USING SIX SIGMA DMAIC METHODOLOGY TO ENHANCE MEDICINES MANAGEMENT WITHIN UK CARE HOMES

Improving the 28-day Supply of Medicines Cycle for Resident Repeat Medications

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THESIS SUMMARY

Background The 28-day supply of medicines cycle manages resident repeat medication.

Aim & Research Questions To improve the 28-day supply of medicines cycle within care homes using research questions: [1] how is the 28-day supply of medicines cycle within care homes carried out? [2] what are the current issues and challenges within the cycle? and [3] how can these be rectified to improve the cycle?

Methodology Exploratory case studies, consisting of semi-structured interviews and direct participant observations, examined the 28-day supply of medicines cycle within three UK care homes to answer research question 1. Data was analysed using Framework Analysis. To answer research question 2 and 3, the researcher employed Six Sigma process improvement methodology, DMAIC (Define-Measure-Analyse-Improve-Control) to each case study.

Results The 28-day supply of medicines cycle consists of five stages: medicines re-ordering, prescription check against re-order, medicines checking-in, changeover and administration. Using DMAIC, the researcher *defined* a key challenge as request discrepancies between repeat order request and prescription generated by the GP surgery, categorised as: omissions, incorrect quantities, additional items and mis-prescribed medications. Discrepancy rates were *measured* and root causes *analysed*. Recommendations were provided to *improve* each case study's cycle, and an error log was created to *control* the cycle. Omissions and incorrect quantities were the most frequent discrepancy, at over 80% of total discrepancies in each case study.

Contributions A DMAIC framework applicable by all care homes to examine their 28-day supply of medicines cycle efficiency and a conceptual framework (recommended process map) for the cycle. The study also discusses the potential role independent prescribing pharmacists and pharmacy technicians could have in managing efficiency, and the lack of communication and collaborative working between stakeholder organisations involved (GP surgery, pharmacy, care home). This study is the first to apply Six Sigma, DMAIC to the care home setting.

Keywords: 28-day supply of medicines cycle; repeat management; medicines management; care homes; Six Sigma

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TABLE OF CONTENTS

Thesis Summary……2
Acknowledgements……3
Table of Contents……4
List of Figures……7
List of Table……8

CHAPTER 1: INTRODUCTION……9
Background……10
Problem Statement……13
Research Questions……14
Definitions……14
Summary……16

CHAPTER 2: LITERATURE REVIEW……18
Method……19
Errors in Care Homes……19
Adverse Drug Events in Care Homes……23
Near Misses in Care Homes……24
Medicines Management in Care Homes……28
The 28-day Supply of Medicines Cycle……30
a. Prescribing……31
b. Ordering……33
c. Dispensing and Supplying……36
Gaps in the Literature……43
Summary……44

CHAPTER 3: METHODOLOGY……46
Qualitative Research Method……47
Appropriateness of Design – Exploratory Multiple Case Study……48
Research Questions……52
Population……53
Sampling……53
Informed Consent……54
Confidentiality……56
Geographic Location……56
Instrumentation……57
Data Collection……59
Data Analysis……60
Framework Analysis……62
1. Familiarisation……62
2. Identifying a Thematic Framework……62
3. Indexing……63
4. Charting……64

5. Mapping & Interpretation....64
Validity & Reliability....66
Credibility, Transferability, Dependability & Conformability....66
Other Methods used to Establish Validity & Reliability....67
Summary....68

CHAPTER 4: RESULTS....70
Interviews and Participant Observation Results for Case Study 1....71
General Information on Medicines Management for CS1....71
Medicines Re-ordering [CS1]....72
Prescription Check against Re-order [CS1]....73
Medicines Checking-in [CS1]....74
Medicines Changeover [CS1]....76
Medicines Administration [CS1]....78
Interviews and Participant Observation Results for Case Study 2....80
General Information on Medicines Management for CS2....80
Medicines Re-ordering [CS2]....81
Prescription Check against Re-order [CS2]....81
Medicines Checking-in [CS2]....83
Medicines Changeover [CS2]....83
Medicines Administration [CS2]....84
Interviews and Participant Observation Results for Case Study 3....86
General Information on Medicines Management for CS3....86
Medicines Re-ordering [CS3]....87
Prescription Check against Re-order [CS3]....88
Medicines Checking-in & Medicines Changeover [CS3]....89
Medicines Administration [CS3]....90
Compilation of Interview and Participant Observation Results for All Case Studies....91
Summary....93

CHAPTER 5: SIX SIGMA – DMAIC....94
Rationale for Six Sigma Methodology – DMAIC....95
Six Sigma in Healthcare....98
Six Sigma and DMAIC Methodology.... 100
DMAIC: The Five Stages....102
Define....102
Measure....103
Analyse....103
Improve....105
Control....106
Summary....108

CHAPTER 6: APPLICATION OF SIX SIGMA TO CASE STUDIES....109
DMAIC Framework....110
Define....111

Measure……114
Analyse……117
Improve……120
Control……120
General Conceptual Framework Recommendations for All Case Studies……120
Six Sigma Application to Case Study 1……122
Six Sigma Application to Case Study 2……136
Six Sigma Application to Case Study 3……149
General Conceptual Framework Recommendations……157
Recommended Cross-functional Process Map……157
Specific Recommendations for the 28-day Supply of Medicines Cycle……158
Summary……161

CHAPTER 7: DISCUSSION……163
Summary of Findings……164
Discussion of Findings……164
Discussion of Six Sigma……181
Limitations, Implications and Scope for Future Work……182
Limitations……182
Implications……184
Scope for Future Work……185
Conclusions……186

REFERENCES……188

APPENDICES……204
APPENDIX A: Interview Schedule……204
APPENDIX B: Participant Observations Schedule……205
APPENDIX C: Stakeholder Feedback Session Schedule……206
APPENDIX D: Participant Information Sheet – Care Homes……207
APPENDIX E: Consent Form – Care Home……210
APPENDIX F: Participant Information Sheet – Healthcare Professionals……211
APPENDIX G: Consent Form – Healthcare Professionals……214

LIST OF FIGURES

Figure	Page
Figure 1: General tasks within 28-day supply of medicines cycle	13
Figure 2: Overview of medicines management system	29
Figure 3: Flowchart for regular prescriptions, taken from CHUMS Report	30
Figure 4: Right-hand side of FP10 prescription depicting a typical 'repeat slip'	34
Figure 5 Example of a multi-dose MDS	37
Figure 6: Example of a single-dose MDS	37
Figure 7: Example of a MAR chart	41
Figure 8: Example of a MAR chart	42
Figure 9: Summary of how data was analysed, using Framework Analysis	65
Figure 10: Sample repeat medication re-order form	75
Figure 11: 28-day Supply of Medicines Cycle within Care Homes	91
Figure 12: Six Sigma Metric Nomograph, depicting multiple industry performance levels.	105
Figure 13: DMAIC Framework	110
Figure 14: Critical-to-Quality (CTQ) Tree	113
Figure 15: CTQ Tree with Measurements	115
Figure 16: Sample Pareto Chart	116
Figure 17: Cross-functional Process Map – Key Features: (A) "Swim-lane" (entity) (B) workflow, (C) "handoff" (internal supplier-customer relationship)	119
Figure 18: Pareto Chart of Discrepancies encountered during Medicines Changeover in one 28-day Supply of Medicines Cycle in CS1	126
Figure 19: Fishbone Diagram of Root Causes	128
Figure 20: 'As is' cross-functional process map for CS1	129
Figure 21: Pareto Chart of Discrepancies Encountered during one 28-Day Supply of Medicines cycle in CS2	139
Figure 22: 'As is' cross-functional process map for CS2	141
Figure 23: Pareto Chart of Discrepancies Encountered during one 28-day Supply of Medicines Cycle in CS3	151
Figure 24: 'As is' Cross-functional Process Map for CS3	154
Figure 25: Recommended Cross-functional process map	157
Figure 26: DMAIC Framework incorporating Six Sigma Tools	165
Figure 27: CTQ Tree with Measurements for Care Homes to use	166
Figure 28: General Conceptual Framework displaying Ideal Timings for Tasks within the 28-day Supply of Medicines Cycle	168
Figure 29: 28-day Supply of Medicines Cycle within Care Homes	169

LIST OF TABLES

Table	Page
Table 1: Rates and Severity of ADEs and Preventable ADEs	23
Table 2: Near Miss Reporting System Examples	25
Table 3: Contributing Factors to Errors in the Medication Process	26
Table 4: Advantages and Disadvantages of Monitored Dosage Systems versus Original Packs	38
Table 5: Key Characteristics Defining Case Study Research	51
Table 6: Care Home Characteristics [CS1]	71
Table 7: Care Home Characteristics [CS2]	80
Table 8: Care Home Characteristics [CS3]	86
Table 9: Similarities and Differences between TQM, Six Sigma and Lean	97
Table 10: Definitions of DPMO, C_{pk}, COPQ and Sigma Level	104
Table 11: Objectives of DMAIC Phases	107
Table 12: Examples of Types of Discrepancies within the 28-day Supply of Medicines Cycle [CS1]	124
Table 13: Estimated Number of Discrepancies Encountered [CS1]	125
Table 14: DPMOs encountered during the medicines changeover task in CS1	127
Table 15: Recommended timeline for tasks within the 28-day supply of medicines cycle	130
Table 16: Summary of Feedback on Recommendations for CS1	133
Table 17: Medicines Discrepancy Error Log	135
Table 18: Examples of Types of Discrepancies within the 28-day Supply of Medicines Cycle	137
Table 19: Estimated Number of Discrepancies Encountered [CS2]	138
Table 20: DPMOs encountered during the medicines changeover task in CS2	140
Table 21: Summary of Feedback on Recommendations for CS2	147
Table 22: Examples of types of discrepancies within the 28-day supply of medicines cycle	149
Table 23: Estimated Number of Discrepancies Encountered [CS3]	150
Table 24: DPMOs encountered during medicines changeover task in CS3	152
Table 25: Summary of feedback on recommendations provided to CS3	156
Table 26: Differences between repeat re-order forms and right-hand side of FP10 prescriptions	159
Table 27: Average Discrepancies Encountered between all case studies	162
Table 28: Differences between means of communication	172

CHAPTER 1

INTRODUCTION

Chapter 1 introduces the reader to the current and predicted older people population, older people living in care homes and the care home setting. The reader is given a general introduction of elements discussed in greater detail later in the thesis, including different types of medication errors (i.e. non-adverse drug events, adverse drug events and near-misses), medication management, including repeat management and the 28-day supply of medicines cycle. The chapter provides a problem statement which leads to the aim and research questions of this study. Finally, a list of definitions used throughout the thesis is provided.

BACKGROUND

The global population has been getting older for decades now. Half a century ago, there were 205 million people aged 60 years and above globally, and it is expected that in the next 50 years the number of older people will increase to 2 billion (United Nations, 2001). In 2016, in the UK alone, 18% of people (11.8 million people) were aged 65 and over, and 2.4% of people (1.6 million people) were aged 85 and over (Office of National Statistics, 2017). The number of people aged 65 and over is projected to rise by over 40% in the next 17 years to over 16 million people in the UK (Office for National Statistics, 2015).

By 2036, over half of local authorities in the UK are projected to have 25% or more of their local population aged 65 and over, the majority of local authorities having more than 4% of their population aged 85 and over (Office of National Statistics, 2017). With lower birth rates, higher life expectancy and the effects of the 1960s baby boom and the "echo" of baby boomers having children; the population of older people in the UK is expected to continue growing (Office of National Statistics, 2017). Whilst longevity is something to celebrate, healthcare sustainability becomes a challenge and national priority (Office of National Statistics, 2017).

As individuals are living longer, there is a higher prevalence of ill health within the aged group and an inability to manage activities of daily living independently, a common reason for admission of older people to care homes (Krause et al., 2011). Additionally, with the current trend of having fewer children and these children more likely to be working, the needs of older people are often not well attended to and as a result, caring institutions provide the most welfare support for seniors (Chen et al., 2013).

A residential home is a special-purpose facility which provides accommodation and other types of support, including assistance with day-to-day living, intensive forms of care and assistance towards independent living, to frail and aged residents (ACT, 2019). Nursing homes are residential facilities for persons who require nursing care and related medical or psychosocial services (Buccheri et al., 2010). There are an estimated to be 4,699 nursing homes and 6,023 residential homes (without nursing) in the UK (Laing and Buisson, 2017), with approximately 405, 000 people aged 65 and over in a total of almost 18, 000 care homes (nursing, residential or combined homes) (AgeUK, 2016). Furthermore, 14.8% of people aged 85 and over in the UK are living in care homes (Laing and Buisson, 2017). In the remainder of this thesis, 'care homes' will refer to both residential and nursing homes. In situations

regarding only one type of home, 'residential' or 'nursing' home will be stated. While several studies have been conducted around the field of healthcare and in various healthcare settings, the care home setting has been largely ignored, with only 2% of research on older people undertaken in this setting (Rolland et al., 2009).

Along with the ageing population comes a plethora of health issues often leading to physical and social changes such as debilitating effects of multiple, acute and chronic diseases, as well as changes to the central nervous system, leading to cognitive decline (Harada et al., 2013; Mafauzy, 2000). Along with changes in the body, there has been an increase in multi-morbidity in older people (Salive, 2013). Multi-morbidity is the co-existence of two or more chronic conditions in the same individual, and is associated with reduced quality of life, higher mortality, polypharmacy and high treatment burden, higher rates of adverse drug events, and much greater health services use (NICE, 2019; WHO, 2016). The prevalence of multi-morbidity has varied across studies, showing 20-30% of people having multi-morbidity when the entire population is considered, and anywhere from 55% to 98% when only older people are considered (Marengoni et al., 2011). In the UK, 54% of people aged over 65 had multi-morbidity in 2015; this figure is expected to rise to 67.8% by 2035 (NIHR, 2018). Due to this increase in multi-morbidity, polypharmacy (the use of multiple medicines) is common in the older population (Masnoon et al., 2017).

In 1997, people aged over 60 in England received an average of 22.3 prescription items, this figure almost doubled to 42.4 items in 2007 (NHS England, 2008). Furthermore, the proportion of people taking five or more medications has increased fourfold (from 12 to 49%) over a 20-year period (1991-2011) (Gao et al., 2018). A median of two medications was taken by older people in England between 1991 and 2001, whereas this figure rose to a median of four medicines between 2001 and 2011 (Gao et al., 2018). As the prevalence of chronic conditions and multi-morbidity in older people continues to rise, the average number of prescribed medications in each older person is also predicted to increase (Green et al., 2018; Loganathan et al., 2011).

Elderly people admitted to care homes (over 65 years) generally have greater multi-morbidity, resulting in more medications per resident in comparison to the overall older person population (Akner, 2009). Care home residents have been reported to be receiving up to four times as many prescription items compared to older people living in the community (Loganathan et al., 2011). The average care home resident in the UK has been reported to be taking between six and eight

medications, with over 20% of care home residents using more than 10 medications (Advinha et al., 2014; Barber et al., 2009; Loganathan et al., 2011).

The increase in the amount of medication prescribed to older people, including those in care homes, as well as the prevalence of multiple co-morbidities, and age-related pharmacokinetic and pharmacodynamic changes, all contribute to the complexity of medication management in the ageing population and within care homes (Loganathan et al., 2011; Mafauzy, 2000). Older people have the highest consumption of medication and polypharmacy (use of multiple medications, often defined as 5 or more medications) is associated with greater risk of adverse reactions, hospitalisation, and poor adherence, as well as unnecessary costs to the patient or healthcare system (Hanlon et al., 2004; Mannesse et al., 1997; Murray, 2003).

Polypharmacy can often include complicated schedules or additional instructions, resulting in a decline in medication adherence and increased risk of medication errors, often leading to a higher use of resources due to a reduction in effectiveness or increased risk of therapeutic failure (Corsonello et al., 2009; Ingersoll and Cohen, 2008; Mansur et al., 2012) . Alongside resident medication regimen complexity, the care home environment encounters medication management complexity by a host of other factors including: levels of staff training, medication follow-up or reviews, pharmaceutical drug form, communication between several healthcare professionals per resident (Castellar et al., 2007; George et al., 2004; Melchiors et al., 2007).

As older people living in care homes are likely to be taking more medications than older people living at home, care home residents are at greater risk of medication error than most other groups (Barber et al., 2009; Maidment et al., 2008). Furthermore, the complexity of the medicines management systems within care homes adds to the burden of managing care home resident medications and can contribute to the error rate (Castellar et al., 2007; George et al., 2004; Melchiors et al., 2007).

There are various types of medication errors, including preventable and non-preventable adverse drug events (ADEs) and near-misses (Greene et al., 2004; Hansen et al., 2006). A definition for each of these terms is given later in this chapter (see 'Definitions' section, page 14), with each type of incident discussed in detail in chapter two (literature review) which covers how each error can be associated with a different part of the overall medicines management process.

A safe and efficient medication management system within care homes has the potential to decrease the rate of medication errors within the setting. A crucial component of the medicines management system includes the management of repeat medications. A 28-day supply of medicines cycle is used for repeat medication management within care homes and forms just one part of the complex medicines management system within care homes. Generally, during this cycle, a care home orders resident repeat medications, the GP prescribes the requested medication, or in some countries (e.g. the Netherlands) specialists prescribe the request medication, the supplying pharmacy dispenses and supplies the medication to the care home, and the care home prepares the medication for administration within resident rooms or medication trolleys. Figure 1 depicts the general tasks within the cycle.

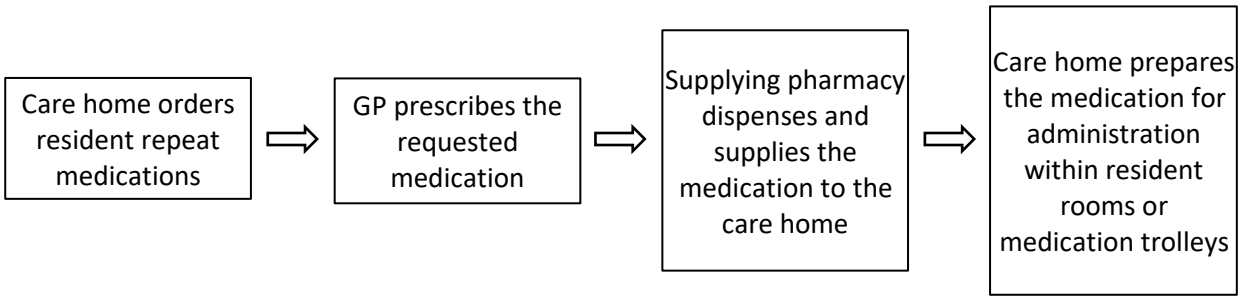


Figure 1: General tasks within 28-day supply of medicines cycle

Good medicines management within care homes includes proper medication procedures, ensuring safety to care home residents, benefit from resident medication regimens and is paramount to providing an adequate level of service to care home residents (Nizaruddin et al., 2017a). A full definition of medicines management is given on Chapter 1 (Definitions, Page 14) and is discussed in greater detail in Chapter 2. As repeat management is a vital component of the overall medicines management within care homes, this study focusses on the efficiency and safety of the 28-day supply of medicines cycle.

PROBLEM STATEMENT

With the ageing population and an increasing number of older people living in care homes worldwide, it is essential for service providers, including care home staff, GPs, specialists, pharmacists and nurses, to deliver and administer safe, efficient and timely medication to their residents. As repeat medications make up a large proportion of the medications administered to care home residents and studies (including: CHUMS, MEDREV, Gurwitz et al., detailed in chapter 2) have reported an

unacceptable rate of errors in relation to medication within care homes; the 28-day supply of repeat medicines cycle must be made safe and efficient.

RESEARCH QUESTIONS

The purpose of this study is to examine the 28-day supply of medicines cycle from start to finish, understanding the process of converting a repeat request, to prescription, to medication within the 28-day timescale and providing a detailed account of each stage of the process from the care home perspective.

The three research questions are:

1. How is the 28-day supply of medicines cycle within care homes carried out?
2. What are the current issues and challenges within the 28-day supply of medicines cycle?
3. How can these issues and challenges be rectified and overcome to improve the overall cycle?

DEFINITIONS

This section lists and defines frequently used terms throughout this study.

28-day supply of medicines cycle: a part of the medicines management process within care homes, which includes prescribing, ordering, dispensing and supply of repeat medicines (NICE, 2014).

Care home: refers to both residential and nursing homes

DMAIC (Define-Measure-Analyse-Improve-Control): a data-driven life-cycle approach to Six Sigma projects for improving process (Sokovic et al., 2010), a performance improvement model or methodology within which all Six Sigma tools can be implemented (Pyzdek, 2000). It consists of five phases: Define, Measure, Analyse, Improve and Control; and is pronounced as 'de-MAY-ick' (Pyzdek, 2000; Sokovic et al., 2010).

Medication errors: incidents in which there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring, or providing medicine advice, regardless of whether any harm occurred. This is a broad definition and most errors do not result in harm (NPSA, 2007).

Medication incident: any incident classified as a medication error, preventable or non-preventable adverse drug event, or near-miss related to medicines (NPSA, 2007)

Medicines Management: 'the entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to producing informed and desired outcomes of patient care' (Audit Commission, 2001).

Medicines Management Process within Care Homes: A definition specifically on the scope of medicines management within care homes is provided by Alldred et al. (2009): Care homes each have their own medicines management system, however the general tasks are as follows: [1] ordering, [2] prescribing, [3] dispensing and supply, [4] storage, [5] administration of medicine to resident and [6] monitoring of effect of medicines; a key component common to each task above is relevant documentation (Alldred et al., 2009).

Medicines Optimisation: a person-centred approach to safe and effective medicines use, to ensure people obtain the best possible outcomes from their medicines (NICE, 2015).

Near-miss (potential harms from medicines): incidents that did not cause harm but which are judged to have had the potential to cause harm. These incidents provide valuable insight into areas of risk and where systems can be improved to prevent death or harm (NPSA, 2007).

NICE (The National Institute for Health and Care Excellence): provides national guidance and advice to improve health and social care, including governance information, up-to-date policies, procedures and publications. This study often refers to the NICE Guideline on 'Managing medicines in care homes' (NICE, 2014).

Nursing home: residential facilities for persons who require nursing care and related medical or psychosocial services (Buccheri et al., 2010)

Preventable or non-Preventable Adverse Drug Events (harms from medicines): a smaller proportion of medication incidents will result in actual harm to patients. These are sometimes called adverse drug events (ADEs). These types of incidents can be divided into two groups depending on whether the ADE was caused by an error (preventable) or not (non-preventable) (NPSA, 2007).

Request Discrepancy or Discrepancy: for the purpose of this study, the researcher has defined a discrepancy as: any difference between the care home's repeat medication order request to the surgery, and the prescription or item subsequently produced. This refers to the items prescribed by the GP surgery from the order request or the items dispensed and delivered by the pharmacy according to the prescription provided by the GP surgery, which should ultimately be in accordance with the care home's repeat medication order request. All discrepancies in this study are classified as near-misses because care home staff identified the discrepancies before any incorrect medications reached the residents.

RPSGB (Royal Pharmaceutical Society of Great Britain): a society with Royal Charter status in the UK, promoting pharmacy in the media and government, contributing to published material of medicines information and supporting pharmacists in their education and development (RPSGB, 2019)

Resident: a person who lives in a care home

Residential home: a special-purpose facility which provides accommodation and other types of support, including assistance with day-to-day living, intensive forms of care and assistance towards independent living, to frail and aged residents (ACT, 2019)

Six Sigma: 'a rigorous, focussed and highly effective implementation of proven quality principles and techniques, Six Sigma aims for virtually error free business performance. Sigma, σ, is a letter in the Greek alphabet used by statisticians to measure the variability in any process. A company's performance is measured by the sigma level of their business processes. Traditionally companies accepted three or four sigma performance levels as the norm, albeit these processes created between 6,200 and 67,000 defects per million opportunities. Six Sigma aims for a standard of less than 3.4 defects per million opportunities' (Pyzdek, 2000).

SUMMARY

Chapter 1 provided background information on older people and older people living in care homes. The complexity of medication regimes and co-morbidity in older people residing in care homes increases the risk of all types of medication errors within this population, and ultimately places importance on the medication management process within the care home setting. Repeat medication management through the 28-day supply of medicines cycle is a vital component to the medicines management process.

Chapter 2 provides a literature review of previous research to understand what is known about medicines management and the 28-day supply of medicines cycle within care homes. The literature review establishes the knowledge gaps within the literature for these topics. To address the gaps in the literature, the researcher used a qualitative explorative multi-case study research design (discussed in Chapter 3) aimed at exploring the 28-day supply of medicines cycles within care homes. The research design determined issues and challenges within the cycle and provided recommendations for improvement.

CHAPTER 2

LITERATURE REVIEW

The narrative literature review consists of six parts. The first two sections discuss errors within care homes. The first section discusses adverse drug events and errors pertaining to certain stages in the medicines management process. The second section discusses another type of error, near-misses within care homes. These two sections indicate the importance of examining errors within care homes and system processes, including medicine processes. Therefore, the third and fourth sections discuss available literature on medicines management and the 28-day supply of medicines cycle, respectively. The 28-day supply of medicines cycle includes subsections describing the following tasks: prescribing, ordering, dispensing and supplying. The final section of the literature review outlines the gaps within the literature and broadly defines the aim of the study going forward.

METHOD

Chapter 2 provides literature on error rates, medicines management and the 28-day supply of medicines cycle within care homes. Key words in the title or abstract (medication management, medicine management, medication optimisation, medicine optimisation, residential long, long term care facility, nursing home, care home, home provider) were used to search the ProQuest, PubMed, Web of Science and Google Scholar databases. Journal articles and book chapters and grey literature including conference proceedings, dissertations and theses were used. In order to retrieve the most published material possible, no restrictions were placed on publication date. The reference list of each paper chosen was also searched. The researcher has used a structured narrative literature review because the literature review covers many topics which are linked. A systematic literature review was not conducted because it would not cover all relevant topics and procedures within the 28-day supply of medicines cycle to give the reader a thorough understanding of current literature on the subject. The narrative literature review allowed the researcher to cover a broader array of topics and link them together. Furthermore, the lack of literature on the process of medicines management within care homes did not allow for a systematic review. The literature review covers the following topics: errors in care homes, adverse drug events in care homes, near misses in care homes, medicines management, process pathway, and the 28-day supply of medicines cycle. It then discusses the gaps in the literature and provides a summary of the chapter.

ERRORS IN CARE HOMES

The average care home resident in the UK takes between six and eight medications per day (Advinha et al., 2014; Barber et al., 2009; Loganathan et al., 2011). Given the number of medications that residents consume daily, there is a high risk of medication incidents however most of these appear not to cause direct patient harm (Cohen, 2010; Mira, 2019). Although there is a high risk of adverse drug events within the care home environment, the rate of these events actually causing direct patient harm is not known and most likely a lot less. One study analysed inappropriate medication use via logistic regression and discovered that residents taking a greater number of medications were significantly more likely to receive an inappropriate agent (Perri et al., 2005). Inappropriate agents include medications prescribed at a higher dose than needed, sub-optimal prescribing or medications which should be avoided in older people because the risk of adverse events outweighs the expected benefit, particularly when more effective or safer alternatives are available (Perri et al., 2005; Roux et al., 2019).

Errors can occur at all stages of medicines management (Leape et al., 1995), involving various professionals, including physicians, pharmacists and nurses (Fontan et al., 2003; Nizaruddin et al., 2017b). A study performed in two tertiary care hospitals found that nurses intercept up to 86% of all errors, and pharmacists 12% of all errors made by physicians, pharmacists and others involved in providing medications for patients (Leape et al., 1995). Values for nurses and pharmacists intercepting errors for care home residents were not found in the current literature.

In England, the CHUMS study found that nearly 70% of the care home residents had at least one medication error (Barber et al., 2009). The study examined prescribing (including omissions, the failure to prescribe necessary medications), monitoring, dispensing and medication administration errors to care home residents (Alldred et al., 2009). The CHUMS study found 39.1% of residents (100 out of 256 residents) had one or more prescribing errors and 94 residents had a total of 187 dispensing errors, providing a mean of 0.73 dispensing errors per resident (Alldred et al., 2009). The study also found eight prescribing errors linked to dispensing errors (Alldred et al., 2009).

A study entitled MEDREV aimed to test the feasibility of staff training (including GPs and care home staff) and pharmacist-led medication reviews to limit inappropriate prescribing (Maidment et al., 2018). The study specifically focussed on inappropriate prescribing of psychotropics (anti-psychotics, anti-depressants, benzodiazepines) in people with dementia in care homes. The study focussed on psychotropics because they are usually used to treat 'behaviour that challenges' in people with dementia, however can also cause a host of harmful side effects (drowsiness, restlessness, muscle spasms, tremor, dry mouth, blurring of vision) if prescribed inappropriately. The pharmacist recommended stopping or reviewing medication in 72.4% of participating care home residents, in which 57.1% of recommendations were implemented within an average of 98.4 days (Maidment et al., 2018).

Inappropriate prescribing of psychotropics has been found in multiple studies and can sometimes be referred to as a medication error, resulting in the movement of 'de-prescribing' (Plakiotis et al., 2015; Reeve et al., 2013). Pharmacy-led medication reviews in care homes can be used to determine prescribed medications that are no longer needed and are therefore suitable for de-prescribing, increasing patient safety related to medication (Alldred et al., 2009; Maidment et al., 2018; Wright et al., 2016). The MEDREV study findings determined the average time it takes for the GP to implement the pharmacist recommendations, which was 98.4 days. The study findings suggest the relationship

between the care home, GP surgery and pharmacist could affect the GP's decision to implement the recommendation and the amount of time it takes to implement (Maidment et al., 2018).

Gurwitz et al. (Gurwitz et al., 2000) reviewed incident reports of adverse drug events in American nursing homes over a one-year period and classified the stage of pharmaceutical care at which the errors occurred. These stages included ordering, transcribing, dispensing, administration and monitoring (Gurwitz et al., 2000). Most errors associated with preventable events occurred during the ordering (68%) and monitoring (70%), and were rarely associated with the transcription (0.7%), dispensing (0.5%) or administration (3%) stages (Gurwitz et al., 2000). There is little information on rates of dispensing errors within nursing homes, possibly because the dispensing of medications does not actually take place in nursing homes.

