7 A breakdown of the value of waste medicines in the four therapeutic areas identified to have the highest value of waste medicines. Medicines that contributed less than 1% of the total value of the waste are not included. It can be seen that a number of these medicines / medicines classes are PIPs.

BNF therapeutic category	Individual medications	Value of medicine	Percentage of total waste
Nervous System – total waste = £832.34			
Non-opioid analgesics	Paracetamol	£219.67	26
Opioid analgesics	Co-codamol	£34	4
Anxiolytics	Diazepam	£15.98	2
	Lorazepam	£26.81	3
Antipsychotics	Amisulpride	£21.18	3
	Zuclopenthixol	£9.96	1
	Promazine	£62.62	8
	Pericyazine	£111.66	13
	Trifluperazine	£10.85	1
Control of epilepsies	Sodium valproate	£27.46	3
Dementia	Memantine	£226.97	27
Anti-Parkinsonian	Madopar	£13.68	2
Gastrointestinal System – total waste = £609.19			
Laxatives	Lactulose	£201.83	33
	Macrogol	£99.55	16
	Senna	£237.43	39
	Movicol	£33.89	6
PPIs	Omeprazole	£16.23	3
Cardiovascular system – total waste = £411.11			
Beta-blocker	Bisoprolol	£33.79	8
ACIs	Lisinopril	£10.69	3
	Ramipril	£8.79	2
AIIRA	Losartan	£75	18
Cardiac glycoside	Digoxin	£15.81	4
Diuretics	Furosemide	£204.23	50
	Budesonide	£25.45	6
Lipid lowering agent	Simvastatin	£21.75	5
Calcium channel blocker	Tildiem	£5.15	1
Antiplatelet	Dipyridamole	£8.05	2
Medicines used in infection – total waste = £365.61			
Bacterial infections	Rifaximin	£180.53	49
	Nitrofurantoin	£183.28	50

4.4.3 Stratification of medicines waste by the cost of a pack.

One argument that is often made about waste medicines is that it is largely as a consequence of a small volume of waste associated with high cost medicines i.e. the unit cost per pack is high. To address this, the value of the overstocked medicines was stratified according to the unit cost of a medicines pack (see **Table 4.8**). The price bands used were the same as those used in the York medicines study (York Health Economics Consort and The School of Pharmacy 2010). As can be seen in **Table 4.8**, the majority of the medicines wasted (82.5%) had unit pack costs that were less than £10 per pack. This indicates that most of the wasted medicines were relatively inexpensive and there were few instances of medications with a relatively high unit pack cost of over £50 being wasted (5.5% of all waste). Of course, even with a low incidence of medicines with a high unit pack cost being wasted, if sufficient volume is wasted, this may disproportionately impact on the total value of the waste. As can be seen in **Tables 4.8** medicines with unit pack costs of less than £10 contributed most to the overall value of the medicines wasted (£1,424.96; ~ 46%) and medicines with a unit pack cost of less than £50, accounted for almost 80% of the total value (£2,472.22). Medicines with high unit pack costs (£50 or greater), meanwhile accounted for approximately 20% of the value of the waste generated (£647.73).

Table 4.8 Medicines waste as overstock from seven care homes stratified by the cost of the medicines pack. The majority of the medicines wasted (82.5%) had pack costs of less than £10. Very few (1.5%) of the medicines wasted were expensive medicines (£100+)

Cost of pack	Frequency of medicines overstocked	Percentage (1.dp)	Value	Percentage of total value
£0 <10	165	82.5%	£1,424.96	45.67%
£10-25	17	8.5%	£658.61	21.11%
£25-50	7	3.5%	£388.65	12.46%
£50-100	8	4%	£304.00	9.74%
£100+	3	1.5%	£343.73	11.02%
Total	200		£3,119.95	

4.4.4 The highest quantities of medicines wasted in care homes

In order to further characterise the waste medicines generated in care homes, the highest quantities of wasted medicines (in terms of dosage units) was examined in each of the seven care homes; the data is presented in **Table 4.9**. As can be seen, in some care homes (4, 8, 9, 11) there were examples of medicines where there were more than 1,000 dosage units overstocked although in terms of value these did not exceed £100 of waste. Paracetamol was particularly over represented in the data featuring in the top five medicines wasted in all seven care homes and indeed was in first place in six of the seven homes, narrowly beaten into third place by ADCAL-D3 and Pericyazine in care home 3. In total, across the seven homes there were 6,363 paracetamol tablets overstocked, all prescribed on a named patient basis. Analgesics on the whole were over represented in the sample with compound preparations of codeine and paracetamol also featuring in the top five wasted medicines in three of the homes. Perhaps as a consequence, the quantity of waste associated with laxatives (senna, macrogol, laxido and movicol) was also high and featured in the top five wasted medicines in five of the seven homes. Similarly, benzodiazepines (diazepam and lorazepam) appeared with a reasonably high frequency in three of the seven homes. It is worth highlighting that analgesics, laxatives and benzodiazepines are normally prescribed on a when required basis. A surprising finding was that in two of the care homes, medicines for Alzheimer's disease featured in the top five wasted medicines.

Table 4.9 The top five medicines with the highest quantities wasted and their total cost in seven care homes. Waste paracetamol featured in the top five in all care homes and was the most wasted medicine in six of the homes.

Medication	Total quantity wasted	Value (£)
Care home 3		
ADCAL-D3 1500mg/400-unit eff. tab.	122	£13.05
Pericyazine 2.5mg tab.	110	£20.39
Paracetamol 500mg tab	84	£2.68
ADCAL-D3 1.5g/Colecalciferol 10mcg tab.	83	£5.41
Lorazepam 1mg tab.	43	£4.05
Care home 4		
Paracetamol 500mg tab	1,057	£47.03
Co-Codamol 8/500mg effervescent tab.	179	£7.11
Macrogol compound oral powder	87	£25.72
Senna 7.5mg tab**.**	74	£8.78
Folic acid 400mcg tab.	53	£1.60
Care home 6		
Paracetamol 500mg tab	882	£28.14
ADCAL-D3 chewable tab.	265	£28.35
Zapain 30mg/500mg tab.	200	£9.34
Co-Codamol 8mg/500mg tab.	148	£5.88
Movicol oral powder sachets	117	£26.04
Care home 8		
Paracetamol 500mg tab	1,084	£34.58
Madopar 125mg cap.	198	£13.68
Movicol oral powder sachets	123	£27.39
Laxido orange oral powder sachets	89	£26.31
Donepezil 5mg tab.	87	£7.78
Care home 9		
Paracetamol 500mg tab	1,116	£35.60
Memantine 20mg tab.	486	£220.61
Sodium valproate 200mg tab.	283	£12.51
ADCAL-D3 chewable tab	246	£26.31
Senna 7.5mg tab.	236	£28.01
Care home 11		
Paracetamol 500mg tab	2,043	£65.17
Co-Codamol 30/500mg tab.	388	£18.12
Laxido orange oral powder sachets	223	£65.93
Diazepam 2mg tab	188	£6.45
Lorazepam 1mg tab.	148	£13.75
Care home 14*		
Paracetamol 500mg tab	97	£3.09
Diazepam 2mg tab	48	£1.65

* care home 14 was a small home (7 residents) and the level of waste was small hence there are only two medicines listed here.

4.4.5 Wasted medicines with the highest cost

In addition to examining the medicines that were wasted in the highest quantities, the medicines contributing the highest costs were also explored.

Table 4.10 shows the top five waste medicines with the highest costs in each of the seven care homes examined. Much like the medicines wasted in the highest quantity (**Table 4.9**), paracetamol and laxatives are over represented with paracetamol featuring in the top five in six care homes and laxatives featuring in four. Beyond this, there is little commonality between care homes. In some homes, the most costly wasted medicine was from a single resident (care homes 3, 6, 8) whilst for other homes, the most costly wasted medicine was due to an accumulation of waste from a number of residents. Of note, with the exception of care home 11, these top five medicines accounted for more than two thirds of the total value of medicines wasted; for care home 11 it was 57% (data not shown).

Table 4.10 The top five wasted medicines with the highest cost in seven care homes.