Research has shown there is need for one person to assume overall responsibility of medicines management to care home residents (Alldred et al., 2009) and that pharmacists may be ideal for this role (Alldred et al., 2009; Avery et al., 2013, 2012; Bond et al., 2000; Maidment et al., 2016; Wright et al., 2016; Zermansky, 1996). Therefore, the on-going, five-year study, CHIPPS (The Care Homes Independent Pharmacist Prescribing Study) proposes pharmacist independent prescribers should assume responsibility for repeat prescription monitoring, authorising and overall management of medications within care homes (Wright et al., 2016). The study is a cluster randomised controlled trial to determine the effectiveness and cost-effectiveness of the proposed intervention (Wright et al., 2016). As the study is due to finish in April 2020, results have not yet been released, however the study is in line with current policy for encouraging NHS investment in care home pharmacists (NHS England, 2019a; RPSGB, 2019a).

While many studies have examined inappropriate prescribing in the nursing home setting (Halvorsen et al., 2019; Liew et al., 2019; Perri et al., 2005; Stojanović et al., 2020), very few studies have been completed on medication error rates within nursing homes (Aspden et al., 2007). The National Patient Safety Agency (NPSA) run by the NHS provides data on all reported patient safety incidents within all healthcare settings in England for the National Reporting and Learning System (NRLS) (NHS Improvement, 2019).

One of the biannual reports created by the NPSA is the National Patient Safety Incident Reports (NaPSIRs) which sets out the number of patient safety incidents reported, describing national patterns and trends on the incidents reported (NHS Improvement, 2019). The care home setting comes under

community nursing, medical and therapy service. From July 2018 to September 2018, a total of 488,242 incidents were reported from all care settings in the report. From October 2017 to September 2018, 1,991,797 incidents were reported across all care settings in the report (NHS Improvement, 2019). The community nursing, medical and therapy service reported 10.7% of these incidents, equivalent to 212,232 incidents (NHS Improvement, 2019). Within the year, the largest percent of incidents were implementation of care and ongoing monitoring/review at 36% (76,025 incidents) and medication was the third largest at 9% (19,443 incidents) from community nursing, medical and therapy service settings (NHS Improvement, 2019).

The NaPSIR further breaks down the incidents per healthcare setting and type of incidents to show the level of harm incurred by patients. Of the total 212,232 incidents reported by this setting, 54% (113,839 incidents) caused no harm, 38% (80,687 incidents) low harm, 8% (16,221 incidents) moderate harm, 0.4% (929 incidents) severe harm and 0.3% (556 incidents) death (NHS Improvement, 2019). Of the 19,443 incidents classified under medication, 89% (187,705 incidents) caused no harm, 10% (21,474 incidents) caused low harm, 1% (1,886 incidents) caused moderate harm, 0.7% caused severe harm (138 incidents) and 0.3% caused death (62 incidents) (NHS Improvement, 2019).

The NaPSIR does not further break down what these medication-related incidents are. All incidents reported are 'actually happening' meaning they occurred in the defined time-period (NHS Improvement, 2019). The NaPSIR data therefore does not capture near-miss data.

Studies which have been completed on error rates within nursing homes largely focus on the medicines administration process, as it is the most frequent process within care homes and one-third of medication errors harming patients are associated with the administration stage (Leape et al., 1995).

Medication administration errors occur at a rate of 6-20 per 100 doses in nursing homes (Baldwin, 2019; Barker et al., 2002, 1982; Cooper et al., 1994). Barker et al. published two studies twenty years apart, both using direct observation to detect errors and reported similar error rates of 12 errors per 100 doses (Barker et al., 1982) and 15 errors per 100 doses (Barker et al., 2002), both excluding doses administered at the wrong time. Omission of an ordered medication is generally the most common type of drug administration error in nursing homes (Aspden et al., 2007).

As the medication administration process has very few safeguards against errors due to its timing at the end of the medication-use process (Aspden et al., 2007), it is paramount that all medication-

related tasks leading up to the administration process are rigorous in isolating errors and maintaining patient safety.

ADVERSE DRUG EVENTS IN CARE HOMES

Adverse drug events (ADEs or harms from medicines) are actual harm to patients, at varying levels of harm and can be divided into two groups, preventable and non-preventable. Preventable ADEs are caused by medication error, whereas non-preventable ADEs are not caused by medication errors and can be unintentional harm as a result of medication use (Bates et al., 1995; NPSA, 2007). ADEs (harms from medicines) can originate from any process during the medicines management process (Alldred et al., 2009; Bates et al., 1995; Gurwitz et al., 2005; NPSA, 2007).

In long term care within care homes in the USA, there are a projected total of 800,000 preventable ADEs, which is likely an underestimate (Aspden et al., 2007; Cerety et al., 1993; Cooper, 1999; Gurwitz et al., 2005). In 2000, Gurwitz et al. found 74% (546 of 734 incidents) of incidents as ADEs, while the remaining 26% (n = 188) were potential ADEs. Of the 546 ADEs, about half (n = 276) were judged as preventable. In 2005, Gurwitz et al. found 78% (815 of 1042 possible drug-related incidents) to be ADEs, with the remaining 22% (n = 227) were potential ADEs. Of the 815 ADEs, 42% (n = 338) were judged as preventable. The table below depicts both of Gurwitz and colleagues study findings (table 1). Neither study by Gurwitz considered errors of omission. Cerety et al. (1993) found 95 of 175 residents experienced 201 ADEs in an American Veterans Affairs nursing home, resulting in one fatality and twelve hospitalised residents. Unlike Gurwitz, Cerety and colleagues did not quote preventable ADEs.

Table 1: Rates and Severity of ADEs and Preventable ADEs (Gurwitz et al., 2005)

			Category of Severity			
Study Year	**Type of Drug-Related Event**	**Number (Percent)**	**Fatal**	**Life-Threatening**	**Serious**	**Significant**
2000	ADEs	546	1 (0.2%)	31 (6%)	206 (38%)	308 (56%)
2005		815	4 (<1%)	33 (4%)	188 (23%)	590 (72%)
2000	Preventable	276 (50%)	1 (0.4%)	25 (9%)	145 (52%)	105 (38%)
2005		338 (42%)	3 (1%)	24 (7%)	110 (32%)	201 (60%)

NEAR MISSES IN CARE HOMES

Patient safety experts suggest that reporting and investigating near-misses are as important as reporting and investigating ADEs (Barach and Small, 2000a, 2000b; Firth-Cozens, 2002; Lawton and Parker, 2002; Reinertsen, 2000). Approximately 8 million adverse events occur in nursing homes in the US each year (Gabrel and Jones, 2000; Gurwitz et al., 1994), and near-misses are thought to occur 7-700 times more frequently than adverse events (Erikson et al., 2003). Near miss incidents can provide valuable information that cannot always be captured from adverse event reporting systems (Sheikhtaheri, 2014).

Near-misses, also known as potential harms from medicines, are incidents that did not cause harm but which are judged to have had the potential to cause harm. These incidents provide valuable insight into areas of risk and where systems can be improved to prevent death or harm (NPSA, 2007).

Near-misses are also thought to have similar root causes to adverse events, hence experts believe monitoring near-miss events helps in root-cause analysis (Barach, 2011; Kaplan, 2003). Root cause analysis is the practice of using formal analysis to identify the root causes of problems or events (Harich and Rosas, 2019). Monitoring near-misses can identify potential system failures, rather than targeting single events (ADEs) which often leads to faulting individuals (Wagner et al., 2006). Therefore, it is important to monitor near-misses within medicines management processes, including the 28-day supply of medicines cycle within care homes and identify system failures proactively according to the near-miss data, rather than reactively after an ADE has occurred.

Furthermore, patient safety experts encourage reporting of near-misses to reduce barriers in reporting adverse drug events and help improve patient safety (Barach and Small, 2000a, 2000b; Firth-Cozens, 2002; Lawton and Parker, 2002; Reinertsen, 2000).

Wagner et al. scoped existing literature in a variety of industries to determine near-miss reporting procedures and benefits (Wagner et al., 2006). The authors identified examples and uses behind each system depicted in table 2 (Wagner et al., 2006).

Table 2: Near Miss Reporting System Examples, information collated from (Wagner et al., 2006)

Name of Near Miss Reporting System American Industry & System Attributes	**Uses**
Aviation Safety Reporting System (ASRS) Airline Industry - created by the National Aeronautics and Space Administration (NASA) - anonymous, voluntary reports from airline workers	- processes between 35,000 – 40,000 near-miss events each year - system has provided: effective redesign of aircrafts, air traffic control systems, pilot training - improved airline safety
Medical Event Reporting System – Transfusion Medicine (MERS-TM) Medical: Blood Transfusion & Anaesthesia - menu-driven online database - organisation must register	- improvement in anaesthesia mortality rates from 2 deaths per 10,000 patients (year 1980) to 1 death per 200,000 to 300,000 patients (year 2000) - includes a root-cause analysis and assignment of the near-miss event into standardised codes to describe the event - generated patterns of errors and data for quality improvements - ability to identify where underlying problems are within system processes
Patient Safety First – Safety Net Peri-Operative Nursing - created by the Association of (peri)Operative Registered Nurses (AORN) - online submission - anonymous, voluntary reporting	- aims to identify strategies to use to prevent adverse events in peri-operative settings
Patient Safety – Reporting System (PSRS) Department of Veterans Affairs - paper-based mailed submissions - voluntary reporting	- helps in policy development and research
Fire Fighter Close Call Reporting System Firefighters - International Association of Fire Chiefs and NASA - online system - confidential, voluntary reporting - reporting without fear of punishment - six categories based on type of near-miss (e.g. training, rescue)	- helps in policy development and research

Many types of near-misses occur in nursing homes, however there are currently no near-miss reporting systems in the UK present in the literature (Wagner et al., 2006), apart from the reporting of near-falls (a type of near-miss) to help determine strategies to prevent future fall incidents (Wagner et al., 2006). An example of a near-miss associated with medication is a nurse discovering the wrong dose of medication was sent from the pharmacy, which could have resulted in a serious adverse event (Wagner et al., 2006).

In North Carolina, all nursing homes must report medication errors annually. In North Carolina, 17.2% (n=1881) of medication errors were reported as near-misses and the primary type of all errors (actual and near-misses) was 'dose omission' at 49.7% (Greene et al., 2004). The study also found that the larger the number of documented medication errors, the greater the number of reported near-misses in nursing homes and that organisations with high reporting rates tend to be more safety conscious (Greene et al., 2004). Nursing homes with low near-miss reporting are less likely to have processes in place to identify and evaluate errors or have decided that certain common errors, such as missed doses, late doses or near-misses are not actually 'errors' (Greene et al., 2004).

Greene et al. listed prevalence of phases in the medication process involved in errors as: administration (56.2%), documentation (37.4%), prescribing and monitoring together (3.0%) (Greene et al., 2004). Then examining personnel involved: licensed practical nurse (54.0%), registered nurse (29.4%), pharmacists (6.9%) and physicians (4.3%) (Greene et al., 2004). Finally, contributing factors from the study are listed in the table below, with policies and procedures listed as the second most prominent at 17.3% (Greene et al., 2004).

Table 3: Contributing Factors to Errors in the Medication Process (Greene et al., 2004)

TABLE 3: CONTRIBUTING FACTORS

Contributing Factors	No. of Responses	Percent Responses
Frequent distractions	5,149	40.8%
Policies and procedures	2,185	17.3%
Workload increase	1,287	10.2%
Inadequate information	923	7.3%
Contract staff	904	7.2%
Pharmacy dispensing	776	6.2%
Improper training	583	4.6%
Shift change	372	2.9%
Illegible handwriting	299	2.4%
Emergency situation	79	0.6%
Poor lighting	57	0.5%
TOTAL RESPONSES	**12,614**	**100.0%**

Regardless of the type of error or near-miss, there is a lack of reporting from all healthcare settings worldwide (NHS Improvement, 2019; Shojania, 2008). However, the number of incidents that are reported has been increasing. For example, from October to December 2003, only 153 incidents were reported to the NRLS in total (NHS Improvement, 2019), whereas from the July to September 2018, 488,242 incidents were reported as discussed previously (NHS Improvement, 2019).

Reason (2000) provides two ways of viewing errors. Human (also known as active) errors are when individuals commit either a slip or a mistake, including omission (knowing what to do but doing nothing) and commission (inadvertently doing the wrong thing). Alternatively, system errors (also known as latent errors) are consequences of technical design or organisational issues and decisions (Reason, 2000). Reason's theory of error causation suggests that system and human errors are linked; if there are system errors then individual errors are more likely to occur (Reason, 2000).

Accidents and adverse events happen from a combination of system and human error, therefore making it imperative to examine human factors and underlying system problems contributing to error (Battles et al., 1998). Vincent et al. (Vincent et al., 2000) suggest organisational factors have a greater role than individual failure in causing medication error. The systems error approach for error management has two components: limiting the incidence of errors, and creating systems that can better tolerate the occurrence of errors, containing any damaging effects (Reason, 2000).

The system of medicines management in care homes must be safe and accurate to sustain safe administration of medication to residents. Care homes in the UK follow a 28-day supply of repeat medicines cycle (NICE, 2014). The cycle is designed to have the correct medications and instructions for residents and nurses ready for the beginning of each cycle. Errors within the medicines management cycle can be near-misses, with potential to lead to ADEs.

A safe 28-day supply of medicines cycle should have no system errors, and therefore a smaller chance of human error occurring (Reason, 2000), ultimately decreasing the amount of potential medication errors at the administration stage. Therefore, a safe 28-day supply of medicines cycle should ensure less chance of adverse events occurring and fewer near misses being caught at the end of the medicines process, the administration stage. Exploring the 28-day supply of medicines cycle will provide data on the system, and near-miss root causes within the process and some ADEs, potentially providing insight into methods to improve system safety and efficiency. Although this study's results have not provide detailed insights or recommendations on the medicines administration phase, the

study has provided details and recommendations on the other stages of the 28-day supply of medicines cycle in order to ultimately reduce the margin for error within the administration phase.

By reporting and examining near-misses, organisations can learn about failures in their processes of care (Affonso and Jeffs, 2004), therefore supporting appropriate changes in the medication process on site to address any problem areas identified. Greene et al. (Greene et al., 2004) recommends a Continuous Quality Improvement (CQI) model to improve near-miss reporting, recognising that adverse events usually result from errors in processes as opposed to individual staff member behaviours.

As medicines management is a crucial component to running a safe and successful care home, this study aims to understand the 28-day supply of medicines cycle. In doing so, the researcher hopes to identify existing near-misses and how they are rectified within the cycle, as well as examine system errors (if any) contributing to near-misses within the cycle. The following section of the narrative literature review will discuss published literature and policies concerning medicines management and the 28-day supply of medicines cycle in care homes.

The following section of this literature review first defines medication management within care homes, then describes the 28-day supply of medicines cycle according to current published policies.

MEDICINES MANAGEMENT IN CARE HOMES

Medications must be managed in a safe, competent, ethical and therapeutic manner by all stakeholders involved, including GPs, pharmacists, nurses and carers (CNO, 2008). Medicines management is defined as:

> *the entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to producing informed and desired outcomes of patient care (Audit Commission, 2001).*

In the most recent NICE guideline on 'Managing medicines in care homes,' published March 2014, updated January 2018, medicines management is considered to include the following topics: 'prescribing, handling and administering medicines to residents living in care homes and the provision of care or services relating to medicines in care homes,' depicted by figure 2 (NICE, 2014). Similar to

the figure depicted below by NICE, Stowasser et al. (Stowasser et al., 2004) describes medicines management as a closed loop pathway where all processes are interdependent and applicable to all medicines, settings and healthcare professionals involved as well as the funding source (Stowasser et al., 2004).

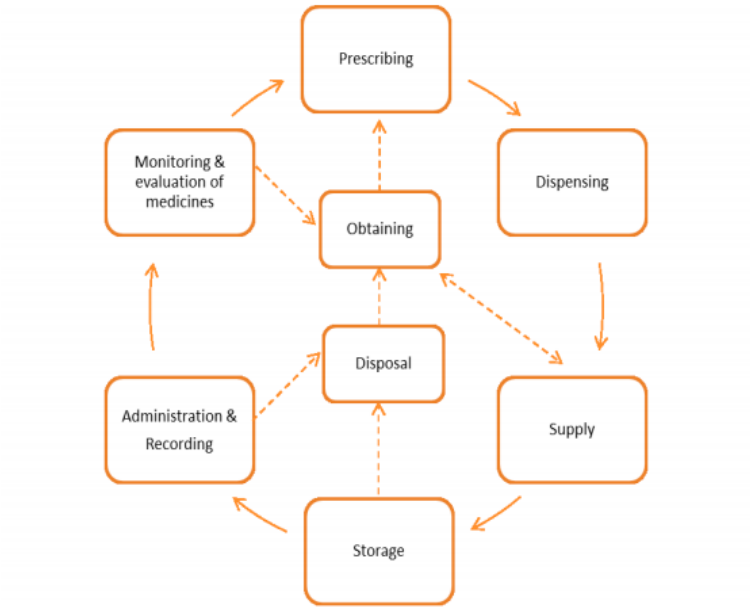


Figure 2: Overview of medicines management system, taken from NICE Guideline 'Managing medication in care homes' (NICE, 2014)

Care homes each have their own medicines management system, however the general tasks are as follows: [1] ordering, [2] prescribing, [3] dispensing and supply, [4] storage, [5] administration of medicine to resident and [6] monitoring of effect of medicines (Alldred et al., 2009), all encompassed in a 28-day supply of medicines cycle (NICE, 2014). A key component common to each task above is relevant documentation (Alldred et al., 2009). This study has chosen to focus on one process of medicines management within care homes, the 28-day supply cycle of medicines.

Nurses spend approximately one third of their scheduled time per shift in long term care to administer medications (Thomson et al., 2009), however how nurses manage medications in long term care remains unclear (Ellis et al., 2012). Multiple authors have expressed the view that nursing practice and system structure issues may be barriers to safe medication management (Baker et al., 2007; Dilles et al., 2011; Forster, 2006).

Ellis et al. (Ellis et al., 2012) describe some of the barriers to medicines management within Canadian care homes as: lack of time, executive documentation, nurse position in hierarchical and blaming

culture, lack of medication knowledge, poor communication among providers, complexity of residents, refusal of medicines, and interruptions (Ellis et al., 2012).

To describe the cycle in greater detail, the subsequent section outlines the prescription to medication pathway between stakeholders involved in supplying medicines to care home residents, then discusses each task within the cycle (prescribing, ordering, dispensing and supplying).

THE 28-DAY SUPPLY OF MEDICINES CYCLE

Alldred et al. (2009) created the flowchart below to depict the typical pathways for requested medications for care home residents. The flowchart also identifies which processes are and are not recommended by the RPSGB (Alldred et al., 2009). Throughout this section of the literature review, the prescription to medication pathway between stakeholders involved in supplying medicines to care home residents will be explained, alongside the 28-day supply of medicines cycle (prescribing, ordering, dispensing and supplying).

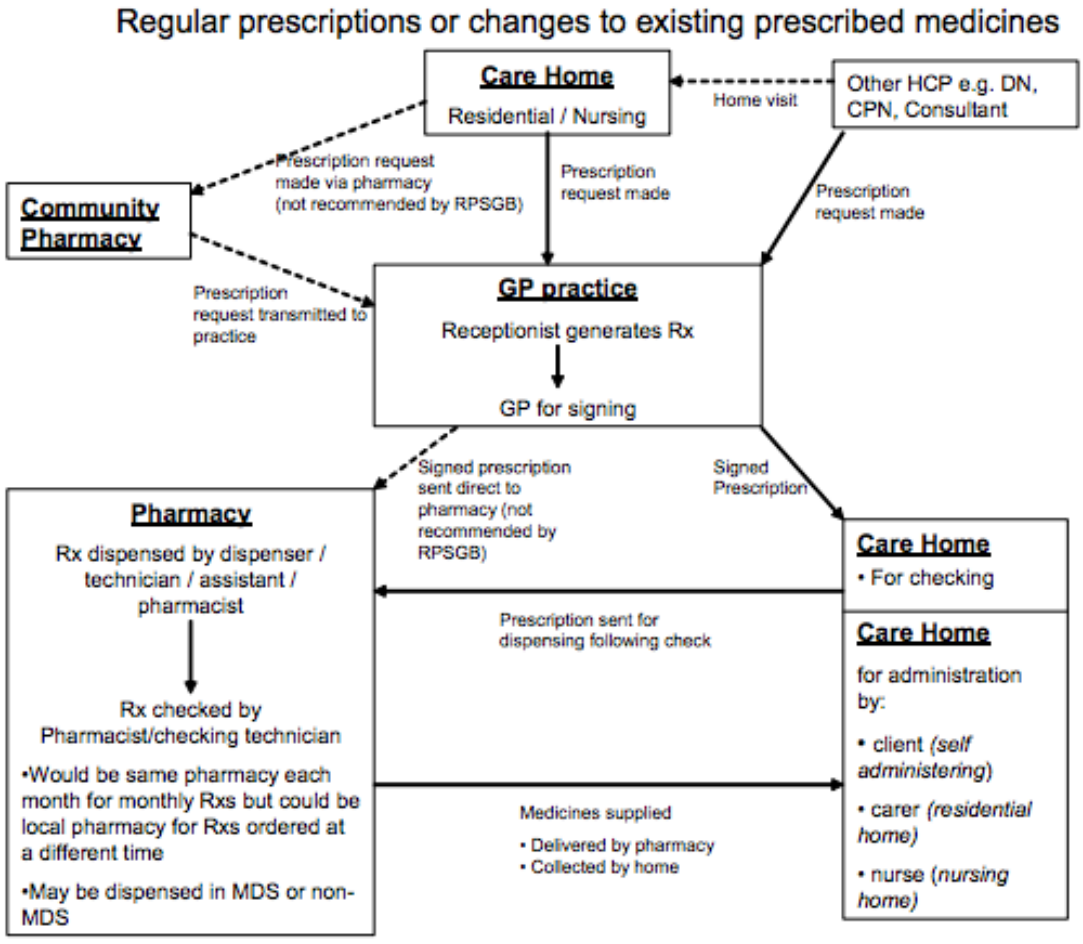


Figure 3: Flowchart for regular prescriptions, taken from CHUMS Report (Alldred et al., 2009).

a. Prescribing

Issuing prescriptions requires the GP practice receptionist to identify each medicine requested and have an up-to-date patient medical record (NICE, 2014). The receptionists at the practice prepare the prescriptions for the doctor to sign using the GP computer system which lists all current authorised repeats for individual patients (Cox et al., 1999). The GP receptionists identify each drug requested by the home and then print off the prescription forms or release them on the computer system for the GP to sign off electronically (Alldred et al., 2009; Price et al., 2017).

The medication must be 'authorised' on the computer system as a repeat by a doctor for it to be selected by a receptionist (Cox et al., 1999; Price et al., 2017). The review interval for the patient must also not have been passed to authorise repeats (Alldred et al., 2009). Accurate repeat prescriptions are therefore based on the doctor having initially authorised each item accurately as there is no detailed check by the doctor signing off repeat prescriptions (Alldred et al., 2009; Avery, 2011; Price et al., 2017). Receptionists in some practices express concern that doctors do not check prescriptions thoroughly before signing and therefore believe they have heavy responsibilities to undertake safety checks themselves, as receptionists (Avery, 2011; Swinglehurst et al., 2011).

Finally, for release of the prescription, the doctor must sign the prescription(s), which does not always involve reviewing the patient medical records (NICE, 2014). The NICE Guideline further mentions that there are only few written processes for GP practice receptionists to follow when generating prescriptions requested by care home staff during the ordering process for GPs to sign (NICE, 2014).

There is generally an arrangement with the GP surgery to provide repeat prescriptions every 28 days (Alldred et al., 2009), a cycle during which medicines are prescribed, ordered, dispensed and supplied (NICE, 2014). In the January 2018 update of the NICE Guideline, the Guideline Development Group (GDG) concluded that GP practices should have written processes for prescribing and issuing prescriptions for their patients living in care homes that consider the following:

- *issuing prescriptions according to the patient medical records*
- *recording clear instructions on how a medicine should be used, including how long the resident is expected to need the medicine and, if important, how long the medicine will take to work and what it has been prescribed for (use of the term 'as directed' should be avoided)*

- *recording prescribing in the GP patient medical record and resident care record and making any changes as soon as practically possible*
- *providing any extra details the resident and/or care home staff may need about how the medicine should be taken*
- *any tests needed for monitoring*
- *prescribing the right amount of medicines to fit into the 28-day supply cycle if appropriate, and any changes that may be needed for prescribing in the future*
- *monitoring and reviewing 'when required' and variable dose medicines*
- *issuing prescriptions when the medicines order is received from the care home.*

Above taken directly from the NICE Guideline on 'Managing Medicines in Care Homes' – Recommendation 1.9.1 (NICE, 2014).

Furthermore, the NICE Guideline outlines measures of good practice for the prescriber to follow when issuing prescriptions for variable doses and 'when required' medicines:

- *note in the resident's care record the instructions for: – when and how to take or use the medicine (for example, 'when low back pain is troublesome take 1 tablet') – monitoring – the effect they expect the medicine to have*
- *include dosage instructions on the prescription (including the maximum amount to be taken in a day and how long the medicine should be used, as appropriate) so that this can be included on the medicine's label*
- *prescribe the amount likely to be needed (for example, for 28 days or the expected length of treatment)*
- *liaise with care home staff to see how often the resident has had the medicine and how well it has worked.*

Above taken directly from the NICE Guideline on 'Managing Medicines in Care Homes' – Recommendation 1.9.2 (NICE, 2014).

Finally, the NICE Guideline concludes that a collaborative approach between health and social care practitioners is needed to ensure effective communication when medicines are started, stopped or changed, and keeping records up-to-date within the care home. Further recommendations in relation to prescribing medicines for care home residents can be found in the NICE Guideline, section 3.9 (prescribing medicines).

b. Ordering

As seen from the flowchart at the beginning of this section (figure 3, page 30), there are typically two pathways in which prescribing and ordering prescriptions takes place: the community pharmacy making a prescription request on behalf of the care home directly to the GP practice or the care home requesting the prescription directly from the GP surgery (Alldred et al., 2009). NICE Guidelines and the RPSGB suggest the care home should order medicines from the GP practice, rather than the supplying pharmacy carrying responsibility for ordering medicines as it can result in overstock of resident medications (Alldred et al., 2009; NICE, 2014).

NICE Guideline states that medicines can be ordered in the following ways:

- *the home orders directly from the GP practice using the repeat prescription ordering form (also known as the 'right-hand side' of the prescription form [FP10]) (see figure 4)*
- *the home orders directly from the GP practice using the medicines administration record*
- *through the supplying pharmacy, with the pharmacy ordering prescriptions after visiting and/or consulting with the care home*
- *through the supplying pharmacy, with the pharmacy ordering prescriptions directly from the GP practice without contacting the care home*

Above taken directly from the NICE Guideline on 'Managing Medicines in Care Homes' (NICE, 2014).

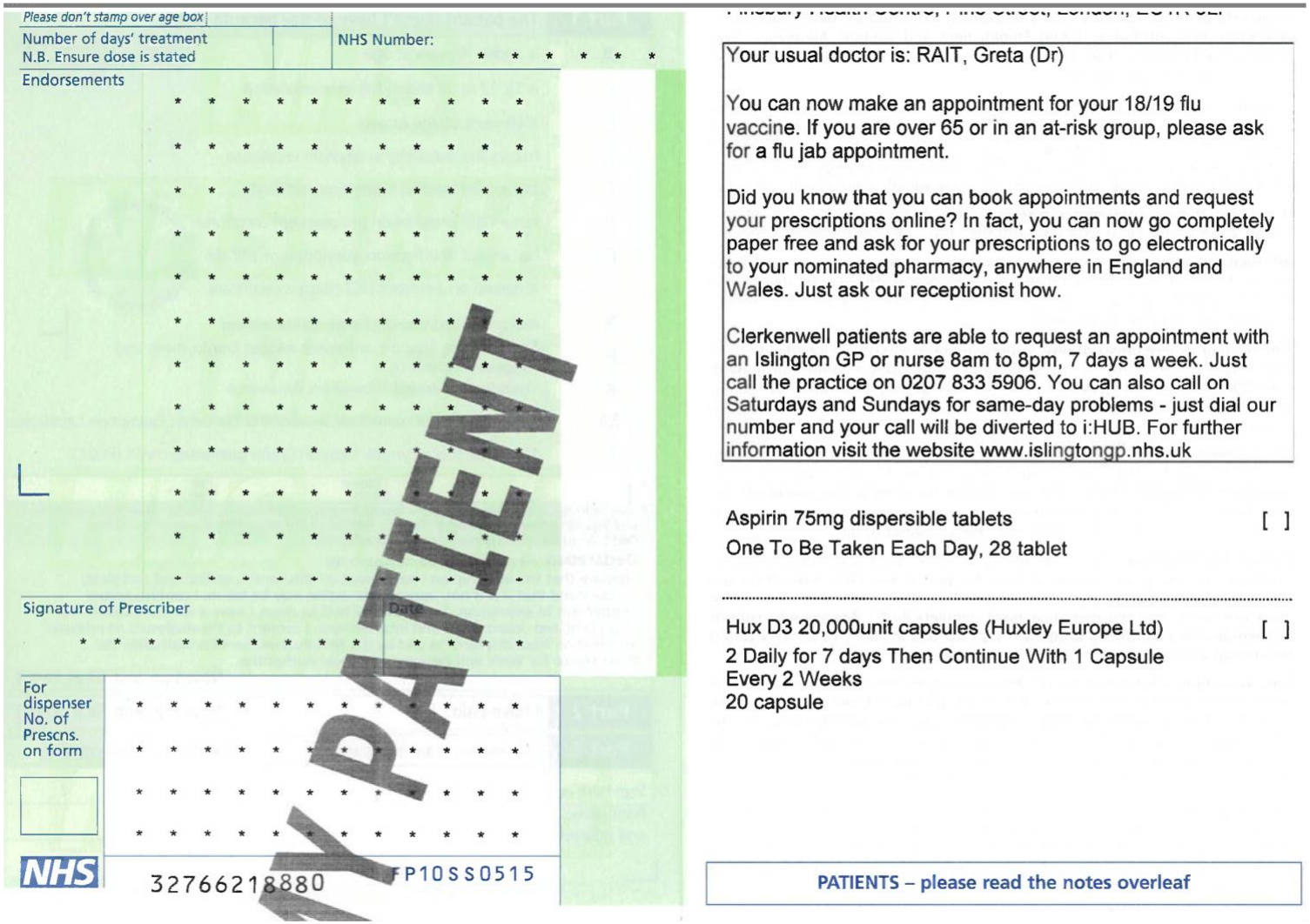


Figure 4: Right-hand side of FP10 prescription, depicting a typical 'repeat slip'

Ad-hoc medicines include any medication the resident is temporarily on or prescribed on a 'when required' basis as well as any additions to resident medication between monthly supplies of existing medicines can be dealt with in various ways (Jokanovic et al., 2016). The home may fax the prescription to the usual pharmacy, the GP practice may contact the pharmacy with the prescription, the home may request a medication to the usual pharmacy by telephone or a GP can telephone in a request to the pharmacy, or the prescription is taken to the nearest pharmacy which often can be the pharmacy the home deals with primarily (Alldred et al., 2009).