Medication	Cost of waste	Percentage of total waste	N° of residents	Quantity wasted
Care home 3 – total waste = £451.25				
Levothyroxine	£139.00	30.80	1	180ml
Furosemide	£100.02	22.17	2	480ml
Losartan	£51.00	11.30	1	190ml
Terbutaline	£47.89	10.61	1	692 doses
Pericyazine	£20.39	4.52	2	(93 tab.+ 17.5ml)
Care home 4 – total waste = £130.68				
Paracetamol	£47.03	35.99	13	1,057 tab.
Macrogol powder	£25.73	19.69	3	87 sachets
Laxido sachets	£12.42	9.50	2	42 sachets
Senna	£8.78	6.72	2	74 tab.
Co-codamol	£7.11	5.44	3	179 tab.
Care home 6 – total waste = £746.41				
Rifaximin	£180.53	24.19	1	39 tab.
Nitrofurantoin	£163.19	21.86	1	250ml
Pericyazine	£91.27	12.23	2	(95tab.+173.75ml)
Paracetamol	£33.65	4.51	14	(898 tab.+670ml)
Symbicort	£31.66	4.24	1	50 doses
Care home 8 – total waste = £304.25				
Symbicort Inhaler	£90.75	29.83	1	330 doses
Promazine	£59.75	19.64	1	755ml
Paracetamol	£46.03	15.13	20	(1143tab.+1160ml)
Laxido sachets	£43.29	14.23	3	89 sachets
Movicol	£27.38	9.00	4	123 sachets
Care home 9 – total waste = £708.57				
Memantine tab.	£220.65	31.14	4	486 tab.
Senna	£170.41	24.05	5	(236 tab.+1200ml)
Fostair Inhaler	£85.52	12.07	1	350 doses
Paracetamol	£37.65	5.31	7	1178 tab.
Stronium sachets	£30.95	4.37	1	32 sachets
Care home 11 – total waste = £774.05				
Complan shake	£179.27	23.16	2	122 sachets
Seretide Inhaler	£114.00	14.73	1	230 doses
Paracetamol	£72.44	9.36	15	(2,043tab.+580ml)
Laxido sachets	£65.94	8.52	4	223 sachets
Saline 2.5ml	£58.71	1.91	1	57 doses
Care home 14 – total waste = £4.74				
Paracetamol	£3.09	65.19	2	97 tab.
Diazepam 2mg tab	£1.65	34.81	1	48 tab.

4.4.6 Medicines wasted characterised by whether the medicine was prescribed with regular or when required dosing

The findings highlighted in **Tables 4.9** and **4.10** suggested that wasted medicines with 'when required' dosage instructions were over represented in the data (paracetamol, laxatives etc.). Therefore, the cost of waste medicines in each of

the homes was categorised according to whether the dosage instructions were when required or regular. **Table 4.11** details this categorisation. The table shows that the waste is actually reasonably skewed towards regular medicines with the cost of wasted 'when required' medicines greater than regular medicines in one care homes (care home 11), in five care homes regular medicines contributed more to the total waste (care homes 3, 6, 9 and 14) whilst in one care home it was evenly split (care home 8). This tendency in the data towards regular medicines contributing more towards the total value of wasted medicines may simply be as a consequence of prescribing which tends towards medicines with regular dosing regimens (see **Chapter 2**). It may also reflect that some medicines that are used on a when required basis (e.g. paracetamol and laxatives) are prescribed on a regular basis.

Table 4.11 Value of waste associated with regular medications versus PRN medications per month. The cost of wasted 'when required' medicines was greater than regular medicines (care homes 11), in four care homes regular medicines contributed more to the total waste (care homes 3, 4, 6, 9 and 14) whilst in one care home it was evenly split (care home 8)

Care home	Value of waste regular medicines	Value of waste PRN medicines	Contribution of PRN meds to total	Total waste
3	£427.01	£24.24	5.37%	£451.25
4	£100.32	£30.36	23.23%	£130.68
6	£434.36	£312.04	41.81%	£746.40
8	£152.53	£151.72	49.87%	£304.25
9	£533.83	£174.74	24.66%	£708.57
11	£247.00	£527.05	68.09%	£774.05
14	£3.88	£0.86	18.14%	£4.74

4.4.7 Quantifying the value of medicines waste from return books

The medicines returns record book from four care homes was reviewed following the end of the preceding month's 28-day medicines cycle (January or April 2015). The value of each of the medicines in the returns book was then calculated and summed in order to determine the total value of medicines returned (see **Table 4.12**). The total value of the medicines returned from the four homes was £1780.64 which equates to £18.54 returned per month for each of the 96

residents in the homes. This is remarkably similar to the estimated cost of medicines wasted using an audit of the overstock in the homes (£20.05 per resident). The range in the value of returned medicines was from £41.26 (care home 4) to £792.53 (care home 11) with an average of £445.16 (± £327.95) returned per home. In order to account for the difference in the number of residents in each home, the average value of returned medicines per resident in each of the homes was calculated. The average value ranged from £1.42 (care home 4) to £42.63 (care home 9) demonstrating significant variability across the homes.

Table 4.12 The value of medicines returned over a 1-month period from four care homes. The total value of medicines returned was £1780.64. This equates to £18.54 of returned medicines per resident per month (based on 96 residents).

Care home	Type of home	Number of residents	Value of waste from returns book	Average value of return per resident
3	Nursing	25	£336.96	£13.49
4	Nursing	29	£41.26	£1.42
9	Nursing	16	£609.89	£42.63
11	Nursing	26	£792.53	£27.25
	Total	**96**	**£1,780.64 (£18.54/resident)**	

4.4 Discussion

There have been numerous debates in the literature on the definitions of medicines waste and at what point it occurs. Does it occur for example at the point it is returned to a pharmacy or when it is destroyed by a medical waste contractor or does that fail to capture medicines that are destroyed inappropriately by individuals in their own homes or by staff in a healthcare setting. Similarly, the literature suggests that patients and staff have a tendency to stockpile medicines unnecessarily, presumably for 'just in case' scenarios or to be returned or destroyed at some point in the future. Together, these considerations make the accurate measurement of waste challenging and most studies recognise any approach to be an estimate of the waste rather than a definitive value. Given the pathways for waste (returned to an organisation that

will dispose of the medicine(s), destruction at home, stockpiled etc) it is likely that methods to establish waste will underestimate the total level. In the care home setting, there is an expectation that any medicines prescribed on a named patient basis (i.e. not ward stock) that are unused at the end of a medicines cycle are returned to the supplying pharmacy (in the case of a residential home) or to a specialist waste disposal contractor (in the case of a nursing home). However, where processes are not robust or there is a culture of stockpiling, then returns records may not be reliable. As a consequence, it is useful to undertake stock audits to understand if medicines are being kept in the home inappropriately in addition to those medicines that are being returned. In this study then, two methods were used to determine the scale of waste. In one part of the study, the stock of medicines that the care home was holding for it's residents was counted towards the end of a medicines cycle. The expected quantity of each medicine remaining (based on the MAR chart) was subtracted from the count and any remaining medicines for the resident was termed overstock. The medicines returns books from four homes were also analysed to calculate the value of medicines returned at the end of a medicines cycle. Ideally, it would have been possible to gather returns books and stock counts in the same month to understand if all the medicines that were unused during the month were indeed returned but this was not possible.

It is worth reflecting on some observations that were made during visits to the homes to count their stock. In most homes visited, the organisation of stock was reasonably poor. As was seen in **Chapter 3**, many care homes had a significant volume of stock errors related to their MAR charts including no records of quantity received, no signature to indicate receipt of stock etc. These types of issues were borne out on visits to the home. Typically, the resident's medicines should be kept in a medicines trolley in a secure location arranged according to the resident's name. However, in some homes, there was evidence of medications that were no longer being taken by the resident, shelves labelled with one patient's name contained medicines for another individual, there were

medicines for residents that no longer resided in the home, medicines stored in communal areas such as the kitchen and in some homes non-medicinal products (food and hair dye) were stored alongside medicines. In some care homes, it was apparent that there was a significant volume of excess stock and that some homes did not operate a robust returns process as the returns books were not available or accessible.

However, four returns books (from the seven care homes that participated) were available. A calculation of the medicines returned at the end of a medicines cycle revealed an estimated waste medicines bill of £18.54 per resident per month (£1780.64 total waste for 96 patients). In Wales, there are estimated to be approximately 26,000 care home beds (Statistics for Wales 2017). With a monthly waste medicines bill estimated to be £18.54 per resident in this small sample of care homes, this extrapolates to an annual medicines waste bill of around £5.8 million in Wales. Across the UK there are estimated to be approximately 410,000 beds (Iliffe et al. 2016) which similarly extrapolates to approximately £90 million of medicines waste. According to research undertaken in 2009, it was estimated that the annual cost of waste medicines was £300 million in England only (York Health Economics Consort and The School of Pharmacy 2010). Of this, 16% or ~ £50 million was related to medicines returned to pharmacies by care homes (York Health Economics Consort and The School of Pharmacy 2010). This is likely to underestimate the total value of waste medicines from care homes because the study methodology only captured medicines returned to a pharmacy from residential homes and did not account for the fact that nursing homes use specialist waste contractors for the return of their medicines. Similarly, year on year inflation costs and increases in the number of items prescribed per annum (grown on average by 5% per annum) along with a growing older adult population may also be expected to increase the volume of medicines waste generated. Nevertheless, the findings in this current study of returned medicines are broadly in line with the literature caveated by the fact that the analysis represents a small sample.