It is the care home's responsibility to update the pharmacy on medication changes including: stopped medications, changed frequencies in administration and adverse drug events (AWMSG, 2015; NICE, 2014). It is good practice for care home staff to have records including: copies of prescriptions, stock order or requisition note, when ordering medicines to allow care home staff to check all medicines requested have been prescribed and supplied as ordered, when receiving the medicines into the care home (NICE, 2014).

The NICE Guideline indicates the following recommendations for the care home medicines ordering process:

- *Care home providers must ensure that medicines prescribed for a resident are not used by other residents.*
- *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.*
- *Care home providers should ensure that at least 2 members of the care home staff have the training and skills to order medicines, although ordering can be done by 1 member of staff.*
- *Care home providers should retain responsibility for ordering medicines from the GP practice and should not delegate this to the supplying pharmacy.*
- *Care home providers should ensure that records are kept of medicines ordered. Medicines delivered to the care home should be checked against a record of the order to make sure that all medicines ordered have been prescribed and supplied correctly.*

Above taken directly from the NICE Guideline on 'Managing Medicines in Care Homes' – Recommendation 1.10.1 – 1.10.5 (NICE, 2014).

When the prescription is ready at the GP practice, it is either sent directly to the pharmacy (not recommended by the RPSGB, as the care home should ideally check the prescription before sending it to the pharmacy) or sent to the care home to be checked and then the care home sends this prescription to the pharmacy for dispensing (Alldred et al., 2009). Some care homes will have a specific attachment to one general practice, meaning residents will have the choice to move to the linked GP or retain their own (Donald et al., 2008). Donald et al. (2008) reported that around 85% of residents opt for the linked GP. However, the current recommendation by the NHS is for each care home to be associated with one GP surgery (NHS England, 2016).

The GP practice, pharmacy and care home may have electronic systems with connected interfaces, therefore allowing to send messages from one organisation to the other. However, these systems are not synchronised, meaning each stakeholder does not have access to each other's computer records therefore providing an obstacle to all stakeholders and adding to the complexity of the medicines management system (Alldred et al., 2009; Burns and McQuillan, 2011; MED e-care, 2018). Therefore, a stopped medication or change in medication or dosage may not be transmitted to all stakeholders at the same time or at all, which can result in errors (Burns and McQuillan, 2011).

c. Dispensing and Supplying

The dispensing process covers the following activities at the supplying pharmacy: [1] receiving and validating the prescription, [2] clinically checking the prescription, [3] preparing the label and selecting items for issue, [4] making a final accuracy check, and [5] issuing the medicine with necessary instructions (NICE, 2014).

Care homes usually obtain their medicines from one pharmacy, however, some homes will deal with one pharmacy for all repeat prescriptions, another pharmacy for ad-hoc items that are needed as soon as possible or not on a monthly basis (e.g. antibiotics or temporary pain relief), and occasionally medicines from secondary care (e.g. hospital pharmacy) (Burns and McQuillan, 2011; RPSGB, 2016).

If the supplying pharmacy is producing and supplying the medicines administration record, the pharmacist's clinical check of prescriptions should include a review of both the prescription and medicines administration record (NICE, 2014). This allows for double checking of dose and dose changes, frequency and times, duplicate entries, review of new medicines and possible interactions with existing medicines (NICE, 2014).

The supplying pharmacy provides the care home with medications packaged in one of two ways: original packs or monitored dosage systems (MDS), available as single-dose or multi-dose.

MDS is a medication storage device designed to simplify the administration of solid oral dose medication (NHS Northamptonshire Trust, 2010). Figure 5 is an example of a multi-dose MDS, in which all medications taken at breakfast, lunch, dinner or bedtime are within one compartment. Figure 6 is a single-dose MDS, in which each card is made up of 28 blisters, each one containing the same medication, to be administered at the same time every day. Each pack is usually a specific colour, represent the time of day to administer the medication. Advantages and disadvantages of using original packs and MDSs are shown in table 4 (NICE, 2014).

Figure 5: Example of a multi-dose MDS

Figure 6: Example of a single-dose MDS

	Monitored dosage systems	Original packs
Advantages (Supply)	• 'added value' element of supply by the pharmacy	• better use of pharmacist's time • re-packaging not required
Disadvantages (Supply)	• not all medicines suitable, including stability issues • possibility of bacterial contamination • re-packaging may often be unlicensed • lack of evidence to support use • pharmacies not reimbursed for use of monitored dosage systems • robust filling and checking procedures required • time consuming to fill and check • issues with variable doses, short courses, once-weekly medicines • issues with medicines started mid-cycle or interim medicines • all labels may not fit on the monitored dosage system	• packaging may be too bulky
Advantages (Administration)	• provide an additional 'visual safety check' to care home staff compared to original packs, when they have been trained to use it correctly • facilitate self-administration and compliance	• maintains resident dignity and independence • the resident is taking the medicine as they would do in their own home • not being re-dispensed (potentially then in an unlicensed form) • take up less space compared with monitored dosage systems • patient information leaflet enclosed in original pack supporting medicines information requirements/needs • resident can see the original pack (identification purposes) • less waste • may be beneficial for patients who go on short-term leave/utilise day services • easier to amend medication following changes (for example, dose changes or if the medicine is stopped) • lower risk of bacterial contamination
Disadvantages (Administration)	• there may be over reliance on monitored dosage systems that may deskill care home staff – e.g. overlooking high-risk medicines, failing to look at the label and description of medicine • difficulties if medicines are stopped, need to be omitted, or to identify if they are being given in an unlicensed way, if a monitored dosage system contains all medicines in single blister • requires two systems to be used, monitored dosage system and original packs for acute and 'when required' medicines • arrangements need to be made for those on short leave from care home	• can be more difficult to keep track of which medications need to be administered • potentially takes longer to take tablets out of original boxes and administer to residents • one study found a significantly higher rate of medication administration errors from original packs (9.3%) compared to multi-compartment compliance aids (3.1%) (Gilmartin-Thomas et al., 2017)

Table 4: Advantages and Disadvantages of Monitored Dosage Systems versus Original Packs from (Adams et al., 2013; Bhattacharya, 2005)

Although the MDS is efficient in organising most repeat medicines into daily and timed intervals, it is not compatible with all types of medications (Alldred et al., 2009). For example, liquids cannot be added into an MDS, as well as buccal, sublingual and dispersible dosage forms because instructions cannot be applied for only one medication in the MDS compartment (Bhattacharya, 2005). Additionally, hygroscopic and photosensitive medications cannot be added into an MDS (Bhattacharya, 2005). A common example of a medicine incompatible with MDS is dispersible (soluble) aspirin.

Care home providers should consider the most suitable medicines supply system for each resident. This involves taking a person-centred approach and aim to maintain each resident's independence and needs (NICE, 2014). Any ad-hoc medicines are usually supplied separately to the MDS, meaning most residents are using both the MDS system and original packaging system.

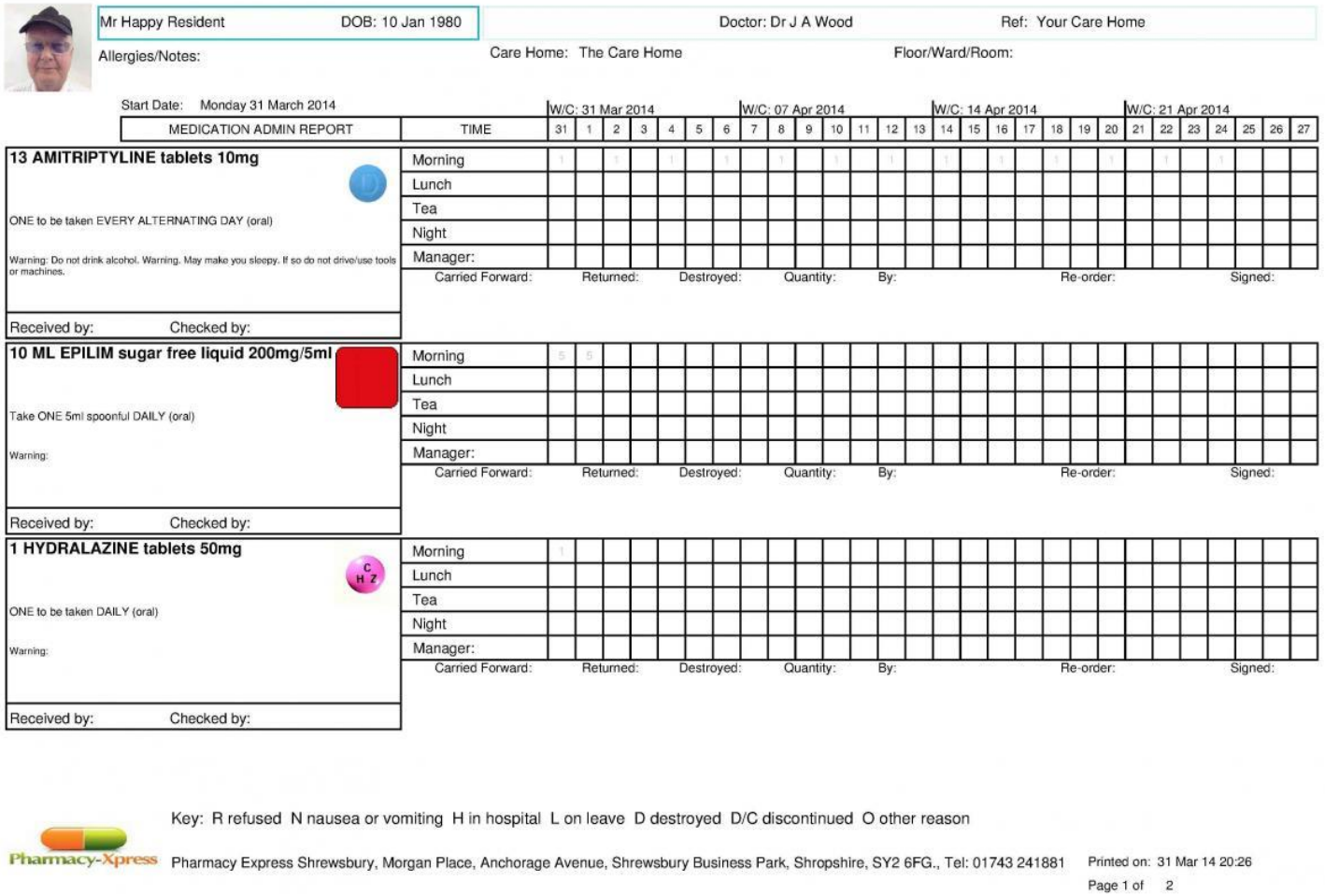
Further to supplying resident medications, the supplying pharmacy often provides medicines administration records (also known as MAR sheets or MAR charts) to the care home (NICE, 2014). MAR charts are used to record the administration and non-administration of medicines in care homes (NICE, 2014) as an electronic document or paper-based document.

MAR charts are a list of medicines an individual is taking. A MAR chart details when the medication should be administered and allows for the person giving the medication to record if the medicine was administered or not. See figure 7 and 8 for examples of a MAR chart. The chart usually accounts a 28-day cycle for one resident, highlighting repeat medicines, ad-hoc, and 'when required' medicines. MAR charts are commonly used within care homes, and are either produced electronically by the pharmacy dispensing the residents medication or hand-written by the home (Gilmartin-Thomas et al., 2017; NICE, 2014; RPSGB, 2009).

Any ad-hoc medicines started between the monthly supplies, will usually be added to the MAR chart by care home staff, usually a trained nurse (Camphill School Aberdeen, 2013). Evidence shows MAR charts produced by the pharmacy are more efficient as they avoid transcription errors and difficult to read handwriting (Alldred et al., 2009). The process is also timely compared to home staff manually preparing MAR charts (CPA, 2014).

The overall responsibility of producing and keeping MAR charts is of the care home provider, however many supplying pharmacies create and supply the MAR charts on the request of the care home

provider (NICE, 2014). Regardless of how the MAR chart is prepared, a process should be in place to check the details of each MAR chart are correct and signed off by a second person before use (NICE, 2014). The GDG discussed and concluded that whenever possible medicines administration records should be produced by the supplying pharmacy (NICE, 2014).



Mr Happy Resident DOB: 10 Jan 1980 Doctor: Dr J A Wood Ref: Your Care Home

Allergies/Notes: Care Home: The Care Home Floor/Ward/Room:

Start Date: Monday 31 March 2014

MEDICATION ADMIN REPORT | TIME | W/C: 31 Mar 2014: 31 1 2 3 4 5 6 | W/C: 07 Apr 2014: 7 8 9 10 11 12 13 | W/C: 14 Apr 2014: 14 15 16 17 18 19 20 | W/C: 21 Apr 2014: 21 22 23 24 25 26 27

13 AMITRIPTYLINE tablets 10mg

ONE to be taken EVERY ALTERNATING DAY (oral)

Warning: Do not drink alcohol. Warning. May make you sleepy. If so do not drive/use tools or machines.

Morning
Lunch
Tea
Night
Manager:
Carried Forward: Returned: Destroyed: Quantity: By: Re-order: Signed:

Received by: Checked by:

10 ML EPILIM sugar free liquid 200mg/5ml

Take ONE 5ml spoonful DAILY (oral)

Warning:

Morning
Lunch
Tea
Night
Manager:
Carried Forward: Returned: Destroyed: Quantity: By: Re-order: Signed:

Received by: Checked by:

1 HYDRALAZINE tablets 50mg

ONE to be taken DAILY (oral)

Warning:

Morning
Lunch
Tea
Night
Manager:
Carried Forward: Returned: Destroyed: Quantity: By: Re-order: Signed:

Received by: Checked by:

Key: R refused N nausea or vomiting H in hospital L on leave D destroyed D/C discontinued O other reason

Pharmacy-Xpress

Pharmacy Express Shrewsbury, Morgan Place, Anchorage Avenue, Shrewsbury Business Park, Shropshire, SY2 6FG., Tel: 01743 241881 Printed on: 31 Mar 14 20:26

Page 1 of 2

Figure 7: Example of a MAR chart

Medication Administration Record for: Harry Test

Address: **1942517, Address Line 1, Address Line 2, POST CODE**

DOB: **10/4/1930** Room Number: Doctor:

From: **07/09/2009** to **04/10/2009** Period: **28** Start Day: **Monday**

Page No: **1 / 1**

Allergies:

Medication Details	Time	Dose	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	1	2	3	4
Simvador 40mg tablets Take ONE at night	0900	0																												
	1200	0																												
	1700	0																												
	2100	1																												

Quantity: 28	Qty Received:	By:	Started:	Qty Returned:	By:	Qty Destroyed:	By:
Quantity:	Qty Received:	By:	Started:	Qty Returned:	By:	Qty Destroyed:	By:
Quantity:	Qty Received:	By:	Started:	Qty Returned:	By:	Qty Destroyed:	By:
Quantity:	Qty Received:	By:	Started:	Qty Returned:	By:	Qty Destroyed:	By:
Quantity:	Qty Received:	By:	Started:	Qty Returned:	By:	Qty Destroyed:	By:
Quantity:	Qty Received:	By:	Started:	Qty Returned:	By:	Qty Destroyed:	By:
Quantity:	Qty Received:	By:	Started:	Qty Returned:	By:	Qty Destroyed:	By:

KEY:

Control Group **Control Group Control Control**

Figure 8: Example of a MAR chart

Once all repeat prescriptions have been dispensed and checked in the pharmacy, someone from the pharmacy delivers the medications or a care home staff member collects them from the pharmacy, as depicted in the flowchart at the beginning of this section (figure 3, page 30) (Alldred et al., 2009). As seen from figure 3, page 30, the system is complex with varying routes for each stakeholder to take during the multiple steps of the system.

It should be noted that the NICE Guidance, CHUMS study and the RPSGB guidance all pre-date the move to e-prescribing, which is being used more in medicines management within care homes. E-prescribing has changed some of the processes within the 28-day supply of medicines cycle. For example, the direct electronic transfer of prescriptions from the GP surgery to pharmacy, rather than a paper prescription picked up by pharmacy or care home staff. In contrast to previous guidance on the 28-day supply of medicines, this study has observed some of the processes of e-prescribing in the management of the 28-day supply of medicines cycle and depicts a realistic view of the process taking place and tasks within the cycle. Care homes, GP surgeries and pharmacies often used a combination of e-prescribing and paper-based techniques within the cycle.

GAPS IN THE LITERATURE

Apart from the NICE Guideline, CHUMS study and RPSGB recommendations, there is limited literature on the overall organisation of the entire 28-day supply of medicines cycle within the medication management process in care homes. Therefore, 'observational data about the current status of medication management processes in nursing homes are needed for the development of targeted quality improvement actions in this setting' (Verrue et al., 2011).

The CHUMS study and NICE Guidelines suggest repeat medications follow a 28-day supply cycle of medicines (Alldred et al., 2009; NICE, 2014), during which medicines are prescribed, ordered, dispensed and supplied (NICE, 2014). Both documents successfully outline the general tasks within each stage, and NICE Guidelines provide a broad set of recommendations during each stage.

Although the CHUMS study and NICE Guidelines have provided a description of the 28-day supply of medicines cycle, research thus far has failed to demonstrate the detail behind the cycle, including its timeline for specified tasks (prescribing, ordering, dispensing and supplying) within the cycle or recommended framework for policy makers and care home managers to employ.

Errors occurring directly to care home residents within processes in the medicines management cycle have been investigated and reported. The CHUMS study investigated significant errors arising in terms of prescribing, monitoring, dispensing or administration errors relating to medications, both acute and repeat, for care home residents. There is currently limited research examining ADEs or near-misses occurring during the repeat medications management cycle, that may or may not reach a resident (as the errors may be picked up during the process, before being administered or reaching the administration stage).

As experts suggest, reporting and examining near-misses throughout any medicines process can provide insight into system errors, human errors and associated problems (Battles et al., 1998; Reason, 2000), including patterns of near-misses and ADEs (Barach and Small, 2000a, 2000b; Firth-Cozens, 2002; Lawton and Parker, 2002; Reinertsen, 2000; Sheikhtaheri, 2014). Furthermore, there is a lack of use of management techniques such as Six Sigma in the care home environment or throughout the medicines management process (Six Sigma in healthcare is discussed in Chapter 5). Therefore, studies are needed to examine the 28-day supply of medicines cycle for repeat prescriptions within care homes, and to determine the level of process efficiency and number of errors occurring within the cycle, and its impact on all stakeholders involved, including care home residents.

The 28-day supply cycle of medicines is a vital process within any care home and contributes to every home's management of medicines. As the care home setting has been largely ignored in comparison to other healthcare settings, as well as in understanding medicine management processes and error rates, the researcher aims to bridge this gap. This study therefore aims to provide an in-depth understanding of the 28-day supply of medicines cycle and examine the near-miss rates occurring during the cycle (if any) by using the Six Sigma management technique. The use of Six Sigma will analyse how current discrepancies (near-misses) are dealt with and possible ways to improve the management of these discrepancies (near-misses). Identifying near-misses throughout the 28-day supply of repeat medicines cycle may provide information on patterns of ADEs within care homes, system and human errors.

SUMMARY

Medication errors within the setting have been explored by few studies, however studies do not capture the rates of near-misses occurring throughout the 28-day supply of medicines cycle. Patient

safety experts suggest recording and understanding near-misses is as important as reporting and understanding adverse drug events and non-adverse drug events.

Repeat management is a component of medicines management and is run through the 28-day supply of medicines cycle. Understanding this cycle may shed light onto medication errors within care homes, specifically near-misses, which may also provide information on non-adverse drug events and adverse drug events within care homes.

There are currently no studies providing an in-depth examination of the 28-day supply of repeat medications cycle within care homes. Current literature therefore does not provide readers with a clear understanding of the complexity of the 28-day supply of medicines cycle. Without this understanding, experts cannot determine if there are concerns of efficiency or safety within the cycle, and how these concerns may be alleviated.

Furthermore, the use of management techniques such as Six Sigma have been proven successful in providing efficient healthcare services. As no studies in current literature have examined the 28-day supply of medicines cycle in care homes using Six Sigma, this study aims to bridge this gap using Six Sigma techniques to examine and improve the cycle's efficiency. The subsequent chapter discusses how the method was employed by the researcher to answer the first research question.

CHAPTER 3

METHODOLOGY

Chapter 3 discusses the methods employed and appropriateness of the study design. The researcher used semi-structured interviews, direct participant observations and stakeholder feedback sessions to form the qualitative explorative multi-case study. The chapter also includes a discussion about the selected population, data sampling, informed consent, confidentiality, geographic location, instrumentation, and triangulation. This chapter describes the methods employed in sufficient detail, allowing a reader to repeat them.

Chapter 3 also includes data collection methods and data analysis procedures. Under data analysis procedures, the researcher briefly discusses qualitative data analysis methods and rationalises the use of Framework Analysis. The final section of the chapter applies the five stages of Framework Analysis, providing a methodology framework on page 65. Finally, the chapter concludes with factors to take into consideration when evaluating the results of the study, including: validity and reliability.

QUALITATIVE RESEARCH METHOD

The most common research methods are quantitative, qualitative and mixed methods (Bryman, 1984; Creswell and Clark, 2011; Tashakkori and Teddlie, 2002). Quantitative methods have a long history of scientific research and analyse the relationship between several related variables (Wittrock, 1986); often with a goal of providing statistical description and establishing facts (Bogdan and Biklen, 1998), validation (Krathwohl, 1998), and testing hypotheses (Gall et al., 1996). They are frequently described as being positivist or empiricist (Bryman, 1984). Quantitative methods are good for viewing entire population trends but do not provide specific and meaningful contexts for information (Castellan, 2010).

As the deductive nature of a scientific top-down approach provides the results for qualitative analysis, qualitative methods help further define the phenomena being studied (Castellan, 2010). In contrast to quantitative methods, the goal of qualitative research can be to develop understanding (Bogdan and Biklen, 1998; Maxwell, 1996), describe multiple realities, develop grounded theory (Bogdan and Biklen, 1998), description (Krathwohl, 1998), or generate insight (Gall et al., 1996). Qualitative methods are frequently described as constructivism (Castellan, 2010).

The combination of both, quantitative and qualitative research methods is referred to as a mixed methods approach, often giving the researcher power to present stronger arguments (Johnson et al., 2007). Qualitative researchers often find mixed methods research can result in a loss of depth and flexibility when qualitative data is quantised; whilst quantitative researchers fear that the need to collect and analyse qualitative data during mixed methods can force researchers to reduce sample size and therefore restrict the statistical tests that can be used (Driscoll et al., 2007). Although quantitative or qualitative methods alone are currently more popular, mixed methods research is a strong research paradigm that is continuously being used more (Johnson et al., 2007; Johnson and Onwuegbuzie, 2004; Mayring et al., 2007).

The preliminary research for this study discovered that there is insufficient quantitative data available on the medicines management process within nursing homes to answer the study's research questions using any type of quantitative research method. The lack of available quantitative data therefore renders it impossible to use quantitative or mixed methods research methods for this study. Furthermore, the researcher wanted to gain an in-depth understanding of *how* the 28-day supply of

medicines cycle works, proposing qualitative exploratory research and multiple case studies as an ideal research method (Yin, 2014).

The qualitative research method is effective for studying institutional issues within an organisational environment (Ashkanasy and Jackson, 2001; Bellot, 2011; Deal et al., 2000; Yauch and Steudel, 2003). In this case, the researcher studied any institutional issues within the 28-day supply of medicines cycle (if any) within the care home organisational environment. Therefore, the qualitative method was a suitable and appropriate approach for this study.

The qualitative research method aimed to provide an in-depth understanding of how the 28-day supply of medicines cycle works within care homes, including the individual tasks involved in each stage, to develop a conceptual model and recommendations for the organisations involved. The researcher considered several qualitative case study research designs: explanatory, descriptive, or exploratory (Yin, 2014).

The explanatory approach was inappropriate because this study does not aim to clarify any formed hypotheses by explanation (Gilgun, 2001) and this study does not explore specific types of behaviours for a specific length of time, therefore ruling out a descriptive case study (Gilgun, 2001). As the primary focus was to explore how the 28-day supply of medicines cycle works within care homes, the exploratory approach with multiple case studies was deemed suitable and is explained in further detail in the subsequent section.

APPROPRIATENESS OF DESIGN – EXPLORATORY MULTIPLE CASE STUDY

Case studies are often considered most useful when little is known about a phenomenon, often acting as the first step in developing knowledge (Yin, 2014). Case studies are generally deemed less useful when testing theory, although many researchers have successfully used them for this purpose as well (Anderson et al., 2005). As little is known about the 28-day supply of medicines cycle within care homes and any challenges within the cycle, the goal of this research was to understand the phenomenon. Furthermore, this study did not test theory and therefore employing case study methodology proved itself to be a viable option.

Several prominent pioneer researchers have contributed to methodologies for case studies (Creswell, 2003; Denzin and Lincoln, 2005; Hyett et al., 2014; Merriam and Tisdell, 2015; Ragin, 2010; Stake,

1995; Thomas, 2011; Yin, 2014). Robert Stake and Robert Yin have each proposed an approach that guides case study methodology (Baxter and Jack, 2008). Both Stake (1995) and Yin (2003) base their approach to case study methodology on a constructivist paradigm.

Constructivists do not generally begin with a theory (as with post-positivists), rather they "generate or inductively develop a theory or pattern of meanings" (Creswell, 2003) throughout the research process. Constructivists researchers usually rely on qualitative data collection methods and analysis or a mixed-methods research, where the quantitative data portion supports or expands upon the qualitative data and deepens the description (Mackenzie and Knipe, 2006).

Furthermore, constructivists claim that truth is relative and that it is dependent on one's perspective (Baxter and Jack, 2008). Constructivist approaches to research have the intention to understand "the world of human experience" (Cohen et al., 1993), suggesting that "reality is socially constructed" (Mertens, 1998). Constructivist researchers tend to rely upon the "participants views of the situation being studied" (Creswell, 2003). In this case, the care home staff perspectives of the 28-day supply of medicines cycle will be studied.

Case studies conduct an empirical investigation of a contemporary phenomenon within its natural context using multiple sources of evidence (Yin, 2014). Case studies allow the researcher to explore individuals or organisations; simple or complex interventions, relationships, communities or programs (Yin, 2014) and support the deconstruction and subsequent reconstruction of various phenomena (Baxter and Jack, 2008). Qualitative case studies are highly valued for health science research to develop theory, evaluate programs and develop interventions because of their flexibility and rigour (Baxter and Jack, 2008).

This research will describe and explore the 28-day supply of medicines cycle using data collected from semi-structured interviews, observations from field work and feedback from stakeholder feedback sessions. Using the case study method, the researcher will be able to explore each organisation and the individuals directly dealing with the cycle within the care home. The research uses the case studies as an inductive approach to develop theory and interventions.

Hancock and Algozzine's, *Doing case study research: A practical guide for beginning researchers* (2006), discusses the key characteristics that define case study research. First, case study research sometimes focuses on an individual representative of a group (e.g. a female principal), however it

more often addresses a phenomenon (e.g. a particular event, situation, program or activity) (Hancock and Algozzine, 2006). *Using Hancock and Algozzine's worked example as a guideline (also see table 5, page 51): a nurse may desire to learn more about employment practices at his hospital (program)* (Hancock and Algozzine, 2006). Similarly, this case study research investigates the program phenomenon of the 28-day supply of medicines cycle.

The second characteristic defining case study research is that the phenomenon being researched is studied in its natural context, bounded by space and time (Hancock and Algozzine, 2006). *The nurse will examine employment practices only in his hospital and for a specific period of time* (Hancock and Algozzine, 2006). Similarly, the researcher will examine the 28-day supply of medicines cycle only within the care home concerned for the specified time of one cycle.

The third main characteristic is that case study research is richly descriptive because it is grounded in deep and varied sources of information (Hancock and Algozzine, 2006). Case studies often involve quotes from key participants, anecdotes, prose composed from interviews and other techniques (Hancock and Algozzine, 2006). These techniques create mental images that describe the complexity of the phenomenon being studied (Hancock and Algozzine, 2006). *For example, the nurse may include a brief narrative story explaining typical employment procedures at his hospital* (Hancock and Algozzine, 2006). In this case study research, the researcher will illustrate the 28-day supply of medicines cycle through semi-structured interviews and written observations from field work. By using varied sources of information derived from the phenomena's natural context, case studies will provide thorough investigations of the 28-day supply of medicines cycle within care homes.

Table 5: Key Characteristics Defining Case Study Research (Hancock and Algozzine, 2006)

KEY CHARACTERISTICS DEFINING CASE STUDY RESEARCH			
No.	**Characteristic**	**Worked Example**	**Relating to Study**
1.	Focusses on an individual representative of a group or addresses a phenomenon (particular event, situation, program or activity)	A nurse may desire to learn more about employment practices at his hospital (program)	The researcher investigates the program phenomenon of the 28-day supply of medicines cycle
2.	Phenomenon being researched is studied in its natural context, bounded by space and time	The nurse will examine employment practices only in his hospital and for a specific period of time	The researcher will examine the 28-day supply of medicines cycle only within the care home concerned for the specified time of one cycle
3.	Richly descriptive because it is grounded in deep and varied sources of information (quotes from key participants, anecdotes, prose composed from interviews, etc.)	The nurse may include a brief narrative story explaining typical employment procedures at his hospital	The researcher will use semi-structured interviews and written observations from field work, using varied sources of information derived from the phenomena's natural context

The topics of case study research vary widely and as mentioned earlier, it may be an individual representative of a group, or a phenomenon resembling an event, situation, program or activity that is relevant to the researcher. Case studies have been used to describe processes (Lawrence and Hardy, 1999), generate theory (Brown and Eisenhardt, 1997; Gioia and Thomas, 1996) and test theory (Johnston et al., 2001; Sambamurthy and Zmud, 1999).

An exploratory case study is an in-depth investigation of an event, activity, process, individual or group based on extensive data collection (Creswell, 2012a). Since this research strives to acquire an in-depth understanding of the current 28-day supply of medicines cycle within care homes and develop theory to enhance the cycle efficiency and quality of life delivered to care home residents, it is classed as an exploratory case study.