In addition to analysing returns books, seven care homes were visited and the medicines stock was counted. Only medicines that were prescribed on a named patient basis were included in the count i.e. no 'ward stock' was counted. To assess the 'over stock' of medicines, the current MAR charts were collected and the number of dosage units needed to meet the prescriber's intentions until the end of the current medicines cycle was calculated. Whilst the time to the end of the medicines cycle was not identical, all stock counts were in the second half of the medicines cycle. The number of dosage units required was then deducted from the total medicines count to determine the over stock. Whilst this approach also has its limitations (more waste could be generated between the count and the end of the medicines cycle), it better captures the totality of the wasted medicines because it accounts for any stock piling. The actual value of the waste counted was in good agreement with the returns book with £20.25 of medicines waste per resident (£3119.95 of waste for 154 residents). In each of the care homes studied, the researcher confirmed that medicines had been returned at the end of the previous medicines cycle and therefore the accumulated over stock is likely to be close to the monthly waste generated including some stockpiling from previous medicines cycle. Extrapolating to the number of beds in Wales this would generate an annual medicines waste bill of approximately £6.3M and across the UK a bill of £100M.

In line with other studies, the majority of medicines wasted were reasonably inexpensive with 82.5% of the waste having a unit cost that was less than £10. For example, in the seminal York study (York Health Economics Consort and The School of Pharmacy 2010), 72.96% of all waste medicines were in this cost banding and in a study in 425 nursing homes in the US approximately 83% of all unused medicines had a unit cost of $1 or more (Bazalo and Weiss 2011). Whilst the volume of waste generated tends towards the less expensive medicines, it is also important to determine if these medicines contribute extensively to the total value of medicines wasted or whether a small volume of expensive medicines overshadows those that are less expensive. The data showed that approximately

80% of the value of medicines wasted (£2472.22 of £3119.95) was accounted for by medicines that cost less than £50 per pack. In contrast, medicines with unit cost of greater than £100 accounted for just 11% of the value of waste medicines. Nevertheless, there are thought to be a number of prescribing practices that can lead to high value waste. The first is the supply of three months worth of medicines which would result in significant waste if there is any change to a resident's medicines regimen during the period and the prescribing of 'specials' where a specialist formulation manufacturer are individually made for a resident. Of course, there are instances where such specials are appropriate but in other cases it is not (e.g. 500ml of 500mg/5ml paracetamol special = £250 vs 1000ml of 250mg/5ml paracetamol standard = £7.32) (York Health Economics Consort and The School of Pharmacy 2010) .

The most commonly wasted medicines in this study were paracetamol (and associated compound preparations) and laxatives (particularly senna and lactulose) accounting for £826.37 (~ 27%) of the value of wasted medicines. In terms of paracetamol, this finding is consistent with a number of other studies that have sought to evaluate medicines waste in an individual's home (Wingard et al. 2005), returned to a community pharmacy (Ekedahl et al. 2003; Mackridge and Marriott 2007; James et al. 2009; Health and Social Care Information Centre 2013; York Health Economics Consort and The School of Pharmacy 2010) and in care homes (Ciullo and Shepherd 1977; York Health Economics Consort and The School of Pharmacy 2010; Herefordshire Clinical Commissioning Group 2015). The same is true of laxatives in the care home setting (York Health Economics Consort and The School of Pharmacy 2010). For example, paracetamol and paracetamol containing preparations accounted for 14.4% of all medicines waste in the York study and laxatives accounted for 15.5%. In total, these two groups accounted for ~ 30% of the medicines waste identified which is remarkably similar to the findings in this study (27%). Of note, many of the paracetamol containing compound preparations also include an opiate which in turn causes constipation which may be driving the prescribing of laxatives in some instances.

Ultimately, there is a culture of prescribing analgesics and laxatives for extended durations when they are only required to manage acute issues (York Health Economics Consort and The School of Pharmacy 2010).

One common feature of laxatives and paracetamol containing preparations is that they are both commonly prescribed on an 'as required' (PRN) basis. They are then sporadically required by the residents during a medicines cycle, but care home staff continue to automatically order them even when there is excess (Aaen 2017; Birchall 2016; Darracott and Johnstone 2012). Indeed, in an earlier study by Howard and Strong nearly 20% of the cost of waste medicines analysed over a four-year period in a 100-bed nursing was related to PRN medications. In this current study, in all but one home, regular medicines accounted for the majority of the value of the waste generated. Nevertheless, their contribution to the value of waste medicines exceeds their prescribing prevalence (see **Chapter 2**).

The reasons that medicines are wasted should be documented as part of the returns procedure. However, in the four returns books that were analysed, the documentation was sketchy at best and the reasons for returns were either listed as a patient refusal or were left blank. The researcher could not be certain of the veracity of the data and therefore it is not included here. Perhaps what is worth highlighting however is how medicines waste may be generated in the care home setting. Medicines are ordered by the care home towards the latter part of the medicines cycle and the medicines are then delivered to the care home by the supplying pharmacy prior to the start of the next medicines cycle. Waste occurs when the rate at which medicines are supplied exceeds the rate at which they are taken by residents. This generally has two causes: (i) there is a significant patient event during the medicines cycle such as a death, hospital admission, change in a medicine(s) or the patient's condition changes to the extent that they cannot or refuse to take their medicine(s); (ii) repeat medicines are ordered irrespective of patient need i.e. there is a breakdown in the relationship between

patient consumption and repeat ordering. The first cause is reasonably intractable and probably represents a source of waste that is not modifiable (unless the particular issue is caused by inappropriate prescribing, polypharmacy or the patient refuses their medicine(s) due to lack of knowledge or the exhibition of adverse drug effects). However, the second cause can be targeted to reduce medicines waste. It might be difficult to identify the underlying issues that result in the over ordering of medicines because responsibility should be shared between care home staff and other stakeholders who involved in the supply of medicines (Bristol Clinical Commissioning Group 2016). Whilst care home staff should manually review the medicines on the MAR charts for each resident and examine the stock before requesting the new monthly cycle, it would also be appropriate that members of the pharmacy team challenge the order where it is evident that medicines are reordered ad infinitum.

In the literature, a number of interventions have been suggested to reduce medicines waste in care homes (Roberts et al. 2001; Crotty 2007; Koria et al. 2018). One of the primary mechanisms is through the use of regular medicines reviews. NICE defines medication review as: "a structured, critical examination of a person's medicines with the objective of reaching an agreement with the person about treatment, optimising the impact of medicines, minimising the number of medication‐related problems and reducing waste" (NICE 2015). Such reviews (undertaken by a GP or pharmacist) would account for any changes in the resident's management plan and would serve to optimise a resident's pharmaceutical care (Duerden M 2013; Royal Pharmaceutical Society England 2016). Not only does this medicines optimisation improve health outcomes (Royal Pharmaceutical Society Wales 2016) and resident safety (Welsh Medicines Resource Centre 2016), as a by-product there is evidence that it leads to reduction in medicines waste (Crotty 2007).

Another area where interventions can be targeted is through the continuous and systematic analysis of why residents refuse their medications. As such, it is

beneficial to record not only that a resident has refused their medicine(s) but also the frequency with which they refuse and also the reasons for refusing. In the analysis of administration data presented in **Chapter 3**, although it was evident that residents refused medicines on occasion (denoted by an R on the MAR chart) there were no examples where the reasons for this refusal were documented, at least not on the MAR chart. This represents a missed opportunity to explore a resident's beliefs about their medicines and to subsequently develop tailored education to support better adherence and maximise therapeutic outcomes (Goodyer et al. 1995; Horne and Weinman 1999; Khurana 2003; Hugtenburg et al. 2006).