Creswell (Creswell, 2012b) argued the exploratory case study design is suitable for a thorough study on an issue or phenomenon. Given the limited data available on the 28-day supply of medicines cycle within care homes, an exploratory case study design is ideal. Through meticulous analysis of data, the

exploratory case study will investigate challenges within the cycle and illustrate relationships of subjects in an easily understandable presentation (Zeng, 2016).

Finally, this research will employ a multiple case study design, enabling replication (by the use of more than one case) to independently confirm emerging constructs, identify complementary aspects of the phenomenon and analyse within and across settings (Baxter and Jack, 2008). The advantage of multiple case design include: representativeness, robustness and reliability (Anderson et al., 2014; Baxter and Jack, 2008). Multiple case designs can be beneficial in understanding the phenomena under study because it allows for replication in data collection across the sites (Anderson et al., 2014).

Berta et al. (2010) used a multiple exploratory case study design to conduct semi-structured interviews within sixteen long-term care facilities to explore how staff characteristics, facility characteristics, external communications, and volunteers influence concepts of operational efficiency, quality of care and the relationship between the two within long-term care facilities (Berta et al., 2010). The study found that intra-organisational communication and level of experience were staff characteristics affecting operational efficiency and quality of care, facility age is related to quality of care, while both facility age and size is related to efficiency, and volunteers impact quality of care and efficiency (Berta et al., 2010).

Suarez-Barraza and Rais-Pujol (2012) conducted multiple (three) exploratory case studies to investigate the implementation of the 5Ss within lean manufacturing in multinational organisations empirically, allowing analysis and comparison against existing theoretical frameworks (Suárez-Barraza and Ramis-Pujol, 2012). The study used direct observation, participant observation, documentary analysis and semi-structured interviews to gather data. The study was able to generate a conceptual framework, establishing a relationship between the 5Ss and other lean improvement programmes (Suárez-Barraza and Ramis-Pujol, 2012).

RESEARCH QUESTIONS

The purpose of this qualitative exploratory case study is to understand the 28-day supply of medicines cycle as well as the issues and challenges within the cycle. Dependent on the findings, the researcher will develop a framework and set of recommendations for process improvement.

Qualitative research questions involve 'open-ended, general questions that the researcher would like answered during the study' (Creswell, 2012b), usually including 'how' or 'why' questions (Yin, 2003).

1. How is the 28-day supply of medicines cycle within care homes carried out?
2. What are the current issues and challenges within the 28-day supply of medicines cycle?
3. How can these issues and challenges be rectified and overcome to improve the overall cycle?

The researcher employed semi-structured, face-to-face interviews with care home managers and staff, as well as general practitioners and pharmacists (where possible) associated with each care home under study. The interviews explained the 28-day supply of medicines cycle and highlighted some of the main issues and challenges faced within the cycle. The interviewer then carried out participant observations field work to examine the cycle from the care home perspective in more detail. This determined how the tasks within the 28-day supply of medicines cycle are linked together.

The researcher analysed results found from interviews and field work using framework analysis; then created one theoretical framework and a set of recommendations for each care home using Six Sigma technique, DMAIC to improve cycle efficiency. Finally, the researcher presented the framework and recommendations for each case study during a stakeholder feedback session to receive feedback.

POPULATION

A population is a group of individuals who share characteristics and as the study group (Creswell, 2012b), allows the researcher to view broad results (Salkind, 2009). The population of this qualitative research was all care homes in the UK. More specifically, the target population was health and care practitioners who have a role in care home resident medicines management. This included, care home managers and staff (including nurses, team leaders and shift leaders), doctors and pharmacists from associated practices. The study's target population excluded care home residents and family carers because the main aim of the research was to explore the 28-day supply of medicines cycle which was ultimately run by the care homes, GP surgery and pharmacy staff.

SAMPLING

A research sample is a subset of the population, in which the sample has the similar characteristics as the population (Creswell, 2012a; Salkind, 2009). There are two broad types of sampling, probability

and nonprobability sampling (Salkind, 2009). Probability sampling strategies are usually appropriate for quantitative research, whereas nonprobability sampling strategies are appropriate for qualitative studies (Simpson, 2002). However, as the case studies in this study are exploratory in nature and although 'the sample' is three care homes, which is a subset of the population, the results cannot be generalised to the entire care home population. Therefore, these case studies do not represent a true sample in qualitative research but followed some of the principles in nonprobability convenience sampling.

Nonprobability sampling refers to samples of convenience (e.g. accessible, volunteer) or more purposeful methods of selection (e.g. judgement sampling, quota sampling, snowball sampling) (Feild et al., 2006). Nonprobability sampling methods are often considered optimal because of feasibility and economic constraints (e.g. when recruiting a sample with a relatively low prevalence rate in the general population). In nonprobability sampling, there is no way to estimate the probability that each element of the population has been included in the sample and it is impossible to estimate sampling errors, thereby limiting the extent to which valid inferences to a population can be made (Feild et al., 2006; Selltiz et al., 1976).

Convenience sampling is where members of the target population meet certain practical criteria, such as easy accessibility, geographical proximity, availability at a given time or the willingness to participate (Dörnyei, 2007). It may also refer to the researching subjects being easily accessible to the researcher (Saumure and Given, 2008). Convenience sampling is easy and affordable, subjects are also readily available (Etikan et al., 2016).

The obvious disadvantage of convenience sampling is the likeliness of bias within the study and therefore, results must be reviewed with caution (Mackey and Gass, 2005). Furthermore, a convenience sample should not be considered an exact representation of the population because the researcher will not know exactly how well a convenience sample represents a population and therefore, limits the generalisability of results (Etikan et al., 2016).

INFORMED CONSENT

Participation in the qualitative exploratory case study was voluntary and consent was obtained at both the care home and individual participant level. A total of five potential participants (care homes) received an email invitation from Mary Tooley, ENRICH Care Home Research Facilitator for the West

Midlands requesting participation in the study. These care homes were invited for participation based on their geographic location, recommendation by ENRICH based on the types of studies these care homes enjoy being involved in and availability. Four care homes (80% conversation rate) showed interest by return of email to Mary Tooley and were forwarded to the researcher. The researcher then emailed the care home manager of each of these four care homes a 'Participant Information Sheet' (PIS) and consent form to be signed on behalf of the care homes involvement (see Appendix D and E). Managers were asked to review the PIS and consent form before the initial meeting with the researcher so that any questions they may have can be addressed in time for the first meeting. Of the four care homes expressing interest, three followed through with participation in the study and one care home decided not to partake as it was during the same timeline as another study the home was involved in. At the first meeting for each of the three participating care homes, the care home managers signed the consent form after the researcher answered any additional questions they may have had.

Additionally, each care home manager was asked for the contact details of their affiliated GP surgeries and pharmacies. Each individual GP and pharmacist regularly involved in the medicines management of the care home residents was contacted via phone and email for their participation, as well as the GP surgery and pharmacy. Two follow-up emails were sent to the individual healthcare professionals and their practices, one week after the other. The third email was the final attempt at recruitment by the researcher.

Each health or care practitioner involved in the study was given a PIS and consent form (see Appendix F and G). These PIS and consent forms were given to GPs, pharmacists, care home managers and staff who participated in the study. Immediately before beginning each participant interview, the participant was given a PIS and consent form to review. Upon reviewing both items, any queries from the participant were answered and then the participant signed the consent form. The contents of the PIS and consent form were similar to that of the PIS and consent form given to each care home (discussed below).

The PIS included an invitation to participate statement, the purpose of the study, the reason they have received an invitation, what will happen if the care home agrees to take part, any potential risks involved in participation, confidentiality, withdrawing from the study and the researchers and institutions contact information. The informed consent form contained nine statements to be initialled by the care home manager and one signature for the entire form. The statements ensured

that the care home manager had read and understood the PIS, understood their right to withdraw at any point, agreed to be audio recorded and transcribed, confidentiality agreements, health and safety agreements, and finally if the care home agrees to take part in the case study.

CONFIDENTIALITY

Participant confidentiality is imperative. The researcher maintained confidentiality of all information concerning all research participants in all case studies as indicated in the confidentiality statements in both the PIS and consent form. All personal information retrieved was kept confidential in line with the Data Protection Act 1998.

The ways in which confidentiality and anonymity were to be managed was explained to participants before beginning the interview. Recordings of interviews were started after initial conversation with the participant, therefore names or other identifying information was not included in the recordings. When the recording started, the researcher used an alpha-numerical code to identify the participant. The letters 'CS' represented 'care study' and was paired with the number 1, 2, or 3 to represent each case in the study, and the letter 'P' represented participants, who were also given a unique number according to the interview number they were for their case study. Recordings were then saved to a password protected computer. The anonymised recording was then typed by the researcher. Any excerpts from participants that were included in the reporting of the project have been anonymised.

All electronic audio data was stored in a locked cabinet in a locked office at Aston University. All other electronic data, including case study field notes, are stored on a password protected laptop and as a backup, to a USB key, accessible to the researcher only. All data will be kept until one year after the completion of the researchers PhD (anticipated to keep data until September 2020). It will then be destroyed by the researcher.

GEOGRAPHIC LOCATION

The geographic location for this study was limited to England, United Kingdom; more specifically the Midlands. ENRICH is a group funded by the National Institute for Health Research (NIHR) that encourages care homes to become 'research ready,' meaning they are willing to participate in various research studies throughout the UK. There are currently 192 'research ready' nursing and/or residential care homes enlisted with ENRICH in the Midlands region. The Midlands was selected

because of easy accessibility to the researcher and voluntary participation within this region via ENRICH. The three care homes chosen for the case studies had volunteered to participate and were approved based on the diversity of each care home. For example, of the three care homes chosen, CS1 (case study 1) is a nursing home, CS2 (case study 2) is a residential home and CS3 (case study 3) is a nursing and residential home. Additionally, the researchers ease of access of each care home was considered when approving each care home. The GP and pharmacist interviewed were those that regularly serve the residents of each care home participating. They were also located in the Midlands, within a reasonable distance to the associated nursing home.

INSTRUMENTATION

There were three sets of instruments used to conduct this qualitative exploratory case study, semi-structured interviews, participant observations during field work and stakeholder feedback sessions. The first instrumentation used in this study was a semi-structured interview schedule, consisting of four questions and four supplementary questions (if needed, to aid in discussion) during audio-recorded face-to-face interviews (see Appendix A for interview schedule). Semi-structured interviews are commonly used of the available qualitative research methods (Alvesson and Deetz, 2000) and involve 'prepared questioning guided by identified themes in a consistent and systematic manner interposed with probes designed to elicit more elaborate responses' (Qu and Dumay, 2011).

Using an interactive format and informal environment during semi-structured interviews supports participants to feel comfortable and respond honestly and comprehensively, improving rigor and reducing bias (Creswell, 2012b). Therefore, interviews were conducted at the participants' worksite, ensuring participants were in a familiar environment and felt comfortable. Furthermore, the semi-structured interview format allowed the researcher to follow a set of predetermined questions but to also explore any topics that emerged during the interview (Leedy and Ormrod, 2004).

The second instrument used to collect data for the multiple-case case study was an observational method referred to as participant observations. Observational methods as expressed by Becker and Geer (1957):

> "the most complete form of the sociological datum is…the form in which the participant observer gathers it: An observation of some social event, the events which precede and follow it, and explanations of its meaning by participants and

> spectators, before, during, and after its occurrence. Such a datum gives us more information about the event under study than data gathered by any other sociological method. Participant observation can thus provide us with a yardstick against which to measure the completeness of data gathered in other ways, a model which can serve to let us know what orders of information escape us when we use other methods" (Becker and Geer, 1957).

Therefore, observational methods are often referred to as the 'gold standard' of qualitative methods, as they provide direct access to what people do and what they say they do, as well as an overall aim to understand the phenomenon, rather than people's accounts of it (Green and Thorogood, 2004).

Observational methods can be participant or nonparticipant observations. In participant observations the researcher is present to some extent in the field studied, whereas the researcher is not present in nonparticipant observations (Green and Thorogood, 2004). Participant observations render it possible to gather all kinds of data (Bernard, 2000). During participant observational research, participant activities are recorded as they occur and is therefore advantageous in exploring deeper topics that may arise (Creswell, 2012b).

Nonparticipant observations are more commonly used with quantitative techniques in health research, where observations are used to count and analyse behavioural phenomena. Although nonparticipant observations could have been employed in this study, participant observation was chosen to allow the researcher to ask any questions during the observations to gain a deeper understanding of related medicines management tasks. The protocol used for participant observations in this study are included as an appendix (Appendix B). Limitations of participant observation include the Hawthorne effect, a change in behaviour as a response to the interest, care, or attention received through observation and assessment (Sedgwick and Greenwood, 2015). As participants may alter their behaviour (usually unknowingly) according to the Hawthorne effect, this can distort research findings (Sedgwick and Greenwood, 2015).

There are four types of participant observation methods: complete participant, participant as observer, observer as participant and complete observer (Gold, 1958; Neergaard and Ulhøi, 2007). This study employed an 'observer as participant' role, also known as the 'focussed participant observer' (Tracy, 2012) or 'reactive observer' (Angrosino, 2005). The 'observer as participant' role, participates to a less extent than that of a complete participant or 'participant as observer' role, as

defined by Gold (1958). As the researcher wanted to be able to ask further questions during observations to gain a deeper understanding of each task, the 'observer as participant' role was best suited. Unlike nonparticipant observation, the 'observer as participant' role allowed just enough participation to gain a thorough understanding of the 28-day supply of medicines cycle without causing disruption.

The final instrument used for each case study was the interview schedule for each stakeholder feedback session (see Appendix C). The researcher originally planned to hold feedback sessions in the form of focus groups, however all three care homes preferred to only invite the care home manager, clinical leads, medicines management lead, GP and pharmacist. The GP and pharmacist did not partake in any of the feedback sessions, due to unavailability. As each feedback session only included the researcher along with two or three care home staff members, the researcher was unable to conduct a focus group. The purpose of each session was to receive feedback on the proposed framework and recommendations set by the researcher, as well as a method of receiving a certain level of validation. Similar to the execution of focus groups, the feedback sessions were audio-recorded and transcribed for analysis (Coreil, 1995; Green and Thorogood, 2004).

Focus groups are useful to determine group perceptions and opinions towards a topic, they can often save time and money in comparison to individual interviews and provide a broader range of information (Acocella, 2012). The feedback sessions in this study had the same goal as focus groups and were therefore chosen for these case studies to explain recommendations to each participant in the same way. The sessions enabled the researcher to gather perceptions and opinions from the group, as well as explore group dynamics and interactions to provide insight on perceptions of the recommendations. The researcher would not have had enough time to gain feedback on the recommendations provided and the study in individual interviews, therefore a group feedback session in each case study was chosen. A possible disadvantage of hosting group feedback sessions is the possibility that members would not share their honest perceptions and opinions (Acocella, 2012).

DATA COLLECTION

Once all the research elements were determined and in place, the research study was approved by the Aston Business School Ethics Committee (REC REF: 12:11/17) on 26th February 2018, ensuring the project was ethical and legal. Upon ethical approval, the research was started. The interview schedule was piloted with five volunteers, consisting of: a pharmacist, a care home area manager, an ENRICH

member, and a PhD student conducting research in care homes. As the semi-structured interview questions were straight-forward to answer during pilot interviews, no changes were suggested and therefore the formal case studies began.

After compiling and analysing interview and observation data generated from each case study, Framework Analysis was used to analyse the data. Data analysis from Framework Analysis provided a definition of the 28-day supply of medicines cycle and each task within the cycle, as well as a visual framework representing the cycle (all delivered in Chapter 4, Results).

Once a thorough understanding of the 28-day supply of medicines cycle was gained, the researcher used the Six Sigma methodology, DMAIC to define an issue within the cycle and produce a solution to rectify the issue, ultimately providing a process map framework and set of recommendations for process improvement within each cycle in each case study. The resulting process map, derived from DMAIC, and recommendations were then presented during each case study stakeholder feedback session. The theme of the stakeholder feedback session discussion was feedback and practical use of the process map framework and recommendations. The use of Six Sigma's DMAIC is discussed after the Results chapter, in Chapter 5 and 6).

DATA ANALYSIS

The researcher captured data by audio recording each interview, participant observation session and each stakeholder feedback session (with stakeholder feedback sessions occurring after application of DMAIC) with a portable recording device. The researcher also took field notes during the participant observation phase of any important information the participants had shared. The researcher first transcribed all interviews and participant observations from the audio recordings. After self-reviewing all transcriptions and field notes, a PhD colleague then also reviewed 10% of the transcriptions and field notes to ensure accuracy.

Researchers must review data collected in pronounced detail, reviewing data continually throughout the data analysis process to derive common themes (Yin, 2014). To do this, the researcher considered three qualitative analysis approaches, phenomenology, grounded theory and framework analysis.

Philosopher Edmund Husserl argued that to arrive at certainty, anything outside immediate experience must be ignored and thus realities are pure phenomena and the only form of absolute

data, creating his philosophical method, phenomenology (Eagleton, 2011). Phenomenological studies therefore attempt to set aside biases and assumptions about human experiences, feelings and responses to situations, allowing researchers to understand perceptions, perspectives and feelings of those who have experienced the phenomenon under study (Kruger and Stones, 1981). As this study is focussed around understanding a process, rather than developing a deep understanding of human life experiences, the researcher felt a phenomenological approach would not be suited to the study.

Sociologists, Glaser and Strauss (1967) created Grounded Theory method of qualitative research that would allow social theory to be generated systematically from data. A more recent approach of qualitative analysis created by Ritchie and Spencer (1994) is Framework Analysis.

Grounded Theory is usually used when the research question is clear, but often broad, identifying the general area to be studied (Lacey and Luff, 2007). Grounded Theory employs rigorous and structured analysis of the data, to produce a theory as the final research output (Strauss and Corbin, 1990). In contrast, Framework Analysis was developed in the context of applied policy research, aiming to meet specific information needs and provide outcomes or recommendations (Lacey and Luff, 2007; Ritchie and Spencer, 1994).

Framework Analysis has gained popularity in health-related research and often enables outputs to be determined within a short timescale (Ritchie and Spencer, 1994). Health-related articles have provided guidance on how to conduct framework analysis in healthcare fields (Gale et al., 2013; Smith and Firth, 2011), nursing (Furber, 2010; Swallow et al., 2003) and policy research (Ritchie and Spencer, 1994; Srivastava and Thomson, 2009). Grounded theory is considered a purely inductive approach (Glaser and Strauss, 1967), while framework analysis is partially inductive, it was better suited to the researcher and allows inclusion of deductive or emergent concepts (*priori)*, for example in coding (Gale et al., 2013; Pope et al., 2000; Ritchie and Spencer, 1994).

As the research questions of this research are based around health-related research or applied policy research, framework analysis is better suited to the research. It is difficult for the researcher to be truly inductive to apply grounded theory as the researcher is a pharmacist and has some existing knowledge about medicines management within healthcare settings, therefore framework analysis is the preferred research methodology (Gale et al., 2013; Glaser and Strauss, 1967).

Furthermore, as the aim of this research is to develop an understanding of the 28-day supply of medicines cycle, its issues and challenges, and a framework and recommendations for process improvement (if needed), framework analysis is an appropriate qualitative approach. It will also enable the researcher to include a *priori* or emergent concepts from previous literature if needed (Pope et al., 2000). The following section explains framework analysis and its key stages.

FRAMEWORK ANALYSIS

Framework Analysis provides systematic and visible stages to the analysis process, that can be taken in a linear fashion or simultaneously with data collection (Lacey and Luff, 2007; Ritchie and Spencer, 1994). Ritchie and Spencer (1994) list the five key stages as follows:

1. Familiarisation
2. Identifying a Thematic Framework
3. Indexing
4. Charting
5. Mapping & Interpretation

1. Familiarisation

The familiarisation stage involves whole or partial transcription and reading of the data (Ritchie and Spencer, 1994). After the researcher transcribed all interviews and typed all field notes, both interview transcripts and field notes were read several times by the researcher to become familiar with the data. The researcher then organised all data into easily retrievable sections, a necessary step during analysis, which also aids with data familiarisation (Ritchie and Spencer, 1994). Therefore, transcriptions and field notes were entered into NVivo 12 Software to organise data. Data was organised based on source, meaning each set of data from interviews and participant observations was organised based on the case it pertained to. Once the researcher was satisfied with data organisation and familiarisation, the remaining framework analysis steps were carried out.

2. Identifying a Thematic Framework

Identifying the thematic framework is the initial coding framework that is developed from *priori* issues and emerging issues from the previous familiarisation stage (Lacey and Luff, 2007; Midgley et al., 2017;

Ritchie and Spencer, 1994). Once the thematic framework is developed, it should be refined in subsequent stages where necessary (Lacey and Luff, 2007). The thematic framework provides a structure to which the data can be further sifted and sorted, further aiding in data organisation (Ritchie and Spencer, 1994). The thematic framework developed for this research aimed to describe each task category within the 28-day supply of medicines cycle from the care home perspective.

3. Indexing

Indexing is the process of systematically applying the thematic framework to all data in its textual form (Gale et al., 2013; Ritchie and Spencer, 1994; Swallow et al., 2003). It involves using numerical or textual codes to identify specific pieces of data which correspond to differing themes (Midgley et al., 2017; Ritchie and Spencer, 1994). Indexing is more commonly referred to as coding in other qualitative analysis approaches.

Codes are categories, tags or labels for allocating units of meaning to the descriptive or inferential information compiled during a study, a significant step in qualitative data analysis (Basit, 2003; Dey, 1993). Indexing (or coding) notices relevant phenomena, collects examples of the phenomena and analyses the phenomena to find commonalities, differences, patterns and structures (Kelle et al., 1995). To ensure accuracy and credibility, codes created were reviewed by the same PhD colleague that reviewed the transcriptions and field notes.

The thematic framework from the previous step was applied to all transcripts and field notes individually to create codes. Therefore, in this step, codes within the thematic framework were developed by "indexing" the data (applying text from interviews and field notes to one or more codes).

The emerging codes from the indexing stage are listed below:

- Medicines Re-ordering and Prescription Check against Re-order
- Medicines Checking-in
- Medicines Changeover
- Medicines Administration

4. Charting

Charting is the process of lifting data from their original context and rearranging it according to the appropriate thematic reference (Ritchie and Spencer, 1994; Swallow et al., 2003). It uses headings from the thematic framework or research questions and considers how best to present and write up the study, creating charts of data that can easily be read across the entire dataset (Lacey and Luff, 2007; Ritchie and Spencer, 1994). The charts can be laid out according to theme (each theme across all respondents) or according to each case (each respondent across all themes) (Ritchie and Spencer, 1994). It is ideal to have each chart follow the same format to allow for easy review of each theme or case. This step allows the researcher to begin building up a holistic picture of the data.

5. Mapping & Interpretation

This final stage in framework analysis allows the researcher to interpret the data set as a whole. The key objectives of this step are to: (1) define concepts, (2) map range and nature of phenomena, (3) create typologies, (4) find associations, (5) provide explanations, or (6) develop strategies (Ritchie and Spencer, 1994). The objective chosen is guided by the original research questions as well as the themes within the data that have already emerged (Gale et al., 2013; Ritchie and Spencer, 1994). The aim of this step is to enable the researcher to visually display ideas from the data as an aid in developing and testing interpretations (Miles et al., 1994; Ritchie and Spencer, 1994).

In an attempt to answer RQ1 (how is the 28-day supply of medicines cycle within care homes carried out?), the researcher used Framework Analysis to define all concepts: the 28-day supply of medicines cycle and all tasks within the cycle, medicines re-order and prescription check against re-order, medicines checking-in, medicines changeover and medicines administration.

Figure 9 depicts the steps the researcher used to analyse data using Framework Analysis. A multi-disciplinary team validated the framework as suggested in published material (Gale et al., 2013).

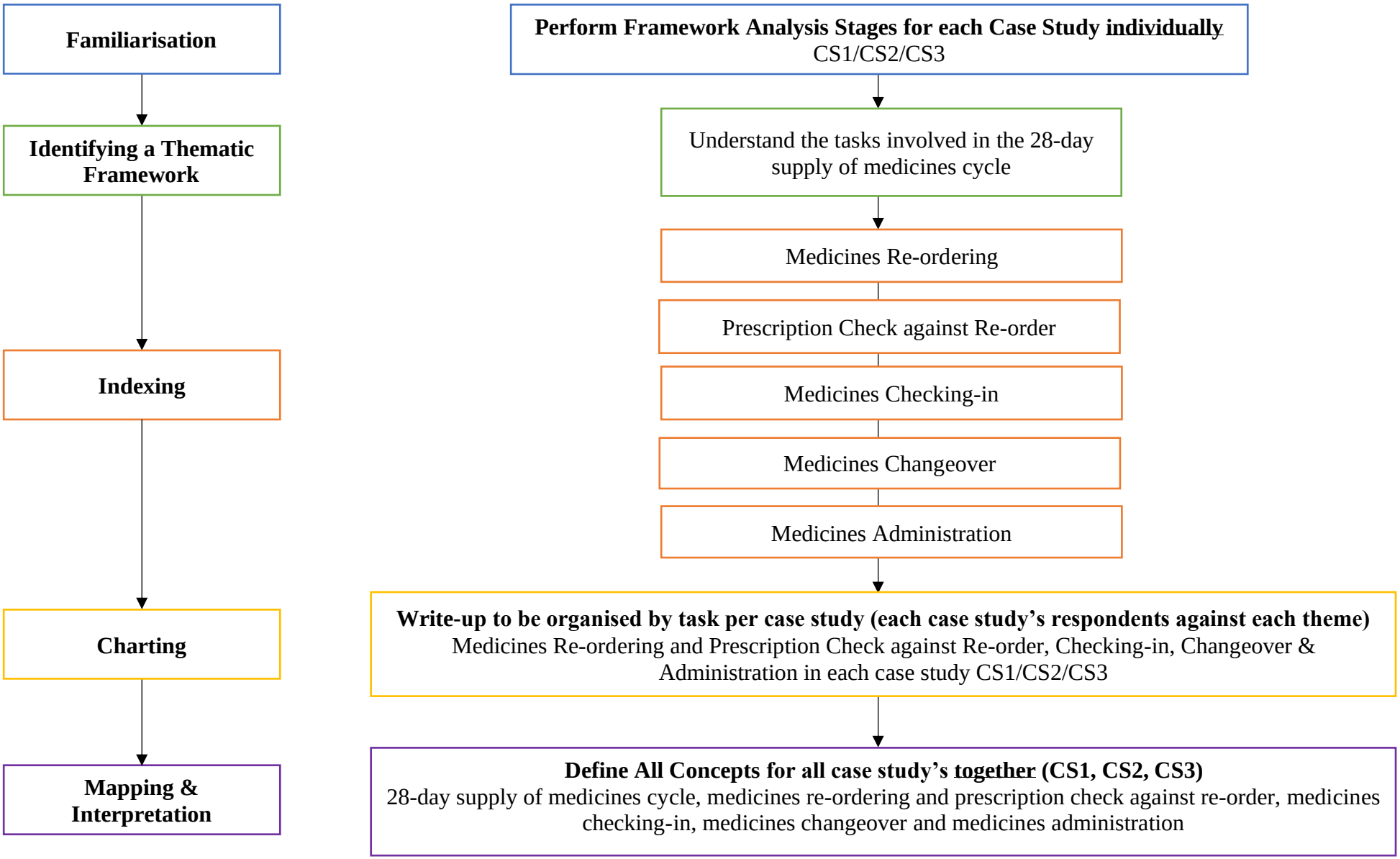


Figure 9: Summary of how data was analysed, using Framework Analysis

VALIDITY & RELIABILITY

Validity is the extent to which the research instrument measures what it is intended to measure, while reliability examines whether the outcome is possible regardless of the procedure used to complete the research (Kirk and Miller, 1986). In qualitative studies, quantitative terms such as "internal validity, external validity, reliability and objectivity" correspond to "credibility, transferability, dependability and conformability (Lincoln and Guba, 1985). Other terms often related to validity and reliability include: trustworthiness, quality, rigour, applicability and consistency (Brink, 1993; Davies and Dodd, 2002; Denzin and Lincoln, 2005; Glaser and Strauss, 1967; Leininger, 1991; Seale, 1999; Stenbacka, 2001; Whittemore et al., 2001).

Credibility, Transferability, Dependability & Conformability

Credibility is defined as a reality that is plausible or seems true, achieved through thick description, triangulation and engaging in member reflections with participants (Tracy, 2012). This study has given dense description, wherever possible, by providing direct interview quotes and narrative description of participant observations during the 28-day supply of medicines cycle. Additionally, it has used triangulation within each case study, discussed later in this section. The stakeholder feedback sessions were member reflections with participants on the conceptual framework and recommendations, further establishing credibility.

Transferability denotes the generalisability or transferability of the study results to other contexts (Lincoln and Guba, 1985; Neuman, 2008). Providing a thick description of the population, demographics and geographic boundaries of a study are one way to establish transferability (Thomas and Magilvy, 2011). This study chose three nursing homes in England, more specifically the West Midlands. Further details of each case study and its participants are in the results section.

Dependability refers to the reliability and consistency of the data collected (Lincoln and Guba, 1985; Neuman, 2008). It stresses importance on the ability to follow the decision trail used by a researcher, particularly in terms of the study purpose, participant selection, data collection and analysis, as well as communicating the specific techniques to determine data credibility (Thomas and Magilvy, 2011). Participants were selected by convenience sampling. The potential of bias from convenience sampling was counteracted by using a multiple case study method, to increase overall credibility and transferability of the research. Multiple cases typically lead to more robust outcomes than single-case

research (Eisenhardt and Graebner, 2007). Furthermore, data collection and analysis is thoroughly indicated throughout this methodology chapter.

Finally, conformability is the degree to which results can be confirmed or substantiated by others (Lincoln and Guba, 1985), occurring when credibility, transferability and dependability have been established (Thomas and Magilvy, 2011). Conformability is established when the researcher is reflective, holding a self-critical attitude to avoid letting one's own preconceptions affect the research, as well as following the flow of interviews and observations rather than taking the lead (Thomas and Magilvy, 2011). In this study, the researcher has held awareness of her biases and tried to maintain an as objective view as possible to retrieve findings true to the research.

Other Methods used to Establish Validity & Reliability

Triangulation is "the use of multiple methods or data sources in qualitative research to develop a comprehensive understanding of phenomena" (Patton, 1999), a strategy used to test validity through the convergence of information from different sources (Carter et al., 2014). It is a common method of enhancing credibility, confirmability, transferability and dependability of the data collected in a study (Patton, 1999; Stake, 1995; Yin, 2003). There are different types of triangulation including: data source, investigators, methodologic approach, theoretical perspective or analytical methods (Denzin, 1989; Kimchi et al., 1991). Methodologic approach triangulation refers to data collection methods or research designs (Lincoln and Guba, 1985).

According to Yin (2009), there are six sources of data for case study research: interviews, direct observations, participant observations, physical artefacts, archival records and documents. This study established validity by using triangulation of three data collection methods per case study: qualitative semi-structured interviews (individual interviews), participant observations and stakeholder feedback sessions (group interviews), as discussed in chapter 3.

Another aspect of establishing study validity and reliability lies in the research instrument itself. The researcher conducted a pilot test of the interview schedule with five pilot participants who were not part of the research study. Pilot testing is a step in determining whether questions provide answers to the research questions (Creswell, 2003; Leedy and Ormrod, 2004; Neuman, 2008). The researcher found the interview questions during the pilot interviews did provide answers to RQ1 (how is the 28-day supply of medicines cycle within care homes carried out?) and each pilot interview participant

found the questions straight-forward and easy to answer, therefore no changes were made following the pilot interviews.

Finally, data collection followed the same procedures in each case. Interviews were completed for each care home manager, staff, GP and pharmacist where possible. Interviews were audio-recorded and transcribed. Each transcription was reviewed by replaying each audio-recorded interview multiple times. Additionally, 10% of interviews were reviewed by a colleague to ensure accuracy between the audio-record and transcribed interview. Participant observations followed the same structure in each case, only observing each medicines management process task for one 28-day cycle. Stakeholder feedback sessions aimed to receive feedback on the model and recommendations. Transcriptions of interviews and stakeholder feedback sessions were organised on NVivo 12, a qualitative data analysis software used to classify, sort and arrange unstructured information (QSR International, 2019). The Standards for Reporting Qualitative Research (SRQR) guideline was used to report the findings from the study (O'Brien et al., 2014).

SUMMARY

Chapter 3 explains qualitative research and exploratory case studies. The use of the qualitative method and exploratory multi-case studies allows for in-depth investigations of the phenomena at hand. The use of semi-structured interviews gave perspectives of stakeholders involved in managing the 28-day supply of medicines cycle. Direct participant observations provide the researcher with a realistic view of how the 28-day supply of medicines cycle is carried out within each of three care homes under study, and any issues and challenges stakeholders come across. Finally, stakeholder feedback sessions were organised to validate study findings and receive feedback.

The chapter also discusses the non-probability convenience sampling used by the researcher, informed consent obtained by participants, confidentiality and the geographic location (Midlands) of the case studies.

Initially, a pilot study for the semi-structured interviews was conducted and then data collection was carried out by selecting three care homes, part of the ENRICH group in the Midlands region. Data analysis was carried out using Framework Analysis, exploring the 28-day supply of medicines cycle and each task within the cycle: medicines re-ordering and prescription check against re-order, medicines checking-in, medicines changeover and medicines administration.

The chapter also discusses the ways in which this study has adequate credibility, transferability, dependability and conformability. A thick description of interviews and observational research maintains credibility, whilst proper description of each case study's geographic location and demographics maintains transferability. Using the multiple case study method strengthens dependability, whilst conformability is supported by self-reflection on the researchers own preconceptions throughout the study. Finally, the use of triangulation through the three research instruments (semi-structured interviews, direct participant observations and stakeholder feedback sessions) strengthens the study design.

The subsequent chapter will present results to RQ1 (how is the 28-day supply of medicines cycle within care homes carried out?) derived from semi-structured interviews and participant observations for each case study, using Framework Analysis. The end of the chapter will provide a general definition of each task within the cycle, compiled from results of each case study.

CHAPTER 4

RESULTS

A total of 18 interviews were conducted, lasting approximately 30-60 minutes (mean time 43.07 minutes) and took place at the participants' place of work. Three GPs and three pharmacists were approached, of which one GP and one pharmacist participated (both in CS3), whilst all three care home managers and all care home staff approached participated. Each care home did have a set of Standard Operating Procedures (SOPs) on medicines management within their care home.

The exact amount of waste produced throughout the 28-day supply of medicines cycle and the exact amount of time medicines administration takes per resident is not known for any of the following case studies as it was not a primary research objective of the study. Instead, the researcher attempted to capture what happens during each task in the 28-day supply of medicines cycle.

The researcher carried out observations throughout one entire 28-day supply of medicines cycle in each case study. Tasks observed were coded by the researcher as: medicines re-ordering and prescription check against re-order, medicines checking-in, medicines changeover and medicines administration.

> *The remainder of the results chapter is organised by each care home which represents an individual case study. To analyse data, each case study followed the Framework Analysis steps described in the previous chapter. The framework from the previous chapter (p. 65) was derived from results and is used to organise this chapter, to understand the tasks involved in the 28-day supply of medicines cycle: (1) medicines re-ordering and prescription check against re-order, (2) medicines checking-in, (3) medicines changeover and (4) medicines administration. Each task is described via data from semi-structured interviews and direct participant observations.*

INTERVIEWS AND PARTICIPANT OBSERVATION RESULTS FOR CASE STUDY 1

General Information on Case Study 1

Table 6: Case Study 1 Care Home Characteristics

Care Home Characteristics [CS1]		
Type of Home	Nursing care home	
Number of Residents	47 nursing home residents 20 on downstairs floor, 27 on upstairs floor	
GP Surgery	All residents are under one GP surgery GP surgery is in close proximity (0.97 km)	
Pharmacy	Pharmacy is in close proximity (1.93 km)	
Medicines Storage	All medicines kept in medicines storage room or medicines trolley, which is also stored in the medicines storage room.	
Medicines Management Lead	One medicines management lead *(qualified nurse)* One clinical lead *(qualified nurse)*	
Staff-to-resident ratio	Nurse-to-resident ratio • Daytime = 1:22.2 • Night-time = 1:47 Carer-to-resident ratio *(not including nurses)* • Morning = 1:4.7 • Afternoon = 1:5.88 • Night-time = 1:9.4	
Type of Medicines Management System	Paper-based	
Number of Interview Participants	5	
Interviewees	Care home manager	CH Manager
	Care manager	Participant 1
	Medicines Management Lead	Participant 2
	Nurse (x2)	Participants 3 & 4
Total Hours of Observation (approximate)	14.5	

All results in the following sections came from case study interviews and direct participant observations. The 28-day supply of medicines cycle follows a four week or 28-day cycle. Week 1 begins on the first Monday residents are administered medication from a new batch of medications prepared by the pharmacy for the care home.

> ***CS1 – CH Manager:*** *Medicines management would be the resident's individual needs when they're admitted to the home, we do a pre-nursing assessment so we can see what medications they're on… I think it's one of the most important things in the resident's day, for them to have correct medication and pain relief, especially for*

patients with dementia. Because I think a lot of times, people can just see it as agitation but it may be pain-driven.

The GP does a weekly medication round for any resident's that need to be checked and aims to do a full medication review for all resident's every six months. The pharmacy also aims to do a full review of all residents every six months.

CS1 – CH Manager: *…we've got the clinical lead, who's the care manager [CS1-P1]; so as a qualified nurse [he/she] will take the responsibility of the day-to-day meds management. And we've also got a lead nurse who does medication management [CS1-P2]. So between the two, they're the main leads for the meds management within the home.*

Medicines Re-ordering [CS1]

CS1 –P2 [medicines management lead]: *I do the medicines re-ordering in week 2 of the cycle, whenever I am on shift. I usually do it on my own.*

As mentioned in the interview with the medicines management lead, and seen later during direct participant observations, this care home uses the repeat slip on the right-hand side of FP10 prescriptions to reorder medication each cycle for their residents. The medicines management lead ticks each item on the repeat slip that is needed for the resident. Items needed are determined by the current cycle's MAR chart and 'checking-in' sheet. Together, these documents identify each medication the resident is taking, the quantity of each medication the pharmacy sent for the current cycle and if any amount of medication was carried forward from the last cycle to the current cycle. Based on this information, the medicines management lead is able to tick each medication needed for the following cycle and identify the correct quantity of medication needed (by calculating any carried forward amounts with the amount sent by pharmacy for the current cycle).

In cases where there is an alteration to the repeat medication stated on the right-hand side of the FP10 prescription (i.e. a different quantity needed for the month or a dose change), the medicines management lead will hand-write the amendment onto the right-hand side of the FP10 prescription.

CS1 – P1 [care manager]: *But before we even order, we'll check what stock we've got in cupboards and just try and minimise our stock levels…*

A sample right-hand side of an FP10 prescription was shown on figure 4, page 34. After completing the re-order process for each resident, all right-hand sides of the FP10 prescriptions are faxed to the GP surgery.

Prescription Check against Re-order [CS1]

When the prescriptions are ready at the GP surgery, the care home collects the prescriptions and the medicines management lead checks the items prescribed against the original re-order requests. This highlights any outstanding items to be prescribed for the medicines management lead to 'chase up' with the GP surgery. A photocopy of all prescriptions is then taken and the pharmacy will pick up the original prescriptions from the care home.

CS1 – P1 [care manager]: *Tick what we need, return that to the GP by fax so we've got the original hard copy… and they aim to turn that around within 24 hours.*

So then the hardcopy script [prescription] goes to pharmacy and we've got our copy [photocopy]; so we know we've got a reference to prove what we ordered.

What we've done now to eradicate the risk of pharmacy saying, 'oh this item is missing off the script this month or they haven't sent this script;' we as a home go and collect the hardcopy scripts once the GPs done them at the surgery. We bring them back into the home and check them against what we've ordered.

Interviewer: *So this is before they [prescriptions] go to pharmacy?*

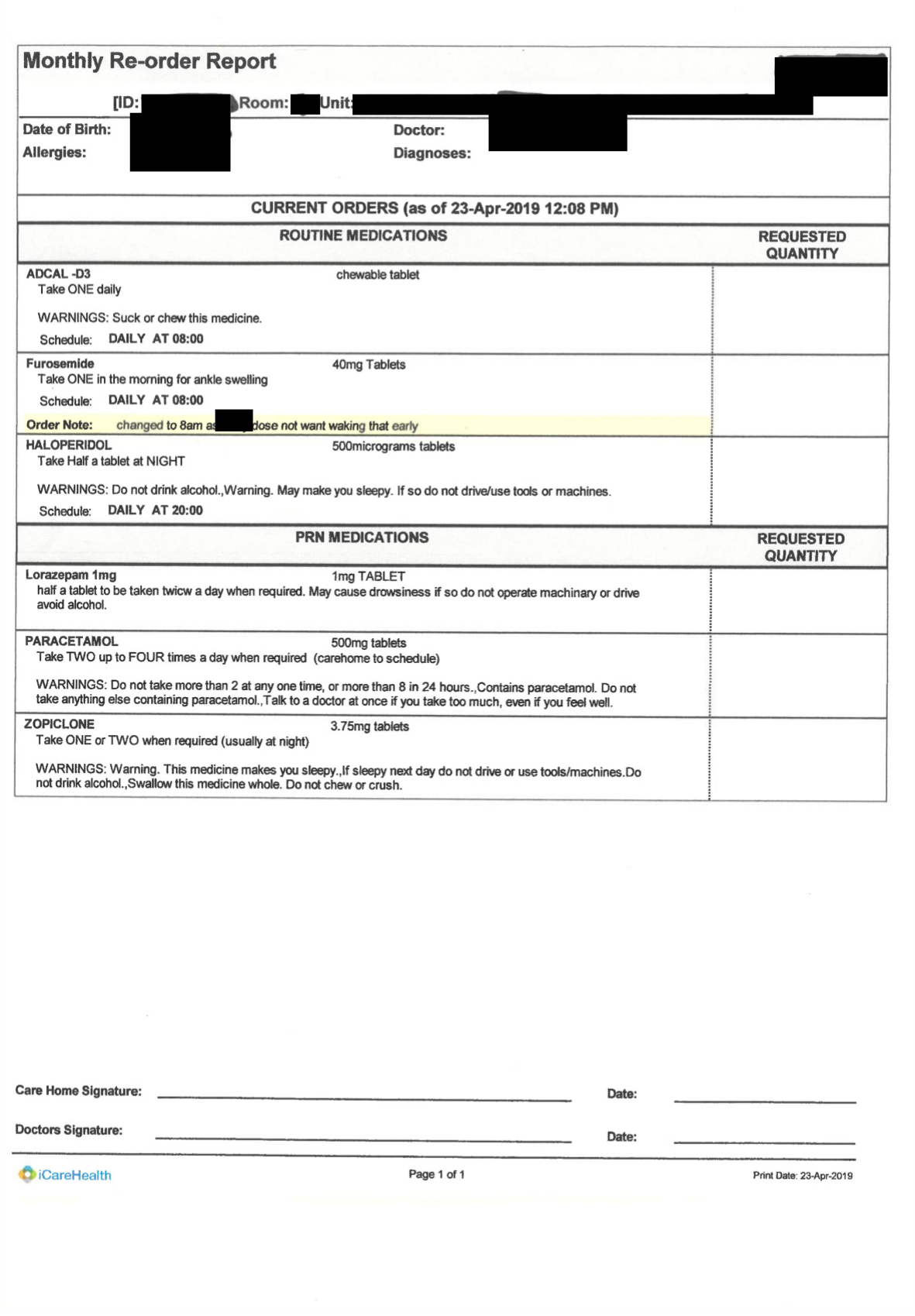
CS1 – P1 [care manager]: *Yes. So we check again, so it's a second checking process and then we will realise 'oh they've missed this off the script' and 'we require this item' so then I'll send another email or fax then back to the GP saying you forgot this item or they'll come back to me and say, 'oh no we produced the script on such and such a day so we can't issue you another script until such and such a date.' Or if we can justify that we need the item and if the doctor will agree.*

So then pharmacy come and collect the hardcopy scripts off us, and they start producing, racking our meds. What they try to do is get all our medications into the home a week before the start of the new drug cycle so two nurses can check in medications.

The pharmacy aims to deliver resident medications to the care home approximately a week before the start of the new cycle, meaning the Monday of week 4, however in reality it is usually mid-week of Week 4.

Medicines Checking-in [CS1]

The medicines management lead will separate all the forms received by the pharmacy into groups: resident medication administration record (MAR) charts (a list of medicines an individual is taking, detailing when the medication should be administered and allows for the person giving the medication to record if the medicine was administered or not (see definitions, page 14), 'checking-in' forms (one form for each resident listing the quantity of each medication the pharmacy has supplied at this time) and re-order forms (one form per resident listing each medication they are on with the all medication details listed, including dose, quantity, strength, formulation that the care home can use to re-order medications by writing the quantity needed for the next cycle, see figure 10).



Monthly Re-order Report

[ID: [redacted] Room: [redacted] Unit: [redacted]

Date of Birth: [redacted] Doctor: [redacted]

Allergies: [redacted] Diagnoses:

CURRENT ORDERS (as of 23-Apr-2019 12:08 PM)

ROUTINE MEDICATIONS		REQUESTED QUANTITY
ADCAL -D3 Take ONE daily WARNINGS: Suck or chew this medicine. Schedule: **DAILY AT 08:00**	chewable tablet	
Furosemide Take ONE in the morning for ankle swelling Schedule: **DAILY AT 08:00** **Order Note:** changed to 8am as [redacted] dose not want waking that early	40mg Tablets	
HALOPERIDOL Take Half a tablet at NIGHT WARNINGS: Do not drink alcohol.,Warning. May make you sleepy. If so do not drive/use tools or machines. Schedule: **DAILY AT 20:00**	500micrograms tablets	

PRN MEDICATIONS		REQUESTED QUANTITY
Lorazepam 1mg half a tablet to be taken twicw a day when required. May cause drowsiness if so do not operate machinary or drive avoid alcohol.	1mg TABLET	
PARACETAMOL Take TWO up to FOUR times a day when required (carehome to schedule) WARNINGS: Do not take more than 2 at any one time, or more than 8 in 24 hours.,Contains paracetamol. Do not take anything else containing paracetamol.,Talk to a doctor at once if you take too much, even if you feel well.	500mg tablets	
ZOPICLONE Take ONE or TWO when required (usually at night) WARNINGS: Warning. This medicine makes you sleepy.,If sleepy next day do not drive or use tools/machines.Do not drink alcohol.,Swallow this medicine whole. Do not chew or crush.	3.75mg tablets	

Care Home Signature: _____ Date: _____

Doctors Signature: _____ Date: _____

iCareHealth Page 1 of 1 Print Date: 23-Apr-2019

Figure 10: Sample repeat medication re-order form

The medicines checking-in process is always done by two members of staff, usually the medicines management lead and one nurse. Together, the staff members will check the medications received from the pharmacy against the current MAR charts and the cycle's prescription order requests. They will also count the number of tablets or capsules for each medication received to ensure the pharmacy has sent the correct amount, according to the prescription. All medications are:

> ***CS1 – P1 [care manager]:*** *blister packed, except those that can't be like sodium valproate and obviously liquids, and some are tablets [in original boxes], like paracetamols.*
>
> ---
>
> ***CS1 – P4 [nurse]:*** *…and then once it comes to us, we have to sign it to say we have received it and count it and also document it on the patient's MAR chart. And usually it's two nurses who signature it to say that this has been checked and this is the amount.*

While the medicines are being checked-in, a list of missing items is made. These items are then chased up with the pharmacy or GP, by the medicines management lead.

> ***CS1 –P2 [medicines management lead]:*** *The checking in, the nurses help with because obviously it requires two staff and sometimes if I'm not on duty and they come in, they'll check them in. But then I just write a list of all the things that are out of stock. So I know what I've requested so I'll refer to my request slips. So I'll do all the chasing up really but they [nurses] will count them and then countersign sometimes. And then with the photocopy of the prescriptions, we keep it and file it with our records and MAR charts.*

Medicines Changeover [CS1]

As mentioned in care home staff interviews and confirmed during direct participant observations, the medicines management lead completes the medicines changeover process on the last evening of each cycle (28th day), which is always the Sunday (evening before) the beginning of the new cycle (Monday).

During the interview with the medicines management lead, the researcher was shown the medicines storage room. In the medicines storage room, there are small baskets for each resident. These baskets contain any other prescribed items, such as creams and any surplus stock. To start the medicines changeover process, the medicines management lead checks all the baskets in the medicines storage room for resident's medication from the current cycle. The medicines management lead then writes down this number to indicate any medication and the amount of that medication being 'carried forward' into the new cycle (starting tomorrow).

Once the amount of medication being 'carried forward' into the new cycle has been documented, the medicines management lead empties all current empty blister packs into waste, as well as any medication in the medicines trolley which is not going to be carried forward. The trolley is then cleaned and wiped down, then blisters and medications for each resident for the upcoming cycle are put into the trolley.

This process generally takes the medicines management lead close to three hours on a Sunday evening, after the nurse has completed the bed time medication round.

Additionally, there are other tasks, such as organising the paperwork into a folder to be ready for Monday morning, Day 1 of the cycle.

> ***CS1 – P1 [care manager]:*** *So what we do, we obviously have our MAR charts all in the folder. So we have two surplus folders so we can set the MARs ready. The two nurses checking the meds put them [MAR charts] back into the [document] trays and then on the day of drug changeover, the night nurse will just set up the trollies and set up the opening dates on the bottles and things like that.*

As discussed during interviews, the medicines management lead and the nurse on shift currently handle the medicines changeover process. This requires the medicines management lead coming into the care home on the last day of each 28-day supply of medicines cycle (Sunday evening), for up to three hours to complete the process in time for the beginning of the next cycle (Monday morning).

During participant observations, staff expressed the view that they need three nurses on shift during medicines changeover, instead of just two nurses, one being the medicines management lead. They explained that it takes at least two nurses (the medicines management lead and one other nurse) to

do the actual changeover and get it done in time and the third nurse can handle the regular shift work on the floor. Whereas currently, the nurse on shift helps the medicines management lead nurse to do the changeover, while also handling any regular shift work on the floor.

Medicines Administration [CS1]

As discussed during interviews, and confirmed during participant observations, the care home has two floors and therefore one nurse does the medication rounds upstairs and another nurse will complete the medication rounds downstairs. Self-administering residents have medications in their room in a locked cupboard and are monitored weekly for correct medication usage.

The general tasks completed by the nurse during medicines administration rounds include: checking the MAR chart, getting the medication ready (for example, taking the medications out of the blister packs, crushing any necessary tablets if approved by the pharmacy, etc.), sometimes getting the resident up and in a comfortable position to take the medication, administering the medication to the resident and signing off the MAR charts. Other tasks that are sometimes performed during medicines administration include taking a resident's pulse or refilling the medicines trolley with plastic spoons if needed.

> ***CS1 – P3:*** *That part [interaction with residents] is actually what I'm trying to get to grips with. Because the nurses know all the individual residents and they'll know straight away if one patient needs to have their tablets crushed or another patient needs to have their tablet on a spoon or in their breakfast and things like that so really you need to know the patients for that.*
>
> *I think they do interact really well with them anyway. Everyone is different so they need to know them all individually otherwise it would just take all day. Some of them, they'll take it with their breakfast, some they'll go down to the lounge and give it to them with their breakfast down there or if they're just sitting watching TV.*

The care home performs four medication rounds per day: morning, afternoon, teatime and bed time. Interviewees said the morning medication round generally takes around two hours, the afternoon round takes less than 30 minutes, the teatime round takes approximately one hour, and the bed time

round takes from 30 minutes to one hour. This equates to roughly four to four and a half hours per day, and approximately two to two and a half hours per nurse's eight-hour shift.

> ***CS1 – P2:*** *In the morning, we start at 8am and it probably takes about two hours. The afternoon one, maximum an hour and the same with the night one. It's just the morning one that's the longest.*

The staff at this care home report that the medication rounds often take longer than it needs to because they are interrupted during the process. One nurse approximated that it usually takes 2 hours to complete the morning medication round, however without interruptions it could be finished in an hour to an hour and a half.

INTERVIEWS AND PARTICIPANT OBSERVATION RESULTS FOR CASE STUDY 2

General Information on Medicines Management for CS2

Table 7: Case Study 2 Care Home Characteristics

Care Home Characteristics [CS2]		
Type of Home	Residential home	
Number of Residents	58 residents	
GP Surgery	Residents are under one of three GP surgeries Surgeries are in close proximity (all within 3 km)	
Pharmacy	Pharmacy is in close proximity (1.93 km)	
Medicines Storage	All medicines are stored in locked cupboards in each resident's room	
Medicines Management Lead	One medicines management lead	
Staff-to-resident ratio	1:4 **The staff-to-resident ratio was given by the care home manager according to information available to him/her at the time, therefore CS2 and CS3 have less detailed information on this figure in comparison to CS1.*	
Type of Medicines Management System	Electronic (although some processes are still paper-based)	
Number of Interview Participants	7	
Interviewees	Manager	Participant 5
	Medicines Management Lead	Participant 7
	Carers (x5)	Participants 1,2,3,4,6
Total Hours of Observation (approximate)	20	

All results in the following sections came from case study interviews and direct participant observations. This care home has an electronic system for medicines management in the home and the pharmacy they work with. Although using the electronic system, they use processes from both the electronic system and traditional paper-based system because the staff are used to working with a paper-based system and have not fully explored ways to complete tasks using the electronic system (e.g. filling out the right-hand side of prescriptions to re-order instead of filling out the re-order form generated by the electronic system, see figure 10, page 75).

The general timescale for each medicines management cycle for this care home is depicted in the following quote from the medicines management lead:

CS2 – P7 [medicines management lead]: *It's a four week cycle. So we have our changeover. In the first week, I redo all the ordering so I usually try to get them done by the Wednesday, Thursday of the first week. Then that gives two weeks for the doctors to get them to the pharmacy. Week three we usually start doing the chasing up and then obviously, the turnaround again at the end of week 4.*

CS2 – P2 [carer]: *The medications champion would do the ordering on a monthly basis. We get four weekly medications. She would ensure that the prescriptions are e-prescribed through to the pharmacy. She would liase with the GP surgeries and pharmacy to ensure that any additional medications, such as antibiotics, or anything that's outside of the realms of the monthly order is picked up and brought here.*

Medicines Re-ordering [CS2]

To re-order monthly medications for each resident, this care home uses the right-hand side of FP10 prescriptions (figure 4, page 34). Each repeat slip is filled out and photocopied. The original copies are then taken to the GP surgeries by hand and the care home keeps the photocopied version. Additionally, the medicines management lead fills out an ordering form on the electronic system to send to the pharmacy (this task appears to be purposeless and is discussed in detail in Chapter 6, CS2). These forms are usually sent directly from the electronic system to the supplying pharmacy through the electronic systems portal, however as this function on the electronic system has not been working recently, the home has been filling out the order form electronically, then printing the forms and sending them by hand to the supplying pharmacy. Therefore, the supplying pharmacy will also have a copy of what medications have been requested for the upcoming 28-day supply of medicines cycle.

CS2 – P7 [medicines management lead]: *On a monthly basis, I do them all [re-orders] through the paperwork on the FP10s [repeat slip] and then send them [re-orders] to the surgeries. The surgeries then EPS [electronic prescription service] the actual prescriptions to the supplying pharmacy…*

Prescription Check against Re-order [CS2]

Once the GP surgery has made up the prescriptions using the right-hand side of the FP10 prescriptions filled out by the care home, the prepared prescriptions are sent electronically to the supplying

pharmacy. As the pharmacy has a copy of what has been requested by the care home, they are able to check the prescribed items against the order forms sent by the care home. During the interview, the care home's medicines management lead mentioned that any discrepancies from the care homes order form to the prescribed items will be noted on a list. The list is then faxed to the care home, where the medicines management lead will chase up any missing items and discrepancies. This is usually received in week three.

CS2 – P7 [medicines management lead]: *…the pharmacy then obviously receive them and then anything they're missing is faxed to me because they know this because obviously, I would have also sent the pharmacy what I had ordered using the ordering form on our system.*

Interviewer: *Is that [re-order forms from system] sent electronically?*

CS2 – P7 [medicines management lead]: *It's supposed to be sent electronically but it doesn't work at the minute so we're actually sending them by paper. And then the supplying pharmacy obviously has that list of what we've ordered, then they get the scripts in from the doctors, then anything that's missing, they then send me that...*

Interviewer: *and is that [list from supplying pharmacy of anything missed being prescribed by the GP surgery] sent to you electronically?*

CS2 – P7 [medicines management lead]: *faxed*

Interviewer: *okay so then I guess if anything is missing, something that you'll still need, you'll chase it up with the doctor's surgery?*

CS2 – P7 [medicines management lead]: *yeah.*

Interviewer: *So you do all the chasing up? The pharmacy doesn't?*

CS2 – P7 [medicines management lead]: *No, I do.*

CS2 – P7 [medicines management lead]: *So we're on week three at the minute so that's why I have the chase-up sheet and then they'll deliver to me usually around about Wednesday next week [week 4] and then the changeover would be that Sunday night.*

Medicines Checking-in [CS2]

When the medicines are received in the care home, the medicines management lead will check all the medications against the order requests and book them into the electronic system. Booking the items in involves checking each medication's strength, dose, formulation and quantity; then entering the amount received into the electronic system.

Interviewer: *So in between getting the delivery on Wednesday and the changeover on Sunday, what do you have to do in that time?*

CS2 – P7 [medicines management lead]: *Check it all, book it in, make sure everything is correct basically. So then I can go back through what I ordered, missing items, what I've got on the system.*

At this point, if there are any missing items or discrepancies, they are 'chased up' again.

CS2 – P7 [medicines management lead]: *Medications will then come in and I book them in on the computer in the eMAR system. And then obviously ensure all medicines are here ready for the date that they go out. If any aren't, I obviously chase them. Then, when they come in, they are booked into the system.*

Medicines Changeover [CS2]

This care home has locked medicine cupboards in each resident's room. All medications are prepared in boxes and kept in each resident's cupboard in their room. Only residents who have the capacity to self-administer have keys to their own cupboard, capacity is determined by the home through an initial assessment of the resident when they decide to reside at the care home and periodically afterwards. All other cupboards can only be accessed by the nurses or care home management.

Medicines changeover is usually done over the weekend directly before the beginning of a new cycle. It usually takes one full day for the medicines management lead to come in and changeover all medications in the resident's personal medicine cupboards. Until the medicines changeover, each resident's medication is stored in the medicines room. On the day of changeover, each resident's medication for the new cycle is put into their medicine cupboard, usually on a separate shelf to the current cycle's medication to avoid confusion. Any unused medication from the cycle which has not been 'carried forward' will be taken out of the cupboards and disposed of at this point as well.

> ***CS2 – P7 [medicines management lead]:*** *I keep them [medications] all in here [medicines room] and then I change them over Saturday or Sunday [of week 4] because I found that if I put them in the rooms too early, people [including carers administering and self-administering residents] tend to use them and then they get mixed up.*
>
> ---
>
> ***CS2 – P2 [carer]:*** *…and then on a particular date of the month, you know, four weeks from the last one, they go into the resident's cupboards and all old stocks taken out.*
>
> *The old stocks then go in one of these books and a bucket, that's collected by the pharmacy.*
>
> *And then we start the new cycle.*

Medicines Administration [CS2]

Medicines administration is also incorporated into this care homes electronic system. The process is largely the same as any paper-based system, however the MAR charts are now displayed electronically. The electronic system also has the added benefit of being able to prompt time-specific medicines administration and flag up any medications which are overdue for administration to residents. Similar to signing off a paper MAR chart once a medication is administered, an electronic signature must also be provided on electronic MAR charts. For self-administering residents, the balance of their medications in their cupboard is checked once weekly by a carer to ensure they are taking the correct amounts of medication. The carer will sign off a balance check sheet to signify this. MAR charts are not filled in for self-administering residents.

> ***CS2 – P6 [carer]:*** *It's all computerised so hopefully it reduces the errors on there. Because for example if you're giving a medication but have to have the space in between and you try to give it sooner than you should be giving it, then the system actually alerts you not to give it. Or also if you miss any medications, alerts will also come up, especially like the Parkinson's medications that are time-specific; it will alert you that they need to be given at a specific time.*

This home has the following medication rounds: morning, lunch, tea-time and bed-time. The carers and care home manager reported the morning medication round takes a minimum of two hours, whereas the others are roughly one hour each. As there are no nurses in this residential home, carers undertake the medicines administration phase or facilitate patient self-administration. One carer explained that some medications are very time-specific, for example Parkinson's medication. Therefore, along with all the regular medication rounds, these patients have additional times when they need to be administered medications.