The findings in this chapter have a number of implications for practice. Much like the data presented in **Chapter 3**, it was evident that practice varied across homes in terms of the extent of waste (some homes had only very small quantities of medicines waste whilst in other homes it was significant) and in the robustness of the processes in place for managing waste. The CQC and analogous organisation have set out clear requirements for the medicines management process that includes standards related to the documentary trail of medicines in the home, from receipt on arrival, administration and return or disposal. However, there was evidence that such practices are not universally adopted or embedded. Developing care home staff to better manage waste would be a priority area for attention. Similarly, better interprofessional co-operation (between the prescriber, pharmacist and care home) on prescribing and repeat dispensing would help to bring medicines waste down. For example, if the pharmacist (or member of the pharmacy team) checked with the care home whether each medicine was required, any unnecessary supply could be avoided. Certainly, prescribing durations of greater than 28 days should be avoided and indeed it may be prudent (although resource intensive) to consider prescribing durations that are less than 28 days.

In summary, the studies conducted in this chapter have demonstrated that medicines waste in care homes remains a significant issue. Some of this waste in unavoidable for example when a resident's medicines change due to a change in their condition or when there is a resident death. However, a significant volume of waste, particularly associated with paracetamol, laxatives and other 'when required' medicines could be at least partly avoidable and should be prioritised in any interventions seeking to reduce medicines waste.

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Chapter 5 General discussion

There is a global challenge in meeting the health needs of a growing older adult population. Estimates suggest that the population of older adults (aged 65 and over) in developed countries will rise from 17.8% of the total population to 24.5% between now and the year 2050. In real terms, this represents an increase of 1 billion people up from 2.4 billion to 3.4 billion (Stegemann et al. 2010). In the UK, by 2040 the population of adults over 65 years of age is expected to have risen from 11.8M to 16M. Consistent with this shift in the population is an expected rise in the number of older adults with multiple-chronic comorbidities that impact on both physical and cognitive function. Of note, at 75 years of age the number of people who are classed as disabled outnumber those that are in good health (Brown 2015). The NHS continues to face considerable financial pressure and this pressure is not predicted to ease anytime in the near future (Robertson et al. 2017). Indeed, the spend on the NHS is greater than it has ever been. In 2017 the Institute for Fiscal Studies reported that £140Bn was spent on health in the UK (30p of every pound spent) which is more than 10 times the investment made 60 years ago (Institute for Fiscal Studies 2018). Even accounting for inflation rises, this represents an incredible increase in spending. Nevertheless, the UK spends proportionately less on health than other EU countries (Appleby and Gershlick 2017). Despite record investment, key metrics continue to underperform. For example, the target of every patient receiving a consultation in A&E within four-hours continues to fall year on year (Dorning and Blunt 2015). An ageing population contributes to these problems. Life expectancy has grown significantly, for example the life expectancy of an individual born today is 13 years longer than when the NHS was founded (Office for National Statistics 2015). For the individual, this rise is fantastic however this rise in life expectancy has consequences. As individuals live longer they are more likely to have chronic conditions such as cardiovascular disease, respiratory disease, cognitive impairments (particularly dementia) and cancer (Nihtilä et al. 2008; Goodwin et al. 2010). Many of these diseases and conditions are not amenable to curative interventions and they require continued health and social

support which requires ongoing resource allocation. Diseases that were once guaranteed killers can now be ameliorated if not cured. For example, 50% of people who have a cancer diagnosis will live for at least a decade (Office for National Statistics 2016). Moreover, managing the health needs of older adults is significantly more expensive than younger adults. A 65-year old is estimated to cost the NHS 2.5 times more than the average 30-year old and an 85-year old five times more (Institute for Fiscal Studies 2018). Of note, despite representing just one-third of the population, individuals with long-term chronic conditions occupy two-thirds of the ~ 150,000 hospital beds in the UK (Institute for Fiscal Studies 2018).

One of the major contributors to the rising number of patients being looked after in secondary care is the shrinking spend on council-lead social care that has squeezed domiciliary care. In the face of a rising population of older adults, the number receiving state social care has fallen by 25% in the last four years (Cromarty 2018). Of note the healthcare budget for 2017/18 was over five times that of the social care budget (£110bn vs 20.8bn)(THE UK'S INDEPENDENT FACTCHECKING CHARITY 2018). This shifts people towards the secondary care environment when policy is to keep people in primary care for as long as possible (Association of Directors of Adult Social Services 2018). As long ago as 2010, unnecessary overnight hospital stays were said to cost the NHS £330M per year (Nuffieldtrust 2010). This is a particularly curious position to be in because many of these individual do not require a health intervention but rather they require social support with their daily living needs.

Care homes, either private or state funded, are in a prime position to relieve some of the burden from the NHS as they can support both the social and health needs of the older adult population who have a requirement for such care. Many people are surprised to learn that there are estimated to be three times as many care home beds in the UK as there are hospital beds. Indeed, many people think the care home population is rather small however there are approximately 420K

individuals residing in care homes in the UK which represents about 0.64% of the UK population as a whole. Care homes are divided into nursing and residential homes. Historically, this division has demarcated by the level of care residents required. Nursing homes which provide round the clock nursing care would typically have supported residents with challenging health and social needs whilst residential homes would support those individuals who needed help in their daily activities rather than medical or nursing interventions. However, in recent years the growth in the older adult population and particularly the rise in the number of individuals with chronic conditions has exceeded the availability of nursing home beds and the boundaries between residential and nursing homes have blurred. It is not uncommon to see residents of residential homes with conditions and health needs that would be better served by a nursing home (Dudman et al. 2018). Indeed, during visits to residential homes, the researcher observed residents with significant health needs.

On average, a residential home costs £600 per week and a nursing home £800 per week (Age UK 2017). Following a care needs assessment, individuals may be entitled to some council support to meet these costs but social care funding as has already been pointed out is significantly constrained. In order to account for those with significant medical needs, the NHS may make some contribution to the cost of care (NICE 2018). Despite these costs, in common with the NHS, the care home sector faces significant financial challenges. Indeed, between October 2010 and December 2015 some 2,444 care homes closed in the UK (Care Quality Commission 2017). This included the collapse of Southern Cross, a major care home group that had 750 homes. Accountancy firm Moore Stephens have estimated that 12% of all care homes have a 30% or greater risk of bankruptcy within the next three years (Stephens 2016). This is as a consequence of a number of factors including a 31% (£4.1bn) reduction in local authority / council funding, a cap on an individual's contribution to their care, the introduction of the national living wage and the introduction of automatic state pension

enrolment which has pushed employment costs up (Roberts and Barnard 2017a).

Not only have the financial pressures increased, but recruitment of staff to the care home sector remains challenging. There is a shortage of UK nurses with for example 42,000 vacant nurse posts in the NHS alone (NHS 2017). Studies have suggested that nurses prefer to work in primary or secondary care rather than the care home sector (Royal College of Nursing 2012; Spilsbury et al. 2015). This is partly as a consequence of improved access to resources and the multi-disciplinary environment in such settings that is deficient in the care home sector (Dilles et al. 2011). In addition, there is a shortage of experienced care home managers with estimates suggesting that some care homes operate for years without a registered manager (Roberts and Barnard 2017b). This trend is expected to continue given the fact that more than 50% of care home managers are over 50 years of age and likely to retire in the next 15 or so years. These issues are compounded by the high turnover of staff (Agboji 2012).

A further pressure on the sector is increased regulatory scrutiny as a consequence of a number of significant incidents in the care home setting (Phelan 2015; Manthorpe and Martineau 2016). This scrutiny is understandable as care home residents often represent the most vulnerable individuals in society. However, it comes at a cost. Regulators such as the Care Inspectorate Wales, benchmark care homes against standards and provide a rating for the care home. Where this rating is below the threshold standard the inspectorate has a range of powers up to and including the ability to revoke the home's registration. Even where it chooses not to do so, a sub-standard rating is likely to deter potential residents. In addition, the cost of monitoring compliance within the home has increased as a consequence of increased scrutiny.

Together, these pressures can present the perfect storm for sub-optimal care. One of the major health interventions employed in care homes is the prescribing and administration of medicines. Commonly, in residential homes and nearly

exclusively in nursing homes, residents do not have the capability of managing their own medicines and therefore care home staff are involved in the management and administration of their medicines. Evidence suggests that care home residents are particularly susceptible to medicines related harm (Barber et al. 2009a). This can be exacerbated by poor prescribing decisions (Ruggiero et al. 2010) and by inappropriate administration practices in the home (Alldred et al. 2009; Dilles et al. 2011) although the field remains underexplored. As a consequence, this thesis explored medicines management in a sample of care homes in the South Wales region focussing on prescribing, administration and medicines waste.