> ***CS2 – P4 [carer]:*** *The drug round consists of one, two, three, four official rounds; but you could have timed medications in between. Sort of like your antibiotics, and your Parkinson's. So you have to be very aware of that, which is all part of your training.*

INTERVIEWS AND PARTICIPANT OBSERVATION RESULTS FOR CASE STUDY 3

General Information on Medicines Management for CS3

Table 8: Case Study 3 Care Home Characteristics

Care Home Characteristics [CS3]		
Type of Home	Nursing & Residential care home	
Number of Residents	39 nursing home residents 20 residential residents	
GP Surgery	All residents are under one GP surgery GP surgery is in very close proximity (374 ft.)	
Pharmacy	Pharmacy is in close proximity (2.0 miles)	
Medicines Storage	Nursing home residents: medicines kept in medicines trolley, additional items administered by carers (i.e. creams) are kept in resident's room Residential residents: medicines kept in locked cupboards in individual resident rooms	
Medicines Management Lead	One medicines management lead	
Staff-to-resident ratio	1:3.4 **The staff-to-resident ratio was given by the care home manager according to information available to him/her at the time, therefore CS2 and CS3 have less detailed information on this figure in comparison to CS1.*	
Type of Medicines Management System	Paper-based	
Number of Participants Interviewed	6	
Interviewees	Manager	Participant 1
	Nurses (x2)	Participants 2 & 3
	Carer	Participant 4
	GP	Participant 5
	Pharmacist	Participant 6
Total Hours of Observation (approximate)	11	

All results in the following sections came from case study interviews and direct participant observations. This care home is both a nursing and residential home. The home has many people who start out as residential but go into nursing and stay within their care home. The 28-day supply of medicines cycle is largely the same for both the residential and nursing sides of the care home. The supplying pharmacy to this care home uses a robot to dispense medication in an MDS, which is then checked clinically and for accuracy by the pharmacist.

This care home follows a 28-day (4 week) cycle in which the medicines management lead re-orders medications in week 2. Once the prescriptions are ready at the GP surgery, the care home picks up the prescriptions and checks them against their re-order. The prescriptions are then picked up by the pharmacy, and once prepared, they are delivered to the care home.

CS3 – P2 [team leader]*: We start a cycle, after one week we re-order for the next cycle.*

Medicines Re-ordering [CS3]

The medicines management lead takes charge of ordering medications each cycle. Re-ordering is done at the beginning of week two. Each resident's medications are checked for quantity and ticked on the re-order form provided by the supplying pharmacy if the items are needed. Medications on the current 28-day supply of medicines cycle are kept in a medicines trolley inside the medicines storage room, while any extra resident medication stock is kept in the medicines storage room cupboards. Once the re-order forms have been completed, one photocopied version is taken to the GP surgery or faxed over and the care home keeps the original version.

This care home follows the following policy for ordering non-blistered items: inhalers for when required use and creams of 500mL are ordered every other month, unless there is a substantial amount leftover to carry through the next 28-day cycle. Creams are used for a maximum of three months before disposal, as advised by CCG infection control.

CS3 – P3 [team leader]: *The pharmacy gives us a re-ordering folder, with all the residents list of medication and things on a separate sheet for each resident. So every month we just tick which medications we need for that monthly cycle. So say the new cycle starts today which is always a Monday anyway but say it starts today, we don't order for next month's cycle up until a week later. Like starting the second week, we order for the next month's cycle.*

So after we do the re-ordering forms, we send them to the GP. We do photocopy it though. We photocopy two copies. We keep the original for the pharmacy, we keep a copy for ourselves, and one copy goes to the surgery. Then they do the scripts and we can either phone to ask if they're ready or we can just go and collect them. It's normally about, a week; say about a week after. They're normally ready about a week after and then we collect them.

CS3 – P6 [pharmacist]: *I think the most important element to having good medicines management within care homes is to have one medicines management lead in the*

home, it makes all the difference to be able know exactly who to contact and communicate with to have a query sorted.

Prescription Check against Re-order [CS3]

Once the prescriptions are ready at the GP surgery, they are picked up by the care home. The medicines management lead now checks the items prescribed against their original order. For any missing items or discrepancies, the care home's medicines management lead will chase this up with the GP. Once all prescriptions are received for all items and any discrepancies are sorted out, the care home will call the pharmacy to pick up the prescriptions. The above explanation is depicted in the following quotes:

CS3 – P3 [team leader]: *And then we have to check them now. We can't just say 'oh we got the scripts, send them off,' we have to check them against the original order to make sure we have everything.*

Interviewer: *Okay, so if something was missing and you send it back to the GP, do you still wait?*

CS3 – P3 [team leader]: *We wait.*

Interviewer: *and then you send everything all together?*

CS3 – P3 [team leader]: *Yeah, we wait until we get all the prescriptions. But sometimes when we order, even though we've given them the reorder forms, sometimes there's one or two items not on the prescription when we get them so we have to send a request to get that prescription.*

So we wait until we get all the prescriptions, check them against the MAR, make sure everything is correct. Dosages, if its changed; but if we don't need it, if we have surplus in stock, and we just got another prescription for it, we just put 'ND' ['not dispensed,' so the pharmacy knows not to dispense those medications as they are not needed for the upcoming 28-day cycle] in pencil on the left side.

And then we just phone the pharmacy to come and collect.

CS3 – P2 [team leader]: *There's times when we have missing medications that aren't on the prescriptions, so we have to write down the medication, the dosage and request it from the GP. So we don't send anything to the pharmacy until we have all the prescriptions.*

CS3 – P5 [GP]: *It goes in phases, where sometimes we're doing well with re-ordering and issuing prescriptions and sometimes it's a bit of a mess. We just need to find a way to be continuously achieving the same results, that are good of course.*

Medicines Checking-in & Medicines Changeover [CS3]

The pharmacy usually delivers the medications to the care home at the beginning of week 4, usually 4-5 days or one week before the beginning of the new cycle.

Interviewer: *and then how long is it usually before the pharmacy delivers the medication?*

CS3 – P3 [team leader]: *Well, we're still waiting now. Our new cycle started on the 5th of this month and we did it the second week, so they collected like the end of the second week. So we're waiting for the medication still [Friday of week 3 in the 28-day supply of medicines cycle].*

Usually 4 or 5 days or a week before we start.

CS3 – P2 [team leader]: *They usually deliver like 4-5 days before we start.*

The supplying pharmacy delivers all medications in blister packs, MAR sheets, 'checking-in' charts and re-order sheets for each resident. The staff state that as there is no time to check-in medicines during a regular shift, the medicines management lead and one other nurse will come in on their day-off to do this task.

To start with, the new MAR charts will be checked against the current cycle's MAR charts. All medications are then checked against the care home's order requests and is documented on the 'checking-in' charts, which require two signatures for verification.

This care home completes the medicines changeover process at the same time as the medicines checking in process. As one nurse is calling out the medication name, strength and quantity sent out loud to the medicines management lead; the medicines management lead checks the item has been received for the correct patient for the correct medication, strength and quantity and then places the medications and blister packs received for the resident directly into a spare medicines trolley.

The only task left for the night before the start of a new cycle is transferring the front page for each resident's medical notes to the next 28-day supply of medicines cycle's folder. The front page includes a picture of the resident and any medication protocols to follow for the resident. This is a short task, that only takes 10-15 minutes and can be completed by any member of staff.

> ***CS3 – P3 [team leader]:*** *But we try to put the new cycle of meds in the spare medicines trolley during meds checking-in to make it easier.*

Medicines Administration [CS3]

Nurses prepare and administer medication to the nursing residents from the medicines trolley. Each medication is checked against the MAR chart, given to resident and the MAR chart is then signed off to indicate the medication was taken.

The excerpt from an interview below discusses the residential medicines administration process.

> ***Interviewer:*** *How long does it usually take for one medication round?*
>
> ***CS3 – P3 [team leader]:*** *Umm, it depends because everybody works at different speeds. The longest one is the morning. Roughly two hours.*

COMPILATION OF INTERVIEW AND PARTICIPANT OBSERVATION RESULTS FOR ALL CASE STUDIES

The final stage of Framework Analysis, Mapping and Interpretation, aims to define all concepts found from the data and use visual displays to aid in interpretation (Ritchie and Spencer, 1994). Therefore, the researcher provides a visual framework encompassing all three case study results, to display the 28-day supply of medicines cycle and each task involved in the cycle from the care home perspective. Along with the framework, a definition of the 28-day supply of medicines cycle, as well as general definitions of each task involved in the cycle are derived by the researcher from the results of this study (figure 11).

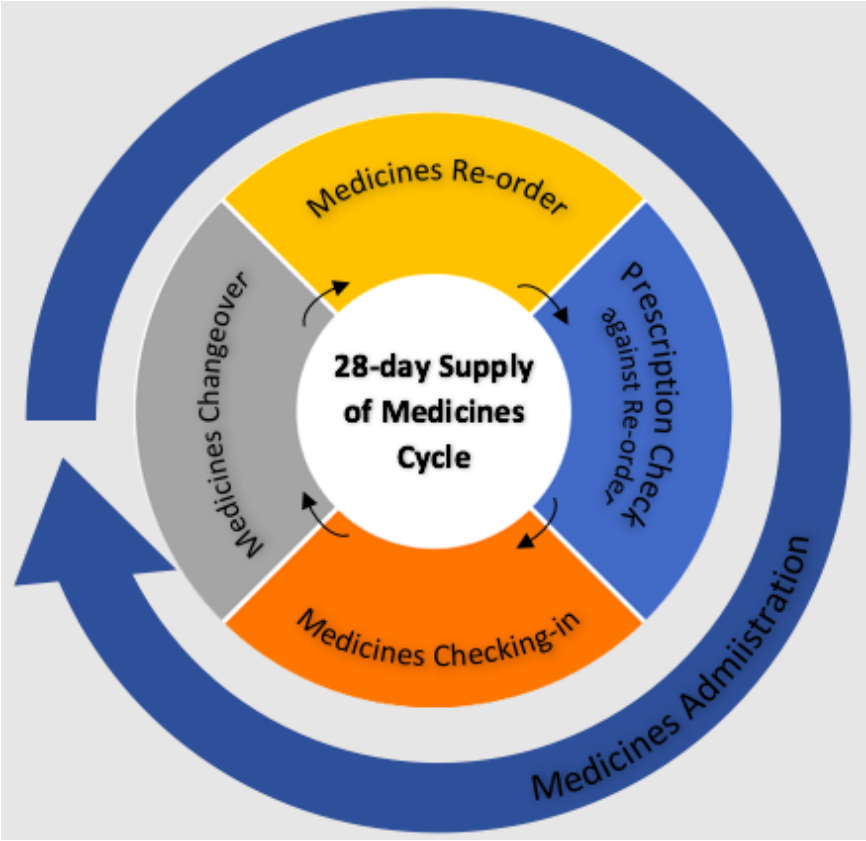


Figure 11: 28-day Supply of Medicines Cycle within Care Homes

The findings from this study thus far reveal what the 28-day supply of medicines cycle entails from the care home perspective: medicines re-ordering and prescription check against re-order, medicines checking-in, medicines changeover and medicines administration.

The figure above represents the order of each task within the cycle: [1] medicines re-order, [2] prescription check against re-order, [3] medicines checking-in and [4] medicines changeover. Medicines administration is depicted as an ongoing task throughout the entire cycle, symbolised by the large arrow surrounding the entire cycle. Each care home's 28-day supply of medicines cycle will be depicted in greater detail via cross-functional process maps in Chapter 6.

28-day supply of medicines cycle: a continuous cycle in which repeat medicines are re-ordered and prescriptions are verified against re-orders. Medicines are then delivered by the supplying pharmacy as a four-week or 28-day supply. Medicines are verified during a 'checking-in' process and then 'changed over' in preparation for the beginning of the new cycle, at which point medicines will be administered to residents.

Medicines Re-order: the process of using the right-hand side of FP10 prescriptions or re-order forms generated by the pharmacy to re-order resident's medication for a 28-day cycle

Prescription Check against Re-order: the process of checking the medication prescribed matches the care home's original re-order requests (correct medication, dose, form and quantity)

Medicines Checking-in: the process of checking each resident's medication delivered to the home by the supplying pharmacy is accurate

Medicines Changeover: the process of removing left over medications from the previous cycle and replacing them with the new medications from the next cycle

Medicines Administration: providing each care home resident with the right medication, at the right dose, time, frequency according to prescribed directions

The researcher has provided a visual framework for the 28-day supply of medicines cycle, whereas NICE guidelines has only provided a visual framework for an overview of tasks involved in medicines management (Chapter 2, page 29) (NICE, 2014). The NICE guideline briefly includes an explanation of each task listed above through their recommendations and under the categories of 'prescribe, order, dispense and supply' (NICE, 2014), however the researcher has formally labelled these tasks as medicines re-ordering, prescription check against re-order, medicines changeover and medicines administration.

Alldred and colleagues provide a flowchart depicting the pathway for regular prescriptions or changes to existing prescribed medicines between the GP surgery, pharmacy and care home (Chapter 2, page 30) (Alldred et al., 2009). In contrast to Alldred and colleagues process flowchart, the researcher has depicted a framework which looks at the 28-day supply of medicines cycle only for repeat prescriptions and only from the care home perspective, providing a definition of the cycle and each task within the cycle.

SUMMARY

Chapter 5 used Framework Analysis, described in Chapter 4, to provide a presentation of study results from semi-structured interviews and direct participant observations for each of the three case studies.

Emerging themes from each case study included: medicines re-ordering, prescription check against re-order, medicines checking-in, medicines changeover and medicines administration. Each of these emerging themes has been labelled as a task within the 28-day supply of medicines cycle from the care home perspective. A definition of each emerging theme throughout each case study under the 'Compilation of Results' section, along with a figure describing the 28-day supply of medicines cycle in care homes (page 91).

Once all data had been analysed via framework analysis, management strategies were explored in existing literature to understand which strategies can be applied to the 28-day supply of medicines cycle to determine any issues within the cycle and strategies for improvements. To answer RQ2 (what are the current issues and challenges within the 28-day supply of medicines cycle?) and RQ3 (how can these issues and challenges be rectified and overcome to improve the overall cycle?), the subsequent chapter uses Six Sigma process improvement strategy, DMAIC to identify emerging issues and challenges within the cycle, and form a suggested framework and set of improvement recommendations for each case study.

CHAPTER 5

SIX SIGMA - DMAIC

This chapter first provides a general overview of operations management strategies commonly used for process improvement within various industries, whilst providing rationale for applying Six Sigma methodology, DMAIC to this particular study. The chapter then explains each stage within DMAIC (Define-Measure-Analyse-Improve-Control).

RATIONALE FOR SIX SIGMA METHODOLOGY – DMAIC

There are many well-known systems used within operations management for process improvement, some of which include: Total Quality Management (TQM), Lean and Six Sigma.

TQM involves the development, deployment and maintenance of organisational systems that are required for various business processes (Kanji and Barker, 1990). It is based on a strategic approach that focusses on maintaining existing quality standards as well as making incremental quality improvements (Kanji and Barker, 1990). It can also be described as a cultural initiative as the focus is on establishing a culture of collaboration among various functional departments within an organisation for improving overall quality (Dahlgaard and Mi Dahlgaard-Park, 2006).

The basic difference between TQM and Six Sigma is the approach. While TQM views quality as compliance to internal requirements (Juran and Godfrey, 1999), Six Sigma focusses on improving quality by reducing the number of defects (Dahlgaard and Mi Dahlgaard-Park, 2006). Although the end-result may be the same in both philosophies (producing better quality products or services), TQM can reach a saturation point, after which no further quality improvements can be made as its focus is to comply with internal requirements (Andersson et al., 2006). In contrast, Six Sigma does not reach saturation as it takes the quality improvement processes to the next level (Andersson et al., 2006).

The need for continuous quality improvement, rather than simply quality improvement according to standards, is especially important in the healthcare field and to a process as important as managing repeat medications safely and appropriately through the 28-day supply of medicines cycle within care homes, where results directly affect resident's lives and health. As Six Sigma emphasises *continuous* improvement of business processes, does not reach saturation and takes quality improvement to the next level, it is better suited to the 28-day supply of medicines cycle.

Furthermore, TQM revolves around improving individual operations within unrelated business processes (Juran and Godfrey, 1999), whereas Six Sigma focusses on improving all the operations within a single business process (Andersson et al., 2006). As the 28-day supply of medicines cycle is a single complex business process or cycle, Six Sigma strategies are used in this research, rather than TQM.

Another common operations management strategy is Lean. Both Lean and Six Sigma aim to eliminate waste and create the most efficient system possible. However, they take different approaches to achieving this goal and in identifying the root cause of waste (Andersson et al., 2006). Lean philosophy states that waste comes from unnecessary steps in the production process that do not add value to the finished product (Liker, 1997), whereas Six Sigma suggests that waste results from variation within the process (Harry and Schroeder, 2006). Lean strives to maximise value to the customer using as few resources as possible and by analysing workflow to reduce cycle time and eliminate waste (Liker, 1997). In contrast, Six Sigma strives for near perfect results that will reduce costs and achieve higher levels of customer satisfaction (in this case the care home) (Harry and Schroeder, 2006). Lean looks at ways to increase flow while Six Sigma focusses on achieving consistent results (Andersson et al., 2006).

Like most processes in healthcare, medicines management is a patient-oriented service (Barnett, 2018; Miller and Fritz, 2019). Unlike manufacturing for retail, healthcare processes are not majorly concerned with producing the most products in the shortest amount of time (Mold, 2017). Instead, the processes need to achieve perfection in delivering medical devices, medications, or services to patients (Mold, 2017). Similarly, the 28-day supply of medicines cycle needs to deliver accurate repeat medications in a timely manner to facilitate safe medicines administration to care home residents, which involves administration of the correct medication, to the correct patient at the correct time, dose and formulation consistently. The table below explains the similarities and differences between TQM, Lean and Six Sigma (table 9).

Table 9: Similarities and Differences between TQM, Six Sigma and Lean (Andersson et al., 2006)

CONCEPTS	TQM	SIX SIGMA	LEAN
ORIGIN	The quality evolution in Japan	The quality evolution in Japan and Motorola	The quality evolution in Japan and Toyota
THEORY	Focus on customers	No defects	Remove waste Improve flow in processes
PROCESS VIEW	Improve and uniform processes	Reduce variation and improve processes	Project management
APPROACH	Let everybody by committed	Project management	Understanding customer value, value
METHODOLOGIES	Plan, do, study, act	Define, measure, analyse, improve (or design), control (or verify)	stream, analysis, flow, pull, perfection
TOOLS	Analytical and statistical tools	Advanced statistical & analytical tools	Analytical tools
PRIMARY EFFECTS	Increase customer satisfaction	Save money Achieves business goals and improves	Reduce lead time Reduces inventory, increases productivity
SECONDARY EFFECTS	Achieves customer loyalty and improves performance	financial performance	and customer satisfaction
CRITICISM	No tangible improvements, resource-demanding, unclear notion	Does not involve everybody, does not improve customer satisfaction, does not have a system view	Reduces flexibility, causes congestion in the supply chain, not applicable in all industries

Having understood why Six Sigma is best suited to this research rather than other major strategies in its field, it is important to differentiate between the methodologies within Six Sigma and why DMAIC was chosen for this research.

There are two well-known methodologies which fall under the Six Sigma category. These methodologies include: DFSS (also known as DMADV), and DMAIC. DFSS, "Design for Six Sigma" has no standard acronym like DMAIC. Organisations have therefore adopted a variety of approaches resulting in the most popular acronym DMADV. DMADV stands for its five stages within a Six Sigma project: Define, Measure, Analyse, Design and Verify (Park, 2003; Shahin, 2008). Overlapping with some of DMAIC's stages within a Six Sigma project, DMAIC stands for: Define, Measure, Analyse, Improve and Control (Harry and Schroeder, 2006; Park, 2003; Shahin, 2008).

The key difference between the two methodologies is the context in which each one should be used. DMADV (DFSS) is aimed at creating a new product or process design, whereas DMAIC is focussed on improving an existing process (Selvi and Majumdar, 2014). As the 28-day supply of medicines cycle already exists in care homes, this research aims to improve the existing process, rather than unnecessarily creating a completely new process. Therefore, this research uses the most-used Six Sigma methodology, DMAIC, to improve the existing 28-day supply of medicines cycle for care homes.

SIX SIGMA IN HEALTHCARE

Quality in healthcare organisations has been improved by continuous improvement strategies, such as Six Sigma (Sandra C. Buttigieg et al., 2016). Six Sigma was first fully implemented into the healthcare organisation Commonwealth Health Corporation (CHC) with General Electric in Kentucky, USA, 1998. The implementation provided over $2.5 million improvements, decreasing the cost of radiology by 21.5% per procedure (Thomerson, 2001).

A three-tier hospital system in Ohio, USA implemented Six Sigma throughout its organisations to provide a significant level of change to improve financial performance in the year 2000 (Lazarus and Stamps, 2002). Mount Carmel has implemented 44 Six Sigma projects, of which 21 are complete (Van Den Heuvel et al., 2005). Examples include: improving processing time in central scheduling, claims denials due to long-stay observations, implementing a procedure-based delivery system in the surgery area to ensure supplies are present when needed during an operation, enhancing clinical documentation, making clinical laboratory results available to necessary stakeholders when

requested, reducing cycle time in various inpatient and outpatient diagnostic areas. The company gained an initial financial return of $3.1 million, and is expected to increase employee and physician satisfaction, with Six Sigma implemented as a methodology into the organisation's performance improvement plan (Lazarus and Stamps, 2002; Thomerson, 2001; Van Den Heuvel et al., 2005).

A large tertiary otolaryngology clinic in the US aimed to apply Six Sigma strategies to eliminate process waste and reduce variation (Lin et al., 2013). The study managed to decrease overall lead time from patient arrival at the clinic to the exam start time by 12.2% and improve on-time starts for patient exams by 34% (Lin et al., 2013).

A study completed in the UK specifically used the DMAIC methodology to generate and examine quantitative evidence of implementing radio frequency identification (RFID) technology of improving effectiveness and efficiency of outpatient surgical processes (Chandra et al., 2012). Using DMAIC, the study estimated annual cost savings with RFID as $1,932,476 to $1.93 million, and per patient average savings of $298 and 1.1 hours per surgery (Chandra et al., 2012).

A medical college hospital in India used DMAIC to reduce the patient waiting time in a registration process in the Health Information Department. The project reduced patients average waiting times by 94%, along with a 91% reduction in queue length and 48% reduction in percentage of scheduled staff needed to complete the process (Bhat et al., 2014).

Finally, Six Sigma strategies have been recognised as powerful improvement methodologies to reduce medication errors, increase patient safety and reduce operational costs (Trakulsunti and Antony, 2018). The methodology is supported by healthcare organisations because it combines cost reduction with an outstanding standard of health service to the patient (Matthias and Brown, 2016). Aiming to reduce medication errors can focus on various parts of the medicines management process, some examples of studies are included below.

A study specifically investigating different types of medication errors in a mid-sized hospital in the US applied a combination of Lean and Six Sigma methodologies to obtain a decrease in the total error rate from 0.33% to 0.14% in five months, estimated labour cost reductions during this time of $550,000 (estimated at $1.32 million annually), improved patient satisfaction and employee morale (Esimai, 2005).

Castle and colleagues utilised DMAIC to reduce medication errors in a home-delivery pharmacy service, consisting of eight prescription processing, three dispensing and six call centre pharmacies (Castle et al., 2005). Wrong dose selection errors were reduced by 33%, wrong direction by 49%, sound-alike,/look-alike (SALA) errors by 69%, supply errors by 48% and patient name errors by 46% (Castle et al., 2005).

A hospital in Taiwan implemented DMAIC methodology to enhance quality and patient safety whilst decreasing cost, to ultimately reduce dispensing errors in the pharmacy department (Chan, 2004). Before the implementation of DMAIC, the pharmacy team was averaging 338.8 errors per one million prescriptions. After implementation of DMAIC, this number reduced to 230 errors per one million prescriptions, providing a 30% reduction in dispensing errors (Chan, 2004). Additionally, there was improved frontline staff productivity as well as patient safety by the reduction of human errors (Chan, 2004). This example will be discussed in greater detail throughout the section titled 'DMAIC: The Five Stages' (page 102), outlining the steps the study took during each DMAIC phase (Define-Measure-Analyse-Improve-Control).

SIX SIGMA AND DMAIC METHODOLOGY

Originally established by Motorola in 1979 as a quality improvement approach, Six Sigma has grown rapidly in the past few decades (Andersson et al., 2006). Motorola's goal was to improve all products – goods as well as services – by a certain magnitude within five years (Klefsjö et al., 2001). The company had a focus on improvement rate, but more specifically of becoming sufficiently better expeditiously and not just 'better.' Setting a clear measure on the improvement work, the Six Sigma program was launched in 1987 (Klefsjö et al., 2001).

Before the Six Sigma program was launched, Motorola was spending between five and twenty percent ($800 to $900 million) of its revenues on correcting poor quality, now known as, defects (Harry and Schroeder, 2006). The Six Sigma program was the first to focus on how products were designed and all the processes involved, rather than focusing on responding to defects of products as they arose (Harry and Schroeder, 2006). Within four years of implementing the Six Sigma program, Motorola had saved $2.2 billion, by providing customers with higher-quality products at a cheaper cost (Harry and Schroeder, 2006).

Six Sigma management theory states the key to greater bottom-line profitability lies not in reducing costs but in improving quality (Harry and Schroeder, 2006). Six Sigma emphasises the creation of business processes in such a way that defects never arise in the first place and provides a significant competitive advantage over companies which are forced to spend time and resources identifying and rectifying product defects or process mistakes (Harry and Schroeder, 2006).

Six Sigma provides the necessary tools and techniques for organisations and quality practitioners to implement systematic approaches to quality improvement, re-creating or improving business processes so that less defects and errors arise in the future (Shankar, 2009). Six Sigma is a proactive methodology process because it focusses on decreasing the number of errors that arise, rather than fixing errors after they have occurred (Harry and Schroeder, 2006). In Six Sigma, companies operating at the highest quality standards will always have the lowest cost structure in its industry (Harry and Schroeder, 2006).

Furthermore, Six Sigma is a performance target which applies to a single critical-to-quality characteristic, rather than the total product (Harry and Schroeder, 2006). Therefore, the more complex a product is, the more opportunities for defects to occur and the greater chance a defect may occur somewhere within the product even if all the individual components are Six Sigma (Harry and Schroeder, 2006).

Sigma is a statistical measure of process variation referred to as the standard deviation (Klefsjö et al., 2001). It relates to the capability of a process, meaning its ability to produce non-defective products, units or parts (Klefsjö et al., 2001). Six Sigma generally implies that the occurrence of defects or for something to go wrong in any organisational process is at a rate of less than 3.4 defects per million opportunities (DPMO) (Klefsjö et al., 2001). Comparatively, sigma levels of three, four and five produce DPMO rates of 66,807, 6,210, and 233, respectively (Klefsjö et al., 2001).

The average for many industries is around four sigma level, equating to 6,210 DPMO. Whereas, the entire service industry in the United States has an average sigma level between 2.0 and 2.5, equivalent to between 158,700 and 208,500 defects or failures per million opportunities (Bandyopadhyay and Coppens, 2005). Specific examples in healthcare include a sigma level of 1.0 in the use of beta blockers to treat high blood pressure and other cardiac problems, a sigma level of 2.0 in treating depression, a sigma level of 4.0 in treating injuries, and a sigma level of 3.0 in antibiotic use (Bandyopadhyay and

Coppens, 2005). These sigma levels appear to be quite low considering the healthcare industry is one in which errors cannot be accepted, as they can have detrimental effects to people's health.

As Six Sigma produces a concrete goal of achieving less than one defect per 3.4 million opportunities, the rate of error within the 28-day supply of medicines cycle could decrease if implemented correctly, therefore providing the potential for safer medicines management to care home residents; or at the very least, areas for improvement can be identified. The additional benefit to implementing Six Sigma within the care home 28-day supply of medicines cycle is the introduction of a proactive process, rather than a reactive process.

As Six Sigma is the goal, it is achieved by DMAIC methodology, which defines critical-to-business processes, gathers data, analyses the results to pinpoint errors and develop ways to eliminate those errors (Harry and Schroeder, 2006). Each stage of DMAIC will now be briefly explained.

DMAIC: THE FIVE STAGES

This section of the thesis will describe each of the five phases of DMAIC.
Define – Measure – Analyse – Improve - Control

Define

Define the problem at hand (Atanelov, 2016).

During the *Define* phase, companies begin to understand the fundamental concepts of Six Sigma and gain a sense of how it can be used as a problem-solving methodology with a unique set of tools (Allen, 2019). This stage is a source of identification, looking at the organisation's ability to satisfy customer expectations in terms of quality, price and delivery with a known degree of certainty (Lynch, 2003). Organisations will recognise how their processes affect profitability and then define what the critical-to-business processes are (Chang, 2016).

Managers and employees begin to realise the organisations processes and degree of variation within their processes must be controlled. Variation has a direct impact on business results in terms of cost, cycle time and the number of defects that affect customer satisfaction (Harry and Schroeder, 2000). Therefore, the company will begin to question inputs, the processes that go into creating a product or

service, rather than simply inspecting the final product or service delivered to the customer' (Harry and Schroeder, 2000).

> *Returning to an example mentioned on page 100, where DMAIC was utilised to reduce dispensing errors within a hospital pharmacy department in Taiwan, the research team identified this goal and scope of the project during the define phase* (Chan, 2004)*. They did this by using the voice of the customer (VOC) analysis to obtain data regarding the customers' needs. In this case, both patients and nurses were identified as customers* (Chan, 2004)*.*

Measure

Measure current baseline (Atanelov, 2016).

The *Measure* phase aims to identify where a process is at the time it is measured and helps identify the goals a company should aspire to achieve. During the *measure* phase, critical-to-quality (CTQ) characteristics in the process are measured and described, performance standards are defined and measurement systems are validated.

> *During the measure phase in the Taiwan-based hospital pharmacy department, the team used historical data and manually collected data to establish baseline performance of the process* (Chan, 2004)*. Frontline pharmacists were trained to use data collection sheets to capture dispensing errors. This provided a double check process before giving medicines to patients. The data sheets were analysed by the team leader at the end of each day* (Chan, 2004)*.*

Analyse

Analyse and identify the specific causes of the problem (Atanelov, 2016).

The *analyse* phase aims to identify the root causes of the problems that were explained during the *measure* phase (Brewer, 2004). The baseline sigma performance level of an organisation can be calculated during the *measure* or *analyse* phase. Based on the sigma level of an organisation, Harry (1998) and Lucas (2002) suggested that these organisations can be classified as either 'world-class,' 'industrial average' or 'non-competitive.'