In **Chapter 2**, the prescribing landscape for 260 residents in ten care homes was explored using a retrospective analysis of anonymised MAR charts that covered a 28 day medicines cycle. This involved extracting a range of data associated with the medicines prescribed including name, strength, formulation, dose, quantity etc. for each resident. This data was then used to identify the prevalence of polypharmacy (more than five medicines prescribed) and excessive polypharmacy (more than 10 medicines prescribed), the prevalence of prescribing of potentially inappropriate medicines (using Beers Criteria) and the anticholinergic burden faced by residents.

The residents included in the study had an average age of 83, firmly placing them in the older adult population. The levels of polypharmacy were significant within the study population with 84% of all residents receiving five or more medicines and 33% receiving 10 or more medicines. Polypharmacy has been shown in a number of studies to be a positive contributor to adverse drug reactions and negative health outcomes (Nguyen et al. 2006; Jyrkkä et al. 2011; Kojima et al. 2012). The reasons for polypharmacy are multifactorial, however the concept of prescribing cascades plays a significant role where an adverse reaction to drug A is misdiagnosed as a new symptom such that drug B is prescribed rather than rationalising drug A (Lavan and Gallagher 2016; Cahir et al. 2010). This is made

more complicated in the care home setting where there are multiple sources of health interventions involving a variety of prescribers who often do not consult the resident directly but rather receive information related to the resident second-hand via the nurse or carer (Bergman et al. 2007).

In common with other studies, a significant number of residents were prescribed proton pump inhibitors (McDonald et al. 2015; Rane et al. 2017) and psychotropic medicines (Ruggiero et al. 2010; Shah et al. 2012; Beers et al. 1988; B. Hagen et al. 2005; Vieira De Lima et al. 2013). The use of proton pump inhibitors and psychotropic agents has come under increased scrutiny in recent years and feature as National Prescribing Indicators where the aim is to reduce their prescribing prevalence. Long term use of proton pump inhibitors in older adults is associated with fractures and clostridium difficile infection (McDonald et al. 2015). In a population that is susceptible to falls (Ding et al. 2014), the increased risk of fractures is particularly problematic. Psychotropic medicines use in older adults is similarly problematic. Many care home residents have some degree of cognitive impairment and the inappropriate use of antipsychotics, hypnotics and anxiolytics can exacerbate such impairment (Foy et al. 1995; Nazareth, Burkhardt 2008). Concerns have been raised over the inappropriate use of psychotropics in care homes and particularly the use of antipsychotics in residents with dementia where they are used off label to sedate residents where there are behavioural issues (Harding and Peel 2013). There have been calls for regulatory interventions in order to safeguard such individuals.

Similarly, the prevalence of paracetamol and laxative prescribing was significant. These medicines were generally prescribed on a use 'when required' basis. Whilst the risk of harm from such agents is much lower than for PPIs and psychotropic agents, there is a tendency to prescribe such medicines chronically rather than to treat acute conditions. Of note, in line with other studies (Darracott and Johnstone 2012; York Health Economics Consort and The School of Pharmacy 2010; Herefordshire Clinical Commissioning Group 2015) in

Chapter 4, paracetamol and laxatives represented the highest quantity and value of medicines wasted.

There is evidence in the literature that not only are older adults susceptible to polypharmacy but that there is a high prevalence of inappropriate prescribing (King and Roberts 2007; Niwata et al. 2006; Varallo et al. 2012; Hosia-Randell et al. 2008; Barnett et al. 2011; Hwang et al. 2015; O'Sullivan et al. 2013; Vieira de Lima et al. 2013; Verrue et al. 2012; Ryan et al. 2013). A number of criteria have been developed that seek to categorise such inappropriate prescribing. Such criteria are either explicit (a list of medicines to be avoided or used with caution) or implicit (relying on the judgement of clinicians). Beers criteria, an explicit criteria, were used in this study. Published by the American Geriatrics Society in 2015, the criteria provides a list of drug to be avoided and those that should be used with caution independent of disease or condition. Overall, 87% of residents were prescribed a medicine that should be avoided or used with caution. Of note, 60% of residents received at least one medicine that should be avoided. Much like polypharmacy this is likely a consequence of infrequent review and optimisation of medicines in the care home setting (Spinewine et al. 2007; De Smet et al. 2007).

More recently, there has been a growing concern on the use of drugs with anticholinergic properties in older adults (Chatterjee et al. 2017; Pfistermeister et al. 2017). Increased anticholinergic burden is associated with dementia, cognitive impairment, falls and increased risk of mortality (Fox et al. 2011) (Marcum et al. 2015; Naja et al. 2016; Chatterjee et al. 2017). Using the Anticholinergic Effect on Cognition scoring system, the anticholinergic burden was calculated for each resident in the study population. Some 11.9% (31 residents) of all residents accrued an anticholinergic score of three or four which is thought to be clinically relevant and 4.2% (11 residents) a score of five or more which is likely to place the resident at a risk of severe cognitive impairment (Pfistermeister et al. 2017).

Taken together, it is clear that prescribing for older adults in care homes could be significantly improved. The use of regular medication reviews (Furniss et al. 2000; Koria et al. 2018) and deprescribing algorithms (Liu 2014) would be beneficial in mitigating any medicines harm that may result from inappropriate prescribing in care home residents.

In **Chapter 3**, the medicines management practices in the care home itself were explored again using a retrospective analysis of anonymised MAR charts. The aim was to identify errors associated with medicines management in care homes. This can be achieved through a number of mechanisms including direct observation, incident reporting systems or documentary analysis (charts, clinical notes etc). The analysis of documentary sources has the advantage that analysis can be done at scale (at least in comparison to observational approaches) but is reliant on the accuracy of the documentation. The researcher was unable to find any protocols within the literature to characterise errors on MAR charts and therefore an in-house protocol was developed. The starting place for this protocol was NICE guidelines (NICE 2014). Using a 'test' care home and historic MAR charts, a protocol was developed and refined that captured errors in five major categories: regulatory errors, administration errors, MAR charts errors, stock errors and miscellaneous errors. An analysis of ten care homes was then undertaken and the error rate was calculated. In terms of administration errors (i.e. those that are directly resident facing) each resident was on average likely to be exposed to six errors per week. There is evidence in the literature that administration errors arise as a consequence of a range of factors including distractions (Barber et al. 2009b) and interruptions (Thomson et al. 2009), workload (Biron 2009), lack of knowledge of medications (Dilles et al. 2011), lack of training (Zimmerman et al. 2011), and incomplete medication charts (Fry and Dacey 2007).

The majority of the administration errors were dose omissions. This finding is in common with other studies (Redley and Botti 2013; Pierson et al. 2007; Greene

et al. 2010) including those that use an observational approach (Alldred et al. 2009; Verrue et al. 2010).

Of concern, was that a number of MAR charts across the care homes contained insufficient information to make an administration. There were examples of the dose, formulation and strength being absent which requires a clinical judgement by staff members in the home who may not have the knowledge or experience to manage such situations and indeed from a regulatory perspective it may not be appropriate for the individual to make such a judgement. Similarly, there were examples of medicines being duplicated on the MAR chart which risks a patient receiving an overdose of their medicine(s). One of the contributory factors leading to this is a lack of interprofessional co-operation (Dilles et al. 2011; Baylis and Perks-Baker 2017). These types of issues are everybody's responsibility i.e. the prescriber's, the pharmacist's and the staff in the care home. However, the literature suggests that the co-operation is poor (Alldred et al. 2009; Welsh Medicines Resource Centre 2016).

In this Chapter, the number of administration and MAR chart errors associated with potentially inappropriate medicines was also examined. The prevalence of administration errors with psychotropic agents was particularly high and is worthy of further investigation.

Whilst it was beyond the scope of this thesis, it would be useful to analyse the likely clinical consequences of such administration and MAR chart errors. There are a number of methodologies that can be employed to predict clinical consequences including independent physicians' review or expert panel made up of a range of healthcare practitioners including physicians and pharmacists (Dornan et al. 2009). All of these methods generally classify the consequences in terms of a level of harm (Gurwitz et al. 2000; Lisby et al. 2005; Bohand et al. 2009; Young et al. 2009) and the predicted outcomes (e.g. unintended hospital admission. A&E visit, death etc) (Davies et al. 2009; Meier et al. 2015; da Silva and Krishnamurthy 2016).

Finally, errors associated with stock were examined. Whilst such errors may not be immediately resident facing, where stock control is poor this can result in the home either running out of medicines (potentially delaying an administration to a resident) or medicines waste. In all care homes studied, the management of stock appeared to be challenging. There were examples where stock was not receipted, quantities were not recorded and there were discrepancies between the quantity recorded and that administered. Given the prevalence of stock errors identified on MAR charts, an exploration of the scale of waste medicines in care homes was explored in **Chapter 4**.

It is widely recognised that medicines waste represents a significant cost to the NHS with estimates suggesting the total value of medicines wasted in the UK is in the order of £300M per annum of which £50 million is estimated to be associated with medicines returned from care homes (York Health Economics Consort and The School of Pharmacy 2010). In this current study, returns books were analysed and physical counts were made of the stocks in the care home to identify the scale of the waste. The waste recorded in the returns books resulted in an average monthly waste of £18.54 per resident whilst overstock was £20.25. Extrapolated to the number of care home beds in the UK this results in a waste bill of approximately £90M per annum. This is broadly in line with other studies that have sought to estimate the scale of waste in care homes (Caswell and Cleverley 1983; Brown and Kirk 1984; Farmer, R G. et al. 1985). Given a residential care home stay costs ~£600 per week, this equates to 150,000 resident weeks lost to waste medicines. Whilst a proportion of this waste is unavoidable, for example when a patient dies or when there is an appropriate change in a patient's medication regimen as a result of a change in their condition or due to an adverse drug reaction, there is evidence that a significant volume of waste could be avoided (West 2015). In care homes, this is normally associated with poor prescribing, ordering and dispensing processes that are insensitive to the actual use of medicines by patients or residents. In other words, repeat dispensing processes are setup for continuous 28-day supply even

when this is unnecessary because a patient or resident has accumulated medicines due to a break in their last medicines cycle (Birchall 2016).

Of note, a significant volume of the waste both in terms of the dosage units wasted and the value of the waste was associated with laxatives and paracetamol containing products (accounting for 27% of all the waste generated). Again, extrapolating to the UK care home population, this represents a potential waste of approximately £4M per annum. As was seen in **Chapter 2**, the prescribing of such products which should be on an acute basis is generally prescribed continuously to residents even when they don't need it. There is a strong argument to only provide paracetamol and laxatives as 'ward stock' rather than on a named patient basis to reduce the waste associated with such medicines.

One theory that continues to be promoted in some circles is that medicines waste is as a consequence of a low volume of high cost waste. In this study, waste was stratified by the unit pack cost. This revealed, in common with other studies, that medicines waste in care home is associated with high volumes of low unit cost waste. For example, over 45% of the total value of waste identified in this study cost less than £10 per pack with just 11% associated with drugs that cost more than £100 per pack. It was clear however that expensive medicines can skew the results, for example the waste associated with Rifamixin which has a pack cost of (£259.23) contributed 5.7% of the total waste and 24% of the waste in the home in which its as generated.

Whilst the process of incremental gains (every little helps) is a valuable approach, if the sector is to tackle the problem of waste medicines in care homes, a rethink of the system is needed. The system for reordering, prescribing and then dispensing remain largely paper-based and unlike others industries, where stock ordering and monitoring would be automated and based on existing stock, in care homes significant human intervention is needed. Medicines would need to be counted in the second-half of the medicines cycle by an individual in

the home prior to the cut-off for ordering the next monthly cycle. This is resource intensive and given the staff and workload pressures (Kavanagh 2017)in care homes this approach is unrealistic. The digital enablement of care homes, and more broadly the healthcare sector (Maguire et al. 2018), is on the horizon and a number eMAR systems (Redley and Botti 2013) are in development that include automated stock ordering based on current holdings of medicines. However, GP prescribing systems are generally not connected to such systems and are designed to generate prescriptions in multiples of 28 days. Any deviation from such an approach generally needs manual intervention. Ultimately, addressing avoidable medicines waste in care homes is a priority and would free up resources both financial and human to better support resident care.

One of the primary issues related to medicines in care homes is the lack of recognition that it is a problem. Indeed, in a recent study to identify the research priorities in care home, not one of the 15 research priorities identified featured medicines (Shepherd et al. 2017). However, the priorities did include for example “What is the public and media perception of care homes compared with other care settings, and what is the impact on care home staff attitudes?”. This is by no means a criticism, these priorities were generated within the sector itself and these are clearly important to the participant of the study but it perhaps demonstrates how medicines management is not seen as an issue in a care home. This is probably a consequence of the system in that negative health outcomes arising from medicines errors are rarely recorded as such and even when they are, for example when an unintended hospital admission occurs due to a medicines error, reporting lines back to the home from secondary care are poor (Smith 2004; Desai et al. 2011) making it difficult to learn from such events. A confounding factor is that it is difficult for regulators to monitor medicines management performance in homes. Despite regulatory standards for medicines management (Welsh Assembly Government 2004; Royal Pharmaceutical Soceity of Great Britain 2007), the MAR chart remains one of the few sources of evidence in the home that provides some indication of the

standard of medicines management. The researcher can personally evidence how challenging and resource intensive it is to analyse MAR charts and realistically it needs to be carried out by a healthcare professional with a background in medicines use (pharmacist, physician etc). If regulators are to better understand the issues of medicines management in care homes it is necessary to work with care homes to develop a series of key performance indicators and associated metrics to better monitor compliance with standards. This is in the interest of the residents, the care homes and the regulators.

Limitations:

The studies presented in this thesis had some limitations. Most notably, the care home setting does not allow for ready access to patient data particularly the resident's diagnoses. This data would have been particularly useful when assessing potentially inappropriate prescribing as it would have allowed for the use of a wider range of tools that require diagnostic information. As a consequence the study employed an explicit criteria (Beers) to mitigate against this. Even in using Beers it would have helpful to have diagnostic information as an assessment could have been made as to whether the medicine(s) was appropriate given the condition. Lack of diagnostic data also made the measurement of potentially appropriate omissions impractical. For example, where a resident's vital signs, clinical condition or biochemical markers indicate that an administration or a medicine should not be made and therefore an omission is entirely appropriate, in this study we could not assess this.

As discussed in chapter 3, this study employed a retrospective review of MAR charts. The researcher made the assumption that the records of administrations were accurate and reflective of resident administrations. However, there may be a degree of error in the records such that they are not entirely reflective of the administrations that took place. Nevertheless, the scale of the errors identified were in line with observational studies. In addition, BNF coding was used in this study which did not allow for sub-coding of medicines as it groups

medications into a single human system however, it was appropriate to use in this study as it is UK based. However, the use of the global coding system 'anatomical-technical-chemical' coding (ATC) which was developed by the WHO would have allowed for further sub-categorisation of medicines within each system.

Future work

Based on the findings in this thesis a number of next steps were identified. These focus on an estimation of the clinical consequences of potentially inappropriate prescribing and medication errors. This could be undertaken using a framework for error rating such as the Equip framework (Dornan et al. 2009) or Fleet model (a model for pharmaceutical care and error reduction in US). This is crucial to understand the impact of medication errors on clinical health outcomes in residents. An important consideration here would be assessing residents against a frailty index to provide a more holistic understanding of their health and wellbeing and how medicines harm might impact on this.

Conclusion

In conclusion, the results described in this thesis have explored issues surrounding medicines prescribing, administration and waste in the care home setting. Although not explicitly tested, the issues identified have the potential to result in resident harm and will likely further constrain health and social care resources. Residents of care homes represent a particularly vulnerable population and efforts should be renewed to enhance or embed a multidisciplinary approach to the health and social care of such residents. Currently, the system does not enable practitioners to effectively collaborate on the care of residents and as a consequence, the pharmaceutical care of the residents of care homes is not optimal.