There are four quality metric terms (defined below) which can be used in Six Sigma projects to emphasize the consistency of products or services: defects per million opportunities (DPMO), C_{pk} (process capability index), cost of poor quality (COPQ) and sigma level.

Table 10: Definitions of DPMO, C_{pk}, COPQ and Sigma Level (Bothe, 1997; Breyfogle, 2003; Pande et al., 2000)

$$DPMO = \frac{(1{,}000{,}000 \times number\ of\ defects)}{(number\ of\ units \times number\ of\ opportunities\ per\ unit}$$

$$Cpk = \frac{distance\ from\ the\ process\ average\ to\ the\ nearest\ specification\ limit}{3\sigma}$$

[where σ represents the process standard deviation]

COPQ: a percentage of sales; poor quality costs are those associated with rework, scrap, solutions, prevention and appraisal

Sigma Level: number of standard deviations (σ), from the process average to the nearest specification

To help apply Six Sigma tools and visualise industry performance for comparative purposes, RBX Industries (chemicals industry, making materials, e.g. rubber) created a nomograph (figure 12). The nomograph visualises the relationship between the performance indexes defined above. The lower horizontal axis represents the sigma levels from zero to six, while the upper horizontal axis indicates the expected DPMO. The left vertical axis provides the C_{pk} values from zero to two, while the right vertical axis provides the typical values for COPQ (Rudisill and Druley, 2004). The diagonal line represents the graphic equivalency of the metrics. For example, a sigma level of three equates to a Cpk of one, DPMO of 66,811, and an estimated 30% for COPQ.

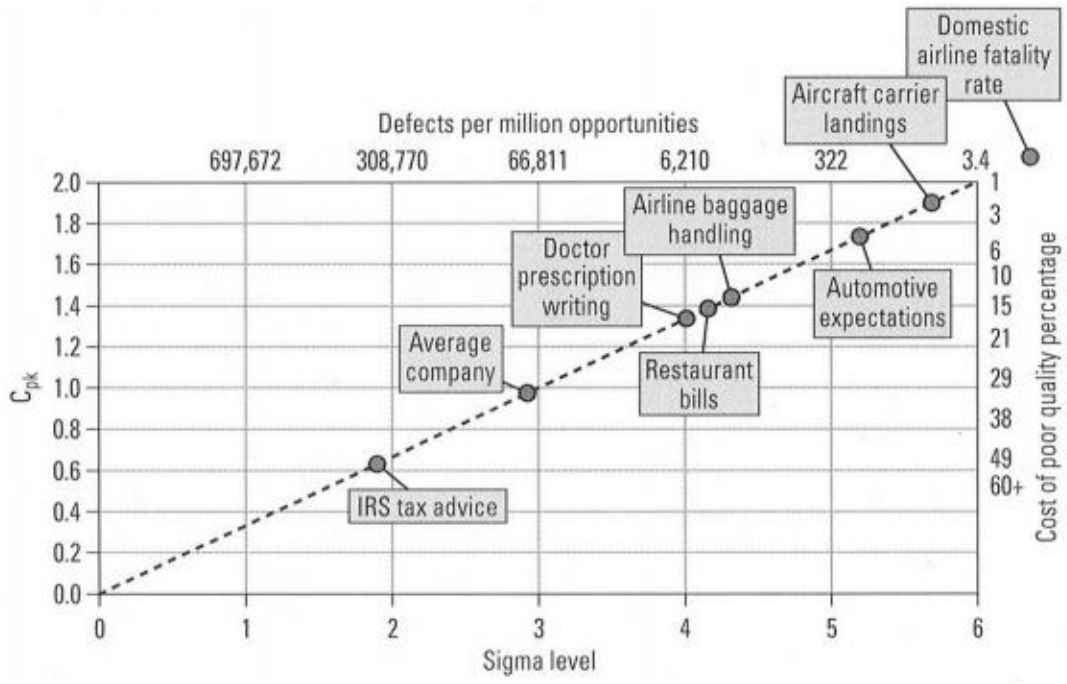


Figure 12: Six Sigma Metric Nomograph (Rudisill and Druley, 2004), depicting multiple industry performance levels.

Example reference points for various industries have been added for comparative purposes. For example, RBX Industries determined the average number of errors (defects) in doctor's prescription writing is approximately 6,210 errors (defects) per million opportunities (DPMO), therefore giving a sigma performance level of 4, equating to a C_{pk} of approximately 1.38 and an estimated 17% for COPQ.

> *During the analyse phase in the Taiwan-based hospital pharmacy department, the team created a process map of dispensing to identify sources of variability in the process* (Chan, 2004)*. The data collected showed that human factors including, working attitude, knowledge and experience were the largest contributor of dispensing errors* (Chan, 2004).

Improve

Improve and implement the intervention to reduce the problem (Atanelov, 2016).

The *Improve* phase identifies steps needed to improve the process and reduce major sources of variation (Harry and Schroeder, 2000). It aims to improve and control those variables that have the greatest influence on a product or service's key characteristics (Harry and Schroeder, 2000). During

the *Improve* phase, adjustments are made to the design of the process and implemented to improve the performance of CTQs (de Koning and de Mast, 2006).

> *During the improve phase in the Taiwan-based hospital pharmacy department, the team implemented an automatic dispensing machine for prescriptions with less than three medications prescribed* (Chan, 2004)*. After implementing the process, the team leader was required to collect data to monitor the process until it was working smoothly* (Chan, 2004).

Control

Control to ensure that the improvement phase lasts and to ensure that deviations from goal performance are corrected without causing defects (Atanelov, 2016).

The aim of the *control* phase is to make adjustments to the process management and control system by implementing control plans in order for improvements to be sustainable, and to gain empirical verification of the project's results to determine the new process capability (de Koning and de Mast, 2006).

> *Finally, during the control phase in the Taiwan-based hospital pharmacy department, the team used control charts to ensure that the improvement was sustained* (Chan, 2004)*. The study was successful in reducing dispensing errors by over 30%. The study concluded that reducing the number of human errors in the process would improve frontline staff productivity and patient safety as well* (Chan, 2004)*.*

Table 11 summarises each stage within DMAIC and the worked example by Agnes Chan of using DMAIC to reduce medication errors:

Table 11: Objectives of DMAIC Phases (Brewer, 2004; Chan, 2004; Harry and Schroeder, 2000)

DMAIC Phase	Objectives	Worked Example
Define Identify key business issues and Define the project's purpose and scope	- Recognise how processes affect profitability/resident satisfaction - Define the critical-to-business processes	- Identified goal and scope of the project as reducing dispensing errors - Used voice of the customer (VOC) (both patients and nurses in this case)
Measure Understand current performance levels by measuring the frequency of defects	- Select critical-to-quality (CTQ) characteristics - Define performance standards - Validate measurement systems	- Frontline pharmacists trained to use data collection sheets to capture dispensing errors, providing a double check process before giving medicines to patients - Data sheets analysed by team leader at the end of each day and established baseline performance
Analyse Understand current performance levels by analysing when and where defects occur	- Establish product capability - Define performance objectives - Identify variation sources	- Process map to identify sources of variability during dispensing - Human factors (working attitude, knowledge, experience) were the largest contributor to dispensing errors
Improve Achieve breakthrough improvement by implementation	- Screen potential causes - Discover variable relationship - Establish operating tolerances	- Implemented automated dispensing machine for prescriptions with less than three items to reduce chance for human errors
Control The Process so that it stays fixed	- Validate measurement system - Determine process capability - Implement process controls	- Implemented control charts
DMAIC Methodology	- Reduce process variation therefore reducing defects to final product or service delivered from the process	- Study Results: decrease in dispensing errors by 30%, less errors caused due to human factors – automated system improved frontline staff productivity and patient safety

SUMMARY

This chapter presented three operations management techniques for process improvement: TQM, Lean and Six Sigma. Six Sigma was chosen as it does not reach saturation and aims to achieve consistent results (Andersson et al., 2006). The Six Sigma methodology DMAIC was chosen, rather than DFSS because DMAIC focusses on improving existing processes rather than creating new processes (Selvi and Majumdar, 2014). The chapter then presents each phase within DMAIC; Define, Measure, Analyse, Improve and Control. Chapter 8 will discuss the application of Six Sigma on each case study from this research.

CHAPTER 6

APPLICATION OF SIX SIGMA TO CASE STUDIES

This chapter describes how DMAIC was applied to the 28-day supply of medicines cycle for each case study (excluding the medicines administration phase). As a similar issue was found from each case study during the Define phase, all three cases focus on decreasing discrepancy rates between repeat re-order requests made from the care home to the prescriptions generated at the GP surgery. The same tools are used in each case study during the Measure and Analyse phase, however depicting data generated from each individual case study.

An individual set of recommendations is then provided for each case study during the Improve phase. The same Control measure is suggested for each case study, therefore the error log presented is the same for each case. Finally, for verification of the suggested process implementations, the researcher conducted stakeholder feedback sessions *to receive feedback on the model and recommendations provided. Results from each* stakeholder feedback sessions *are also presented under the Control phase of each case study in this chapter. Finally, with the compilation of recommendations to each case study, the researcher created a generalised process map and set of recommendations for all care homes to follow.*

The layout of this chapter is as follows: the first section (DMAIC Framework) details each stage of DMAIC and the tools used by the researcher in all three case studies. The second section presents the 'Application of DMAIC' on each individual case study, (forming subsections of Case Study 1, 2, 3). The final section of this chapter (Generalised Recommendations) provides the suggested process map and recommendations for all care homes.

DMAIC Framework

The figure below represents the tools used in each DMAIC phase of this study. Each tool will be explained under its associated phase in the subsequent sections.

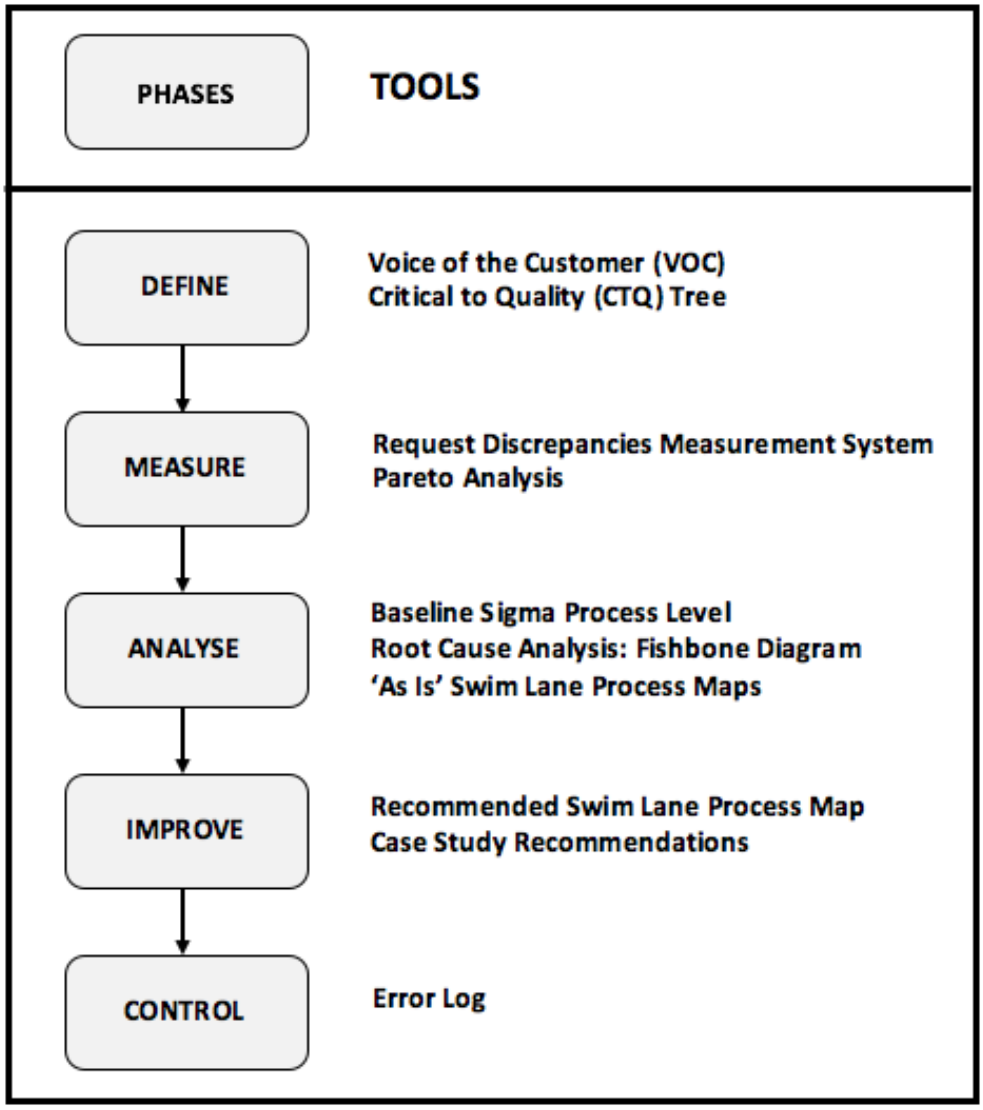


Figure 13: DMAIC Framework using Six Sigma Tools

DEFINE

The *Define* phase involves recognising the care home's ability to satisfy its care home responsibilities in terms of receiving and then providing the correct medications to residents. Variation within the 28-day supply of medicines cycle has a direct impact on time taken to complete each task within the cycle, as well as the number of defects or discrepancies. This can negatively impact organisational responsibility and safety: increasing the risk of near-misses and medication errors, as well as the cost to the NHS in terms of medication waste.

The inputs considered during the define phase include the end-to-end 28-day supply of medicines cycle and all its tasks involved, which support the delivery of the following outputs (services delivered): [1] the care home receiving all the correct medications for each resident, [2] decreased medication waste, and [3] the correct medication administered to the correct care home resident at the correct time, in the correct strength, form and dosage.

1. VOC

The *Define* phase used the 'Voice of the Customer (VOC)' to determine the scope of the Six Sigma project. Although the final client within medicines management is the care home resident, this study labelled the care home staff as the customer because the care home is placing the medication order and subsequently receiving it (as the customer) during the 28-day supply of medicines cycle. For nurses or carers to administer the correct medications at the correct time to the correct resident, or give the correct medications to self-administering residents in a timely manner; the care home must receive the correct medications, with sufficient time to check and organise them into the medicines trolley or resident medication cupboards. It is common for management studies to employ industry or process experts as the customer during VOC (Chan, 2004). Therefore, the care home staff are the primary customers for this study. The VOC was captured by all 18 semi-structured interviews and direct participant observations of one 28-day supply of medicines cycle in each care home. The VOC is the task of identifying customer needs, structuring customer needs and providing priorities for customer needs (Griffin and Hauser, 1993).

One of the key challenges that surfaced from the VOC for all case studies was receiving prescriptions from the GP surgery for *all* medications that were requested, and at the *requested quantity* from the care home. As requesting medication and receiving the correct prescription is an early stage in the 28-

day supply of medicines cycle, it is fundamental to the smooth running of subsequent processes in the cycle.

The researcher identified this as a key area for improvement using Six Sigma, DMAIC in all case studies and therefore, the primary input investigated was labelled *'Request Discrepancies'* by the researcher. A definition by the researcher is now provided:

> ***Request Discrepancies:*** *any difference between the care home's repeat medication order request to the surgery, and the prescription subsequently produced from the order request or the item subsequently dispensed*

2. Types of Discrepancies derived from CTQ Tree

The researcher then employed Critical-to-Quality (CTQ) trees to translate the VOC into specific requirements (Brewer, 2004). CTQ is:

> *the key measurable characteristic of a product or service whose performance standards or specification limits must be met in order to satisfy the customer. In practice, a CTQ tree, a tree diagram for finding a problem or something to be improved in the product through the customer's eyes, is the most useful tool for ensuring the configuration or transformation from critical customer requirement to CTQ (Wu et al., 2014).*

The researcher created a CTQ tree on the basis of the VOC and project objective to establish the essential CTQ characteristics (figure 14).

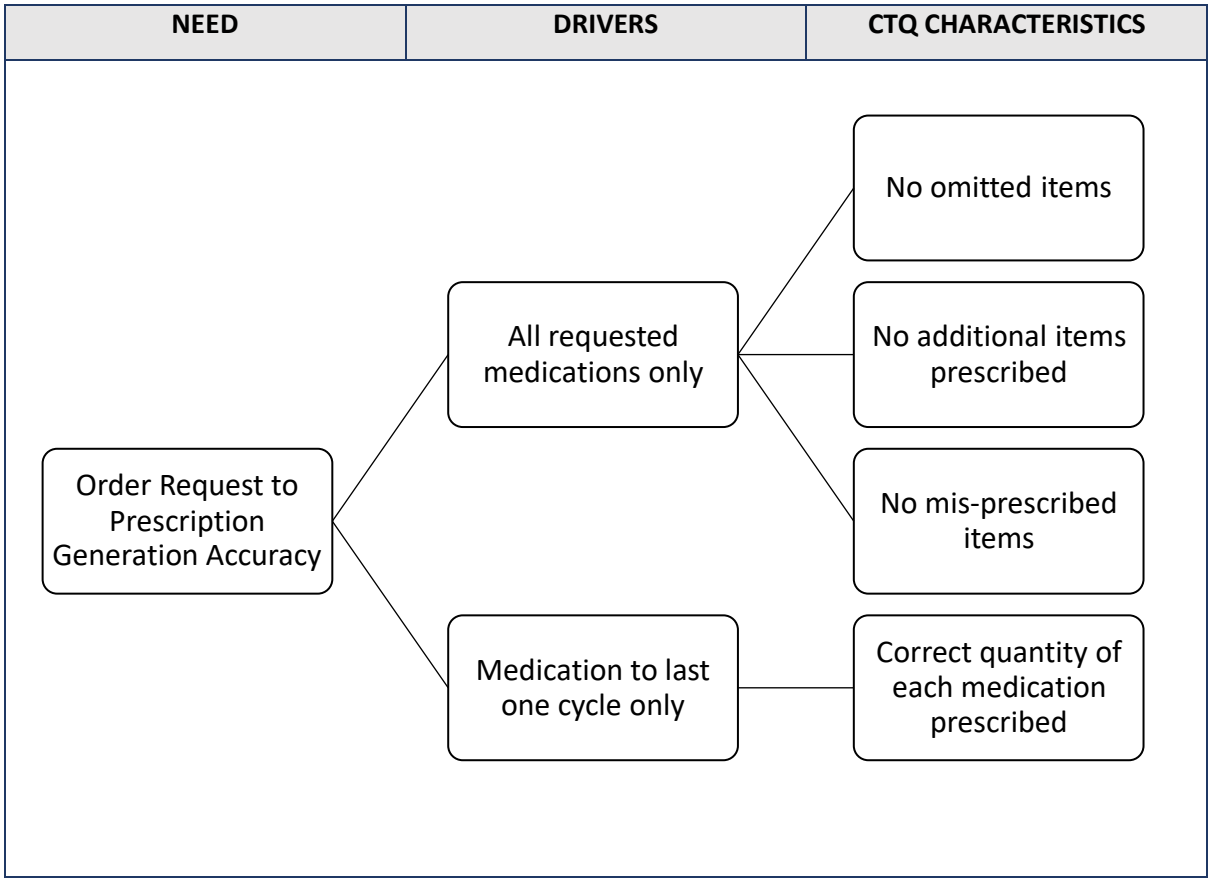


Figure 14: Critical-to-Quality (CTQ) Tree

The CTQ tree provided the CTQ characteristics necessary to ensure order request to prescription generation accuracy. These CTQ characteristics were therefore labelled as *avoidable discrepancies*. The resulting CTQ characteristics have been named and defined:

CTQ Characteristics/Avoidable Discrepancies

(Avoidable Discrepancies to ensure Order Request to Prescription Generation Accuracy)

1. ***Omitted items*** *– any item appearing on the repeat medications list that has been requested by the care home, but has not been prescribed by the GP surgery*
2. ***Additional items*** *– any item appearing on the repeat medications list that has not been requested by the care home this cycle, however the GP surgery have still prescribed it for the cycle*
3. ***Incorrect quantity*** *– any item appearing on the repeat medications list that has been requested by the care home in a specific amount (quantity), but the GP surgery has prescribed a different amount (usually the amount already specified on the repeat medications list)*
4. ***Mis-prescribed items*** *– any medication that has been requested by the care home and prescribed incorrectly by the GP surgery this cycle, including any medications which have been switched to a different brand name or different medication within the same class of medications. For example, when new dosage instructions are started mid-cycle under directions of the GP or specialist and may or may not be on the repeat medications list at this point. The new dosage has been requested by the care home for the subsequent cycle and has been prescribed incorrectly (perhaps with the old dosage instructions) by the GP surgery.*

An example of each type of discrepancy listed above from each case study is given in a table under each case study's *Define* phase (table 12, page 123 [CS1], table 18, page 136 [CS2], table 22, page 149 [CS3]).

MEASURE

3. Request Discrepancies Measurement System – determined by CTQ Tree

To establish factors that needed to be measured during this phase, the researcher revisited the CTQ tree created during the *define* phase. A way to measure each CTQ characteristic/avoidable discrepancy generated from the CTQ tree in the previous phase was determined. Figure 15 depicts how each CTQ characteristic would be measured in each case study.

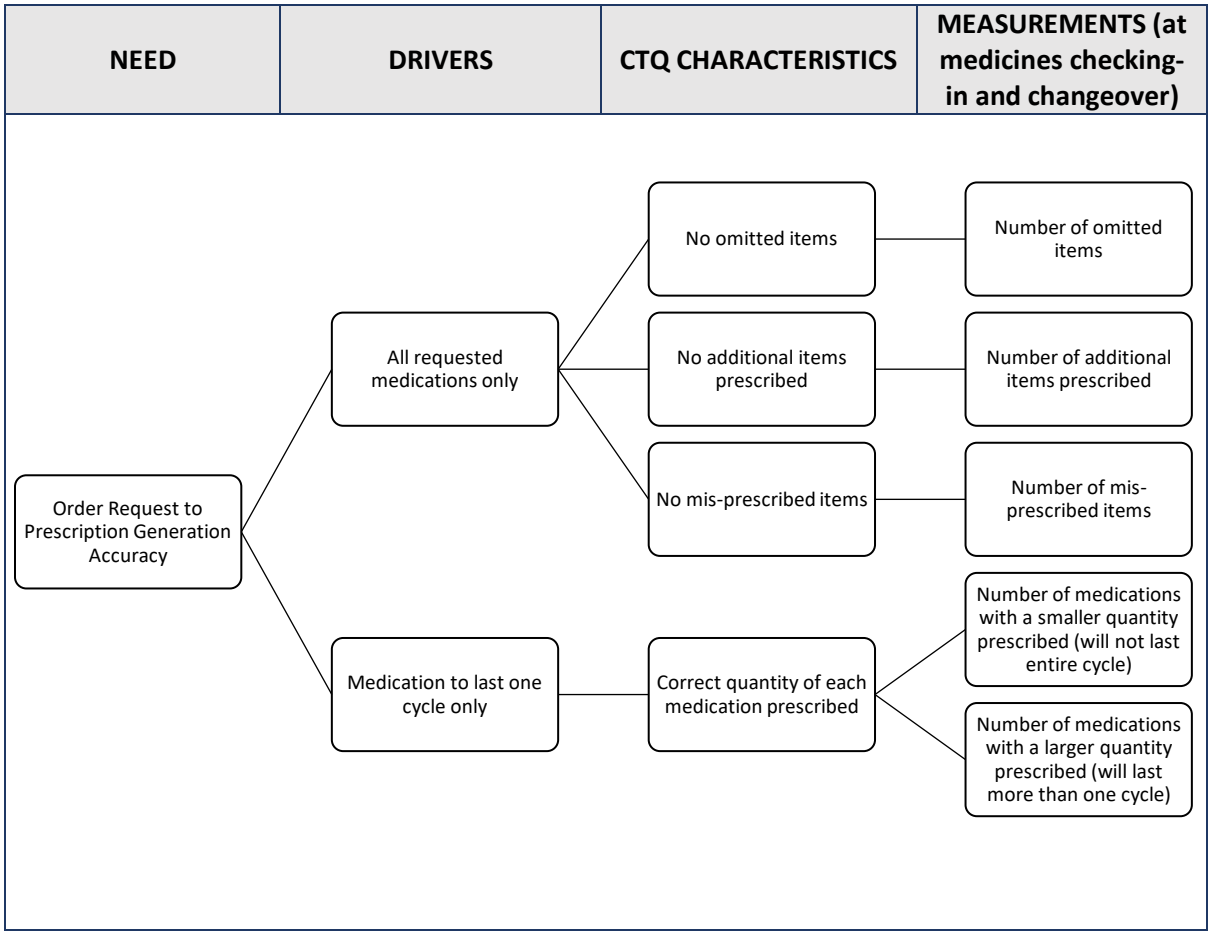


Figure 15: CTQ Tree with Measurements

Once the measureable parameters had been determined, the researcher documented each discrepancy encountered during the medicines checking-in task; between the medications dispensed (in accordance to the prescriptions that were generated) and the order request prepared by the care home. Tables in the subsequent sections (table 13, page 124 [CS1], table 19, page 137 [CS2], table 23, page 150 [CS3]), show the number of discrepancies encountered at the medicines checking stage during one 28-day supply of medicines cycle for each case study.

4. Pareto Chart

To illustrate the discrepancies encountered in each case study, Pareto Charts have been used (figure 18, page 125 [CS1], figure 21, page 138 [CS2], figure 24, page 151 [CS3]), for each case study. The Pareto Chart was named after the Italian economist, Vilfredo Pareto. The Pareto Principle, also known as the Rule of 80/20, suggests that 80% of problems can be traced to as few as 20% of root causes (Sanders, 1988). In quality control, practitioners such as Juran and Deming have used the principle to

identify problems and rank these problems from most important to least important. The practitioners propose that once the problems that account for 80% of 'bad' quality have been identified, one can seek solutions for fewer problems of lesser importance, rather than attempting to tackle all problems at once (Sanders, 1988).

Pareto Charts are widely used in Six Sigma projects, particularly during DMAIC projects to display categorical data arranged in order of highest to lowest frequency by bar graph (Wilkinson, 2006). The line graph depicted on the same chart represents the percentage amounts seen on the right-hand side axis. Figure 16 depicts how Pareto Charts are set up.

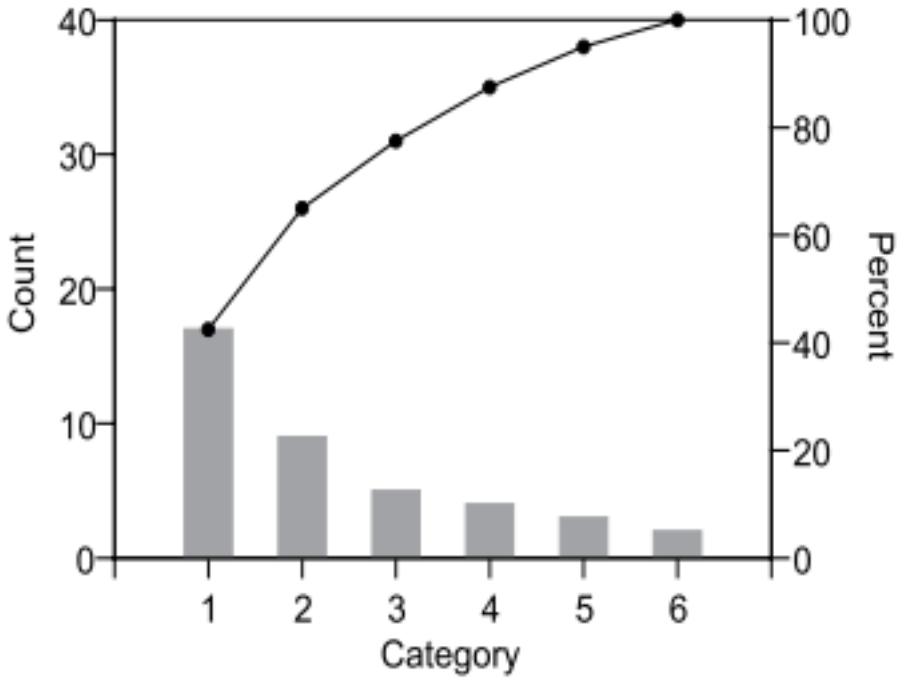


Figure 16: Sample Pareto Chart (Wilkinson, 2006)

The Pareto Charts in this study (figure 18, page 125 [CS1], figure 21, page 138 [CS2], figure 24, page 151 [CS3]), show the type of discrepancies encountered (in highest to lowest frequency from left to right) in one 28-day supply of medicines cycle for each case study. The bars on the chart amount to the number of discrepancies encountered (count), whereas the line amounts to the percentage of the total amount of discrepancies encountered.

ANALYSE

5. Sigma Performance Levels

As discussed previously, the aim of Six Sigma is to achieve less than 3.4 defects per million opportunities (DPMO). To determine where each care home currently stands in regard to their 28-day supply of medicines cycle, the current number of DPMO was calculated. To calculate the DPMO, first the total number of opportunities for defects for each case study was calculated. To do this, the total number of residents in each case study were multiplied by the average number of medications care home residents receive (e.g. the denominator), which is eight according to Barber et al. (2009). Furthermore, an average of eight medications per resident was used because studies found in the literature quoted care home residents usually take between six and ten medications on average (Barber et al., 2009; NHS England, 2019b; RPSGB, 2016), therefore the researcher chose to take the median between six and ten. The number of defects encountered (e.g. the numerator) were recorded during each case studies participant observations. These two values were then converted into the number of defects that would be present in one million opportunities. Calculations for each case study are shown on page 126 [CS1], page 139 [CS2], and page 152 [CS3].

Sigma performance levels were also calculated at this point. When data is continuous, it is calculated by using the standard deviation, significance level and Cpk (Tenera and Pinto, 2014). However, with discrete data, or categorical data, it is not possible to calculate these components (Tenera and Pinto, 2014). Therefore, the sigma level was calculated using the Process Sigma conversion table or the equation below (where *p* represents metrics proportion in concern).

$$n = \binom{Za/2}{\Delta} \times p \times (1 - p)$$

6. Fishbone Diagrams

To identify the root causes of discrepancies, focussing on omitted items and incorrect quantities, as suggested by the Pareto Analysis, the researcher used a Fishbone diagram. Fishbone diagrams were pioneered and named after the Japanese quality control statistician, Kaoru Ishikawa in the 1960s (Juran and Godfrey, 1999). They are therefore also known as Ishikawa diagrams (Juran and Godfrey, 1999) and sometimes Cause & Effect diagrams (Watson, 2004). Fishbone diagrams are a common tool used in Six Sigma projects to identify and group the root causes of quality problems (Ilie and Ciocoiu, 2010).