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Appendices

Appendix 1 – Ethical Approval

8/9/14 v12

Cardiff School of Pharmacy and Pharmaceutical Sciences, Research Ethics Approval

This form has been signed by the School Research Ethics Officer as evidence that approval has been granted by the Cardiff School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee for the following study:

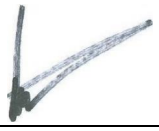
Project title:	1415-04 Review of Medicines Administration (MAR) charts from care homes

This is a/an:	Undergraduate project	X
	ERASMUS project	
	Postgraduate project	
	Staff project	

Name of researcher: (PG/Staff projects only)	
Name of supervisor(s):	Mat Smith, Delyth James, Rebecca Price-Davies, Efi Mantzourani & Mark Gumbleton

STATEMENT OF ETHICS APPROVAL

This project has been considered and has been approved by the Cardiff School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee



Signed _____ Name R Price-Davies Date 19/9/14
(Chair, School Research Ethics Committee)

Appendix 2 – Guidance used in developing MAR chart analysis rulebook

Sub-categories of the guidance used to develop the rule book (adapted from '*Full guideline Managing medicines in care homes'* (NICE 2014)

Sub-categories of the guidance	Recommendations
1.4 Ensuring that records are accurate and up to date	Health and social care practitioners should ensure that records about medicines are accurate and up-to-date by following the process set out in the care home medicines policy
1.7 Accurately listing a resident's medicines (medicines reconciliation)	The care home manager or the person responsible for a resident's transfer into a care home should coordinate the accurate listing of all the resident's medicines (medicines reconciliation) as part of a full needs assessment and care plan. The care home manager should consider the resources needed to ensure that medicines reconciliation occurs in a timely manner
1.10 Ordering medicines	Care home providers should ensure that care home staff (registered nurses and social care practitioners working in care homes) have protected time to order medicines and check medicines delivered to the home.
1.12 Receiving, storing and disposing of medicines	Care home providers should assess each resident's needs for storing their medicines and should provide storage that meets the resident's needs, choices, risk assessment and type of medicines system they are using.
1.14 Care home staff administering medicines to residents Recommendation	**1.14.1** Care home providers should consider: (i) the 6 R's of administration: – right resident – right medicine – right route – right dose – right time – resident's right to refuse; (ii) making a record of the administration as soon as possible; (iii) how to record and report a resident's refusal to take a medicine(s). **1.14.7** Paper-based or electronic medicines administration records should: (i) be legible (ii) be signed by the care home staff (iii) be clear and accurate (iv) be factual (v) have the correct date and time (vi) be completed as soon as possible after administration (vii) avoid jargon and abbreviations (viii) be easily understood by the resident, their family member or carer.

1.14.8 Care home providers should ensure that medicines administration records (paper-based or electronic) include:

(i) the full name, date of birth and weight (for example, frail older residents) of the resident

(ii) details of any medicines the resident is taking, including the name of the medicine and its strength, form, dose, how often it is given and where it is given (route of administration); (iii) known allergies and reactions to medicines or their ingredients, and the type of reaction experienced; and (iv) any special instructions about how the medicine should be taken (such as before, with or after food).

1.14.9 Care home providers should ensure that a new, hand-written medicines administration record should be checked for accuracy and signed by a second trained and skilled member of staff before it is first used.

1.14.11 Care home staff must record medicines administration, including the date and time, on the relevant medicines administration record, as soon as possible and ensure that they: (i) make the record only when the resident has taken their prescribed medicine (ii) complete the administration before moving on to the next resident (iii) record when and why medicines have not been given (iv) correct written mistakes with a single line through the mistake followed by the correction and a signature, date and time (correction fluid should not be used).

1.14.14 Care home staff responsible for administering medicines should add a cross- reference (for example, 'see warfarin administration record') to the resident's medicines administration record when a medicine has a separate administration record.

1.14.16 Care home staff should make appropriate records of controlled drugs that have been administered to residents. The care home staff responsible for administering the controlled drug and a trained witness should sign the controlled drugs register. The staff member administering the controlled drug should also sign the medicines administration record.

Appendix 4 – MAR chart error collection form

Care Home	Patient Number	Total Number of Medications	Chart	Number of Medications On Chart	Medication	CD	BNF Section	BNF Category	Error Present	Day	Round	PRN Protocol	Error Type	Error Defined	Error Description

Appendix 5– Protocol for counting total number of administrations

The developed protocol for counting total number of administrations.

First, the counting includes regular medication, where a distinct instruction for each medicine was written. This was considered as a theoretical administration from which, any missing boxes were reported as an omission and it didn't count. Note (theoretical administration means if the medicine should be given once daily as a regular treatment, the total number of administration should be 28 administration for 28 days' cycle regardless the fact that there were empty boxes since each empty box was considered omission and counted as an error)

Secondly, all the medicines with "as directed" note, the counting was done as follows:

1- Medicines with full instruction were treated as the regular ones.

2- Other medications without any instruction especially; emollient, dressing, nutritional supplement, they were counted according to the actual administration with the exception of any box with codes i.e. (offered not required, refused etc.), because this indicates that these medications were not given. The codes may be different according to the care homes.

There was an exemption to some medications according to specific drug or issue:

1. For analgesics, this class of drugs represents the majority of medicines administered in care homes particularly, Paracetamol and Paracetamol containing product. If the product was written as a regular treatment, the counting was according to the actual administration since the staff didn't follow the instruction and offered it according to the resident need and most boxes were filled with codes referred to (offered not required or refusal) therefore all these boxes were excluded.
2. Antibiotics, with this class of drugs, the administration was for short term course and in some cases, they didn't specify the time to complete the course, therefore the actual administration were counted while the ones with full instruction, it was counted as theoretical administration.
3. For Warfarin, it was counted according to the actual administration because; there was a need to measure the INR before the administration.

4. For double entry of the same medicine, it counted just one entry.
5. For medication with no entry, the counting was similar to the theoretical administration depending on the instructions.
6. For medicines with unclear instructions about the frequency of administration like: “take up to three times a day”, it was counted according to the actual administration.
7. For hand amendment to the times of administration, the counting was according to the frequency of administration presented in the boxes to know if they followed the amendment or not.

Meanwhile, there were some exceptions:

1- For cases where written (maximum twice a day) and there was no administration for example; (Movelat gel), it counted for the minimum (once).

2- Any treatment discontinued during the cycle, the counting was for the actual administration not theoretical.

3- Any regular treatment with codes of refusal, it was excluded from the whole administration).

Appendix 6 - Conference abstracts

A Retrospective Analysis of Medicines Administration Records to Quantify Medicines Related Issues.

Al-Hamadani F, Mantzourani E, Smith M, James D

Int. J. Pharm. Practice 24 (S3), pp.22-104 DOI: 10.1111/ijpp.12289

Focal Points:

- The majority of care homes use paper-based 'Medicines Administration Record' charts to document administrations.
- In this study we collected MAR charts from 11 care homes and retrospectively analysed the charts for errors in medicines administration to care home residents against the prescriber's intentions.
- On average, 8% (S.D± 3.6) of all administrations were associated with an administration error.

Introduction: In the seminal 'CHUMS' study[1] researchers directly observed medicines administration rounds in care homes and highlighted the significant potential for patient harm in the medicines administration process. In the main, care homes use paper-based 'Medicines Administration Record' (MAR) charts to document medicines administrations against the prescriber's intentions. The aim of this study was to analyse MAR charts to determine the types and frequencies of errors that occur in the administration and management of medicines in a cohort of care homes.

Methods: MAR charts for each resident in 11 care homes in South Wales were retrieved from each home for a 28-day medicines cycle in September 2014. The research team (11 members) analysed all MAR charts using an 'in house' protocol for errors that were categorised using NICE guidance [2] for medicines management. The error categories were: (i) CQC regulatory compliance; (ii) incorrect medicines administration against the prescriber's intentions; (iii) issues associated with risk to the patient such as medicines prescribed as 'when required' or 'as directed'; (iv) incorrect stock recording and (v) miscellaneous issues that could not be categorised through MAR charts alone. Data were analysed using descriptive statistics. Ethical approval was obtained from the School's ethics committee.

Results: The analysis period accounted for medicines administration to a total of 297 patients and the frequency of errors identified and the error rate per resident is shown in Table 1. A total of 7739 errors were identified directly relating to the administration of medicines to patients i.e. no record of administration, a deviation from the prescribed dose, a cancelling of the administration without explanation. Care home 8 had the lowest number of administration errors per resident per week 1 error and the highest number of errors was 13 administration-related errors per resident per week in care home 10.

Discussion: This study has demonstrated that medicines administration in care homes remains a significant challenge and the recording of administrations on the MAR chart can best be described as inconsistent. Such inconsistency has the potential to lead to significant patient harm. Whilst MAR charts are the de facto record of medicines administration, a limitation of this study is that the MAR charts may not accurately reflect the administration process in the home. Nevertheless, pharmacists as experts in medicines, are ideally placed to play a significant role in the education and training of care homes staff to ensure that medicines are administered safely and effectively.

References:

1. Barber ND, Alldred DP, Raynor DK, Dickinson R et al. Care homes' use of medicines study: prevalence, causes and potential harm of medication errors in care homes for older people. Qual Saf Health Care 2009; 18: 341–56.

2. National Institute for Health and Care Excellence (2014) Managing medicines in care homes. NICE guideline (SC1). Available at [https://www.nice.org. uk/guidance/sc1]

Data in Care Home Settings – Can We Get it Right?

Mantzourani E, Smith M, Al-Hamadani F, Safaei H, James D 2016 Capturing Medicines Waste Int. J. Pharm. Practice 24 (S3), pp.22-104 DOI: 10.1111/ijpp.12289

Focal Points:

- This study addresses the challenges of quantifying medicines waste in care homes in South Wales.
- Analysis of paper-based returns log and/or visits to count all overstocked medicines was completed across ten different care homes.
- Results indicate that medicines returned to the pharmacy may under-estimate the amount of waste and that there is a tendency to overstock medicines which may contribute to patient harm and avoidable waste.

Introduction: It is estimated that £50 million worth of medicines are wasted in Wales each year[1]. One study found that wasted medicines in care homes (CHs) accounts for 16% of the total medicines wastage and that 50% of wasted medicines can be avoided[2]. The cause of medicines waste in CHs is multifactorial and accurately quantifying such waste is methodologically challenging. It is recognised that using data from returns logs alone provides an incomplete picture. The aim of this study was to quantify medicines waste utilising two different methodologies namely (i) analysis of waste medicines 'return logs' and (ii) direct counts of overstocked medicines in the CH.

Methods: Twelve CHs in one Health Board were invited to provide baseline waste data from their 'returns log' and were offered a visit from a researcher to calculate the amount of overstocked medication over a one month period. The patients' paper Medication Administration Record (MAR) chart were used to calculate the stock requirements for each medicine up to the start of the next medication cycle. A physical count of stock was conducted by the researcher to determine the quantity of overstock. A standardised protocol was developed for calculating overstock for all formulations including solid dosage froms, those in liquid form, dermatological preparations and nebulizers. An average value of returned and overstocked medicines per resident was then calculated; unit costs of medicines were determined using the British National Formulary 68[3]. Items not specifically named for an individual resident and medicines where the returns log was not complete were excluded. Approval was granted by a University Research Ethics Committee.

Results: Ten CHs participated in the study. Data for both returns log and overstock were obtained for four; return logs only for three and overstock only for another three CHs. Values of medicines waste from returns log in the seven CHs ranged from £41.26 to £1299.32. The average value of return per resident in each care home ranged from £1.42 to £36.09 with an overall average of medicines returned estimated at £19.01 per resident per month. The value of total overstock calculated was over £3000 (range from £4.74-£774.05 across seven CHs), equating to an average overstock of £20.25 per resident per month.

Discussion: This study quantified medicines waste across 10 different care homes utilising two different methodologies and is the first time that real-time data on medicines overstock in care homes has been reported. A number of limitations may be associated with the interpretation of these data. For example, the two methods were conducted at different time points, and therefore determining an average value per resident per month enabled us to normalise the data and compare the two different measures of waste. This study confirms that a significant number of medicines are overstocked and this surplus is not always returned to the pharmacy at the end of the subsequent month. This may contribute towards avoidable medicines waste and risks developing a culture of keeping medicines which may then exceed their expiry date or inadvertently be administered to other residents. Further studies are required to explore how CH staff manage the supply and returns of medicines.

References:

1. Welsh Government. Reducing Medicines Waste: A team approach across health and social care. 2010. Available at: http://wales.gov.uk/docs/phhs/publications/100921pharmwsttoolfinalen.pdf (accessed 11th March 2016)

2. Evaluation of the Scale, Causes and Costs of Waste Medicines, Final Report, York Health Economics Consortium and the School of Pharmacy, University of London, 2009
3. British National Formulary edition 68

FIP conference Glasgow 2018

High risk medications in care homes: a retrospective analysis of administration errors

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Background: Residents of care homes are particularly at risk of medicines related harm due to complex pathologies and polypharmacy. The American Geriatric Society produces Beers Criteria, a list of medications that are potentially inappropriate in older adults as they pose an unwanted risk of medicines related harm.
Purpose: The purpose of this study was to identify the administration errors associated with Beers Criteria medications in Care Homes
Methods: A retrospective analysis of Medicines Administration Records (MAR charts) was carried out in ten care homes over a 28-day medicines cycle to identify administration errors associated with Beers Criteria medications. Administration errors were defined as (i) omitted does; (ii) deviations from the prescribed dose; (iii) extra doses; (iv) medicines omitted for the medicines cycle; (v) medicines administered at the wrong time and (vi) medicines administration struck through.
Results: Some 82,817 medicines administrations were analysed and a total of 6770 administration errors were identified for all medications representing an error rate of 8.2%. Of these administration errors, 858 were related to medications found in Beers Criteria. This equates to 12.6% of all the administration errors. The majority (58%) of these administration errors were associated with antipsychotic and anxiolytic drugs.
Conclusion: This study has revealed a high prevalence of administration errors associated with high risk drugs in care homes. Whilst the clinical impact of such errors remains to be elucidated, pharmacists as experts in medicines can play an active role in addressing medicines administration issues in care homes to reduce the risk of medicines related harm.
References: Wiley Online Library. (2016). American Geriatric Society 2015 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. [online] Available at: http://onlinelibrary.wiley.com/doi/10.1111/jgs.13702/pdf [Accessed 2 Apr. 2018].

Appendix 3 – MAR chart analysis rulebook

PRN rules in Blue
AS DIRECTED rules in pink
PRN
Structured PRN (e.g. Take ONE four times a day when required) should show record of given or offered/refused. Blank box = yes (error) - cannot assess - cannot assess PER blank box
Unstructured PRN (e.g. take ONE when required) Blank Boxes = Cannot be judged - cannot assess- cannot assess PER med.

REGULATORY ERRORS

- Any dose/form/strength hand amendments require TWO signatures
- Changes mid-month need to be stopped (TWO signatures) and a new entry written (2 signatures)
- Pulse left blank = error if nursing home. Hand written signature required
- Everything handwritten entry requires TWO signatures.
- Discontinued requires TWO signatures.
- Abx course completed requires ONE signatures.
- Abx stopped required TWO signatures.
- Clarification of instructions requires ONE signature.
- Defined code required. Error PER DRUG undefined code. (NOT per entry)
- If "C" is recorded for a dose, a carer administered the dose and this is not an error.
- Variable doses, if dose on label is 1-2 tablets or 10-15ml, doses given on specific administrations should be clear, if not its an ERROR = missing chart information.
- CD witness signature missing - error per dose given.
- Apply as directed - 2 errors (As directed written AND incomplete dosage instructions RISK)
- As directed (on its own) - 2 errors (As directed written AND dose missing.)
- If its as directed, NOT an error if the time isn't written but dose is required.
- As directed is an error by default.
- Food "as directed" still an error.
- Unstructured PRN requires MAX PRN, regardless of whether it is GTN spray, inhaler
- Topical (creams/ointments etc.) PRN do not need max PRN
- Structured PRN does not require max PRN as daily dose given.
- Handwritten times for prn fine – alterations to regulars require a signature.

ADMINISTRATION ERRORS

- Crossed out signature no explanation – error (scribble)
- If a scribble has been corrected underneath with the correct code, this is NOT an error.
- One error PER omission and per PER deviation from dose
- Omission = Doses missing
- Deviation from stated dose = Extra doses given
- "AS DIRECTED" meds are not assessed for omissions - can't tell if they've been directed not to give

RISK ERRORS

- Apply as directed - 2 errors (As directed written AND incomplete dosage instructions RISK)
- As directed (on its own) - 2 errors (As directed written AND dose missing RISK)
- Absent dose / form / strength are 3 separate errors.
- Time missing in prn is a risk ERROR (missing time).
- Time not required for as directed because you assume that they know how often to take it.
- "Read leaflet" – error (incomplete dosage information)
- Anything with "Space doses evenly" on label where doses have not been administered evenly = error (Deviation from stated dose)
- Creams and ointments require site of application and frequency.
- "Apply to affected area/eye" is error-Incomplete dosage information.

STOCK ERRORS

- Stock not received but given / stock quantity mismatch = error
- Existing medication can be "carried forward"
- Quantity of meds must be booked in but is not required on label.
- N/A in signature box error (No sig)
- 0g in quantity = 1 error each no sig and no date.
- If quantity is "0" and it has been signed, if the chart is empty there is no error.

CANNOT BE ASSESSED

- ½ hour before/after food cannot be judged and cannot be assessed - unsure of exact meal/drug round completion.
- "At night" dose given at 5pm cannot be judged due to patient individual bedtimes.
- Drainage bags treat like other meds

OTHER POINTS OF NOTE

- Care homes will be numbered
- 2 individual entries of same drug are counted as 1 drug
- 2 formulations are 2 separate medications.
- Chart errors vs medication errors.
- Patients given their own medication is handled the same as the others.
- "Space doses evenly" absent NOT an error.
- BD/TDS/QDS individual judgement as to time intervals.
- Schedule 2 & 3 drugs counted as CDs.
- Creams and QOL?
- Dressings are treated as medications – ANALYSIS POINT