The root causes depicted in the fishbone diagram for the case studies were generated by the researcher during participant observations. Potential root causes were discussed with the medicines management lead during participant observations and the fishbone diagram was shown to each stakeholder feedback session for each case study. Each stakeholder feedback session agreed to the root causes listed in the fishbone diagram created by the researcher. As the scope of each DMAIC project on each case study is the same and similar processes are followed for each task in the 28-day supply of medicines cycle, the resulting Fishbone Diagrams are the same for each case study.

7. 'As is' Cross-functional Process Map

Levels of performance can be viewed from three different perspectives: organisation, process and job or performer (Damelio, 2011). Cross-functional process maps, also known as swim-lane diagrams show the path of work that 'crosses' several functions and how the relevant activities, people or organisations, information systems or resources are connected *(Damelio, 2011).*

Cross-functional process maps have the following key features: swim-lane, workflow, supplier-customer relationships, depicted in figure 17. Each swim-lane is a horizontal band, showing work activities according to each organisation or team that performs those activities. The 'A' icon depicts an example swim lane in the figure below and each swim-lane is labelled as 'customer' or 'entity' in figure 17. All activities shown on a cross-functional process map are interrelated, creating and delivering value throughout the process. Activities are highlighted by the 'B' icon, displaying each activity by the boxes numbered one to six in figure 17. Finally, supplier-customer relationships demonstrate the handoff of work items between any two entities, acting as the interface between two components (Damelio, 2011). This is depicted by the 'C' icon in figure 17.

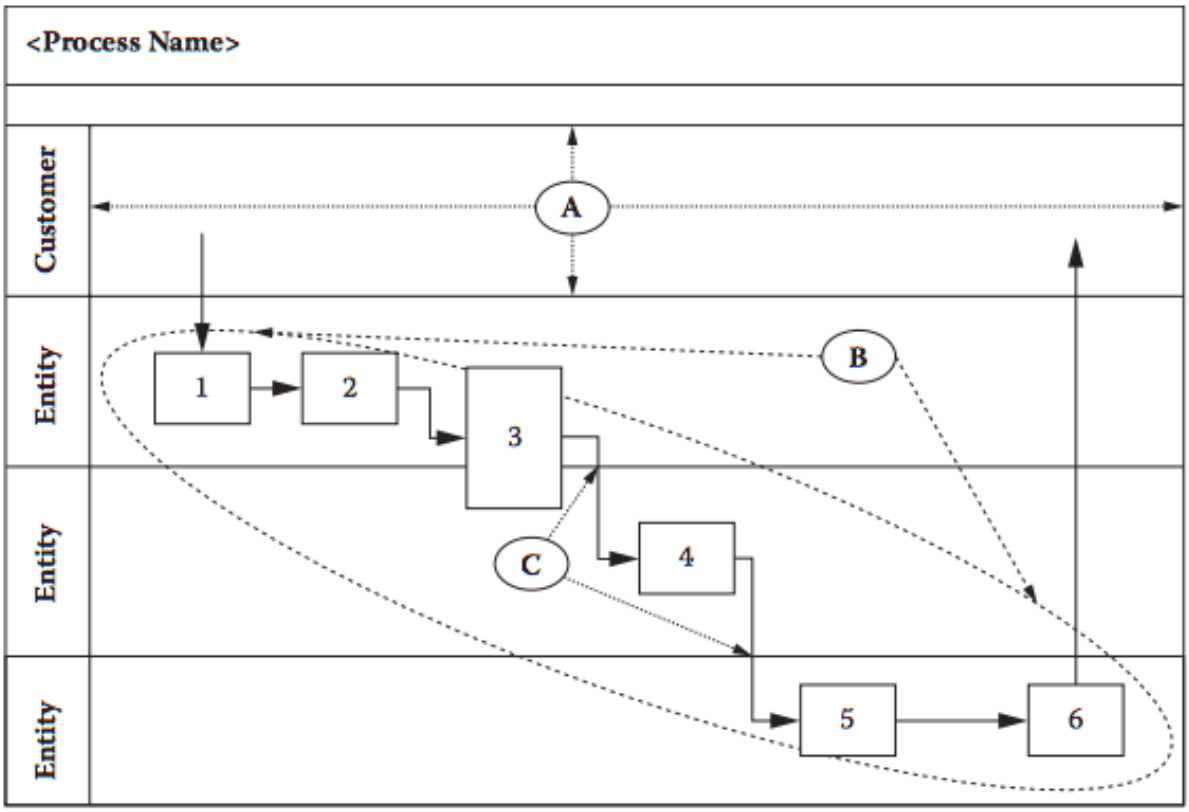


Figure 17: Cross-functional Process Map – Key Features: (A) "Swim-lane" (entity) (B) workflow, (C) "handoff" (internal supplier-customer relationship) taken from (Damelio, 2011)

The cross-functional process maps shown later in this chapter represent the care home, GP surgery and pharmacy, as separate entities in each 'swim-lane.' The maps represent workflow of tasks including medicines re-ordering, prescription generation, prescription check against re-order, dispensing medications, medicines checking-in and changeover, as well as the organisational relationships displaying where activities and resources are 'handed off.'

Each case study's cross-functional process map was derived during participant observations for each care home. Each map was presented and discussed during each case study's stakeholder feedback session, to ensure the researcher had accurately depicted the order of each task and its' timeframe within the 28-day supply of medicines cycle.

IMPROVE

8. Recommendations

The researcher has produced a set of recommendations for each case study. The aim of the recommendations was to provide a 28-day supply of medicines cycle that is more efficient and less prone to producing discrepancies or near-misses. Each set of recommendations are presented on: table 16, page 132 [CS1], table 21, page 147 [CS2], table 25, page 157 [CS3].

CONTROL

9. Error Log

As Six Sigma projects aim for continuous improvement, a control parameter must be enforced to determine if improvements have been made after implementation and to establish a method of verifying processes are continuing to achieve better results over time. As a control parameter, the researcher provides each case study with the same error log, highlighting the total number of discrepancies encountered each cycle and the total number of each type of discrepancy (omissions, incorrect quantities, additional items and mis-prescribed items) each cycle. Although auditing the improvement in the 28-day supply of medicines cycles in each care home was not within the scope of this PhD, the researcher created the error log to allow care homes to recognise any emerging patterns or trends and determine strategies to tackle those issues (involving the concerned stakeholders where necessary), once multiple cycles are logged.

10. Stakeholder Feedback Session

In order to receive feedback and validate the recommendations and suggested process map, the researcher carried out stakeholder feedback sessions within each case study. Results from each stakeholder feedback session are presented during the final part of the *control* phase.

GENERAL CONCEPTUAL FRAMEWORK RECOMMENDATIONS FOR ALL CASE STUDIES

11. Recommended Cross-functional Process Map

12. Specific Recommendations for the 28-day Supply of Medicines Cycle

Additionally, the researcher has developed a recommended cross-functional process map for all care homes to employ, along with a generalised set of recommendations, both presented at the end of this chapter (page 158-159)

SIX SIGMA APPLICATION TO CASE STUDY 1

DEFINE – CASE STUDY 1

1. VOC

The VOC indicated that many discrepancies between repeat re-order requests from care homes and the items prescribed by the GP surgery occur. The quotes below are from the semi-structured interviews conducted and are used to depict the challenge of request discrepancies. The quotes are mentioned under each case study's VOC, rather than in Chapter 4 (results), because the purpose of Chapter 4 was to explain the process of the 28-day supply of medicines cycle and the tasks within it using Framework Analysis, whereas the purpose of this chapter is to use Six Sigma, DMAIC to define the challenge the care homes face and provide recommendations to resolve these issues or challenges.

> ***CS1 – P1 [care manager]:*** *But before we even order, we'll check what stock we've got in cupboards and just try and minimise our stock levels but where we do end up overstocked is, and this is kind of the weakness in the circle of ordering is, obviously doctors get their receptionists or whoever's in charge of meds management at their surgery to print off the scripts and I don't think the doctors always have time to check the levels of items so we might, say if normally someone has 100 paracetamol every month and we've got plenty of stock because they haven't had paracetamol as much that month so we've ordered 50 tablets.*
>
> *But the script is set to 100 and doctors aren't always great at checking that they've only required 50 this month [the quantity required] so they still send us 100. So that's when we end up overstocked and having to chuck medicines away.*
>
> *So obviously, GPs have got constraints on time so they just sign the scripts sometimes and overstock us. And I've raised this with the GP and it's a case of them having to go into the system and amend the script so that's obviously extra work for them.*

CS1 – CH Manager: *…if the GP would dispense the wrong dosage or the wrong amount, it won't meet the cycle.*

Then halfway through the cycle, our nurses send in faxes to the GP, and then they'd have to phone the reception, 'has the doctor done the prescription yet?'

'Oh, it's out now or no there's nothing.'

It would be nice to say, this is what we've requested, and you can see whether it's prescribed, dispensed, or if it's on its way…

Everything's like backlogged so to me, the ideal system would be if we could logon to our GP. I know there's different portals we can have access to, but to my knowledge, there's nothing like that transparent with medication.

So, we can see yeah, the last time he was prescribed this was then. I know the GP can see it but don't have access to it. And now with this GDPR, I don't know that we'll ever get access to it so it will be like so and so has got this, it was requested, it was prescribed, it was sent to pharmacy, it was dispatched, this is when that medication will run out. That will flag up on your screen, computer system then, seven days before that medication's due to run out or if there's any changes.

Furthermore, the care home manager explains issues arising when the GP surgery fails to respond to queries or amendments suggested by other healthcare practitioners in a timely manner with the following example.

CS1 – CH Manager: *I mean the study that we took part in, that was a disaster because of that GP [previous GP]. We'd do our part and people doing the study would come in, sit with the family, sit with the staff, get the behaviour, look at the medications and everything, get the pharmacist to come and check everything and then say okay then, stop that medication or we'll alter that medication and then three months down the line we're still chasing the GP to do it.*

And three months down the line they want to come back in and see the difference it's made, but the GP hasn't even done it yet.

The care manager explains a weakness in the medicines management process below, highlighting communication as a key role in the process.

CS1 – P1 [care manager]: *I'd say the only kind of weakness in the chain at times can be if, say we have drug changeover on a Monday, and pharmacy get stuck a little late with meds say on a Wednesday and then it's just a time factor.*

So, if at that point, we do have missing items, then you're limited on the amount of working days then that you've got left to get that med into stock for the Monday and sometimes you'll find that you're on that Monday, and haven't got this medication so that person hasn't got that med that morning until on a Monday morning then you can chase that med again. That can be the weakness in the chain.

The VOC describes the following key issues: request discrepancies, communication with the GP surgery, lack of a transparent system and medicines changeover process happening too late in the cycle causing concern.

2. Types of Discrepancies derived from CTQ Tree

Examples from CS1 of each type of discrepancy are given in the table below.

Table 12: Examples of Types of Discrepancies within the 28-day Supply of Medicines Cycle [CS1]

Examples of Types of Discrepancies within the 28-day Supply of Medicines Cycle [CS1]	
Omitted Items	The care home had requested ferrous fumarate tablets (which is on the resident's repeat medication list) for a resident, however the GP surgery has not prescribed the tablets.
Additional Items	The care home did not request chlorhexidine mouthwash or a salbutamol inhaler for one resident, however the GP has still prescribed both items for this repeat cycle.
Incorrect Quantity	The care home requested 300mL of paracetamol solution for a resident, however the GP has prescribed 1000mL of paracetamol solution.
Mis-prescribed items	One resident used to be prescribed a Clenil inhaler. The GP had switched the resident's inhaler to QVAR mid-cycle. The care home therefore requested QVAR during the medicines re-ordering task. However, the GP prescribed Clenil again by mistake.

3. Request Discrepancies Measurement System – determined by CTQ Tree

The table below represents the estimated number of discrepancies encountered during the medicines checking-in and changeover task. Of the discrepancies found during medicines checking-in (second column), the third column represents the number of discrepancies still present at the changeover stage (which is the night before day 1 of the new cycle in this CS1). Therefore, the estimated number of discrepancies may be the same number in both the checking-in and changeover columns, meaning the discrepancy caught at the checking-in stage still hasn't been resolved by the time of medicines changeover. The total number of estimated discrepancies at medicines changeover for CS1 is 40. The remainder of the DMAIC tools employed use data produced from the estimated number of discrepancies during medicines changeover, as these are the discrepancies which were not solved in time for the new 28-day supply of medicines cycle.

Table 13: Estimated number of discrepancies encountered during medicines checking-in and changeover task in CS1

Estimated Number of Discrepancies Encountered [CS1]		
Category	**Medicines Checking-in**	**Medicines Changeover**
Omitted Items	6 items + 8 entire residents (all medications therefore 8 residents x 8 medications → 64) = 70	4 items + 2 entire residents (all medications therefore 2 residents x 8 medications → 16) = 20
Incorrect Quantity	13	13
Additional Items	6	6
Mis-prescribed Items	1	1
Total Discrepancies	26 items + 8 entire residents (all medications therefore 8 residents x 8 medications → 64) = 90	24 items + 2 entire residents (all medications therefore 2 residents x 8 medications → 16) = 40

Two residents in CS1 did not have medications for a full cycle's supply the day before the start of the new medicines cycle and the care home was unable to secure an emergency supply of medication from the supplying pharmacy for these two residents in time for the Day 1 morning medication round, therefore leading to ADEs classified as wrong timing.

4. Pareto Analysis

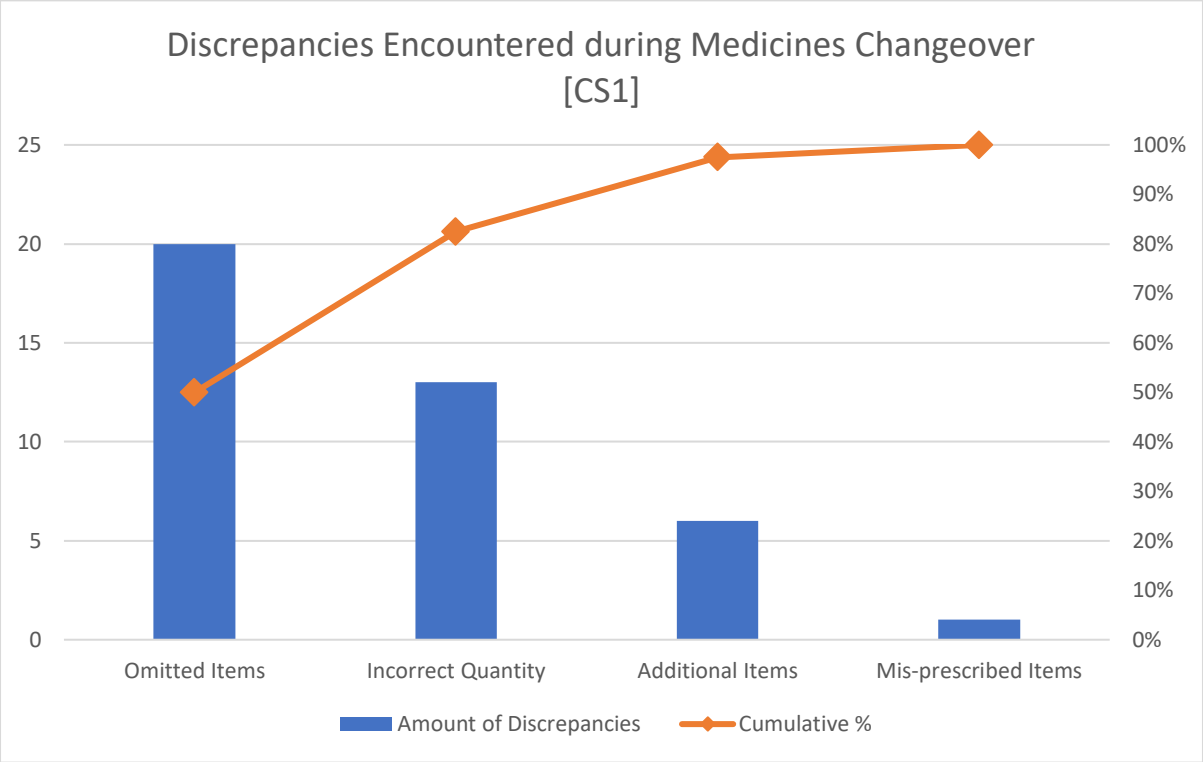


Figure 18: Pareto Chart of Discrepancies encountered during Medicines Changeover in one 28-day Supply of Medicines Cycle in CS1

The Pareto Chart highlights that omitted items and incorrect quantity discrepancies account for over 80% of quality problems in Order Request to Prescription Generation accuracy during medicines changeover for this case study. According to the Pareto Principle, these problems (omitted items and incorrect quantity discrepancies) can be traced to 20% of root causes. Potential root causes to these discrepancies will be discussed in the *Analyse* phase.

5. Sigma Performance Levels

Barber et al. (2009) state care home residents are on an average on eight medications. The total number of residents (47) in CS1 were therefore multiplied by eight medications to obtain the number of opportunities for defects.

$$Opportunities\ for\ Defects$$
$$= Care\ home\ residents\ \times\ average\ no.of\ medications\ per\ resident$$
$$= 47\ \times\ 8$$
$$= 376$$
$$Therefore, there\ are\ 376\ total\ opportunities\ for\ defects\ for\ CS1$$

Table 14: DPMOs encountered during the medicines changeover task in CS1

DPMOs Encountered during Medicines Changeover [CS1]		
Type of Discrepancy	**Defects in total opportunities (376)**	**DPMO**
Omitted Items	20	53,191.49
Incorrect Quantity	13	34,574.47
Additional Items	6	15,957.45
Mis-prescribed Items	1	2,659.57
Total Discrepancies	40	106,382.98
		Sigma Performance Level: 2.75

Therefore, the current DPMO is 106,382.98; giving a sigma performance level of 2.75. As mentioned previously, the sigma performance level is number of standard deviations (σ), from the process average to the nearest specification.

6. Fishbone Diagram

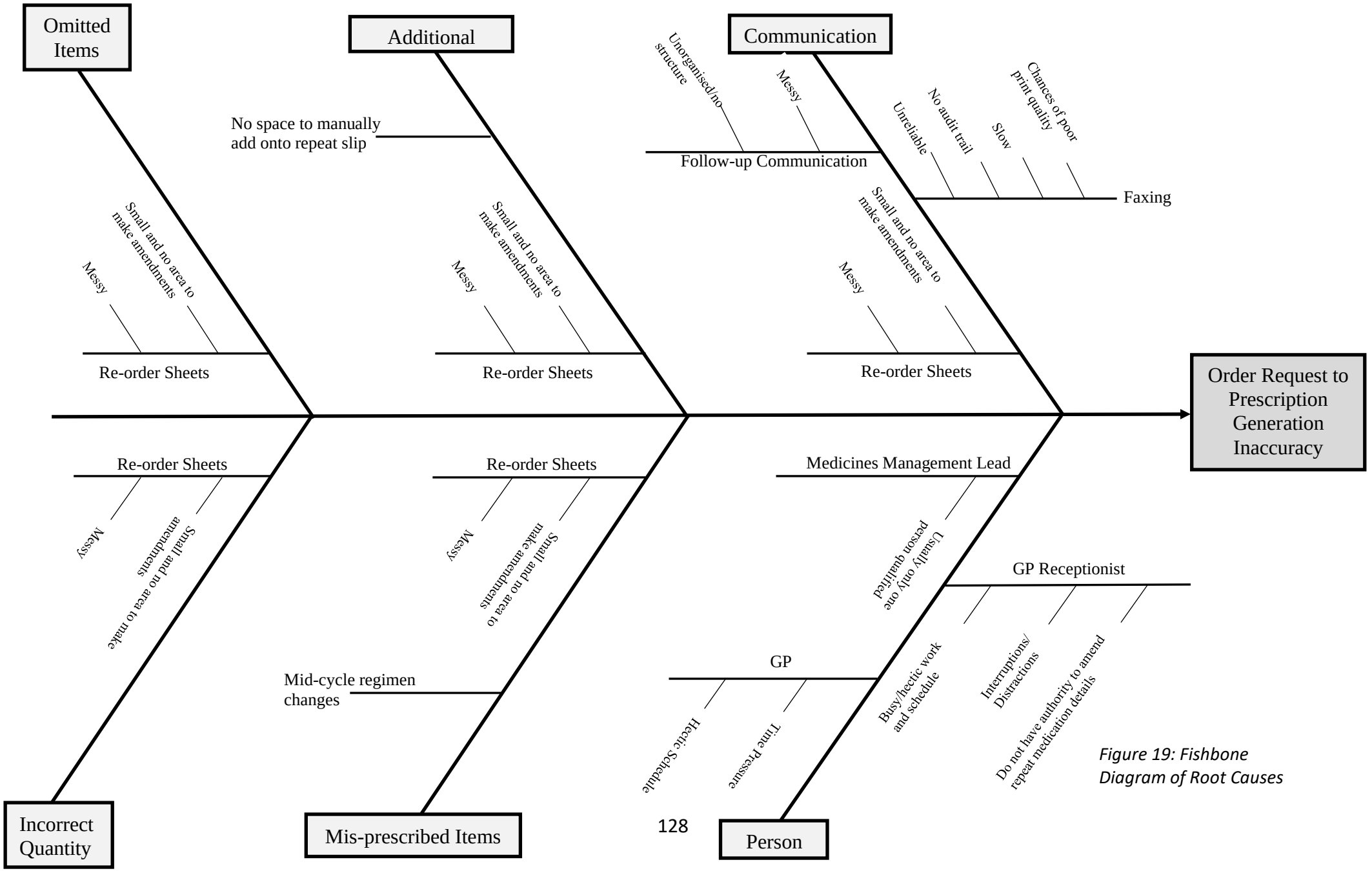


Figure 19: Fishbone Diagram of Root Causes

7. "As is" Cross-functional Process Map [CS1]

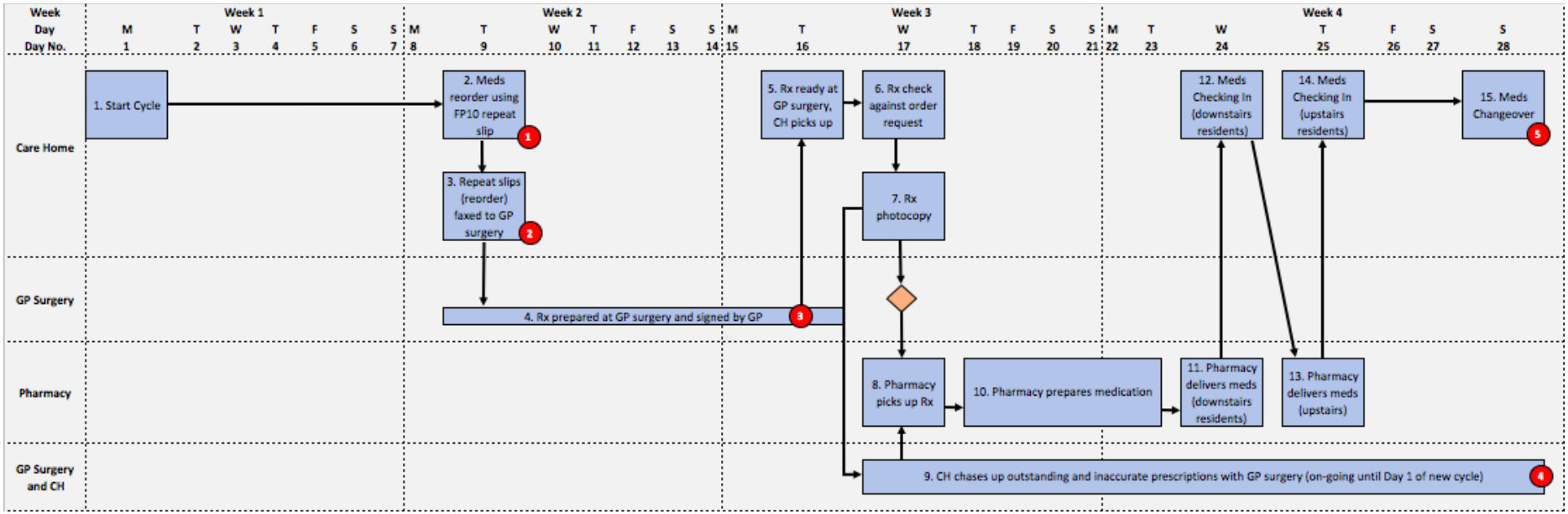


Figure 20: 'As is' cross-functional process map for CS1

**Each number enclosed in a red circle represents an area for improvement which corresponds to the order of recommendations in the Improve phase (next section).*

Abbreviations: meds (medicines); GP (General Practitioner); Rx (prescription); CH (care home)

8. Recommendations & Stakeholder Feedback Sessions [CS1]

This section explains each recommendation and provides quotes from stakeholder feedback session participants on their perspective of each recommendation.

The feedback session for CS1 was 46 minutes with the care home manager and care manager. The medicines management lead was also meant to be present, however was unfortunately sick on the day of the feedback session. The care home manager and care manager said they would relay the information to the medicines management lead on return.

The *first* recommendation provided to this home was to re-order medications on Week 1 – Day 2 of the medicines management cycle (instead of the current timeframe, Week 2 – Day 2) to allow for sufficient time in each step of the cycle. Additionally, the researcher gave a guideline of dates during the cycle to aim for each task to be completed to stay on top of the process throughout the cycle. The recommended time scales are shown in the table below.

Table 15: Recommended timeline for tasks within the 28-day supply of medicines cycle

Recommended Time	Latest Time	Task
Week 1 – Day 2	Week 1 – Day 3	Medicines Re-order
End of Week 1	Beginning of Week 2	Prescription Check against original request, address any chase-ups
End of Week 2	Beginning of Week 3	all chase-up items have been prescribed and checked against original request
End of Week 2		pharmacy collects all prescriptions from care home at once
Beginning of Week 4	Wednesday Week 4	pharmacy delivers medications to care home, medicines management lead does medicines checking in process
Rest of Week 4	Rest of Week 4	sufficient time to address any outstanding medication or errors

> ***CS1 – CH Manager:*** *I think doing the re-ordering in week 1 will bring the whole cycle forward by a bit and give every step a little more time instead of feeling so rushed and stressed in week 4 for the medicines management lead.*

The *second* recommendation was to use the re-order forms provided by the pharmacy, instead of the right-hand side of FP10 prescriptions to re-order medications from the surgery and to hand deliver the FP10 repeat requests to the GP surgery, or scan and email them to the surgery and pharmacy in the same email. However, the care home stated that the GP surgery only accepts FP10 repeat slips to re-order medications. Therefore, the only amendment possible was to hand deliver the FP10 repeat requests to the GP surgery, or scan and email them to the surgery and pharmacy in the same email.

> ***CS1 – P1 [care manager]:*** *our new GP wanted us to use the FP10s when we changed over. The GP surgery's policy is good, they aim to turnover requests within 24 hours.*

The *third* recommendation is for the home to retain all prescriptions until all discrepancies related to requests and chase-ups are completed by the GP surgery and collected by the care home. Once all prescriptions are ready, only then should the pharmacy collect all prescriptions from the home at once.

This ensures that the home has every item prescribed that is needed for the following medicines management cycle and any discrepancies going forward should be dealt with the pharmacy rather than GP surgery. Furthermore, it is more efficient if the pharmacy only collects all prescriptions from the home once, rather than the pharmacy picking up, or the care home dropping off prescriptions at multiple times throughout the cycle. Additionally, the pharmacy should still have enough time to dispense, check and deliver the medications to the care home as the medicines re-ordering task has begun in week 1 of the cycle, rather than week 2.

> ***CS1 – CH Manager: …****and to not send them until all the discrepancies are dealt with. That should solve a lot of the issues. And as you [care manager] said, I think that will sort out the problem where you're thinking, is this the GPs error or the pharmacy's error.*

> ***CS1 – P1 [care manager]:*** *I think that holding back of the scripts will also kind of help when other nurses are faxing and trying to figure out if things have been faxed already or chased up or not, and the thing is we'll feel like we have that time where we can hold back the prescriptions because we would have re-ordered in week 1.*

The *fourth* recommendation was to complete the medicines checking in and changeover process simultaneously. To do so, the home would need to purchase a spare medicines trolley. The home was positive to the suggestion but quick to point out their home does not have enough space within their medicines rooms for a spare medicines trolley and therefore would not be able to implement the recommendation, although they would have liked to.

The *fifth* recommendation was for the GP surgery to hold one person responsible for generating the prescriptions at the GP surgery and have an independent prescribing pharmacist at the GP surgery sign off repeat prescriptions for the care home. If a practice pharmacist at the GP surgery is able to take on this role, there is potential for less errors occurring and reduction in waste. This is because they will have the authority to go into the system and change the quantity prescribed on repeat medications according to the care home's request as well as any other changes in the monthly medication requested.

Furthermore, only one receptionist or prescription clerk should manage the care homes monthly repeat medications. By having one receptionist or prescription clerk in charge of managing the care homes monthly repeat medications and one pharmacist in charge of signing off the prescriptions, there is potential to eliminate communication barriers as any queries can be directly passed onto one of those two individuals at the surgery.

> ***Researcher:*** *...and then the prescriptions at the GP surgery should be done by the pharmacist if possible…*
>
> ***CS1 – P1 [care manager]:*** *yes, that's what is going to happen and they are also going to be part of the GP rounds, so they'll also get to know the residents.*
>
> ---
>
> ***CS1 – P1 [care manager]:*** *We will implement the electronic scanning of the scripts once we've got that person in place at the surgery.*
>
> ***CS1 – CH Manager:*** *The pharmacist is in place, we got an email. We can get read receipts on that so we know they've been printed.*

The *final* recommendation was for the care home to implement a 'Medicines Discrepancy Error Log' to keep track of discrepancies throughout each 28-day supply of medicines cycle. The error log forms the *Control* phase of DMAIC and is depicted and further explained in the following section. CS1 stated they will start using the 'Medicines Management Error Log' on their current 28-day supply of medicines cycle.

> ***CS1 – P1 [care manager]:*** *that's great, so we can see our progress and we'd be happy to share it with the GP and practice pharmacist too if we have continued to have troubles so we have actual figures as evidence.*

Table 16: Summary of Feedback on Recommendations for CS1

SUMMARY OF RECOMMENDATIONS & FEEDBACK FOR CS1		
	Recommendation	**Will it be Implemented [Y/N]?** **Feedback on Recommendation**
i.	Re-order medications on Week 1 – Day 2 and follow the timeline given for the rest of the medicines management cycle (see table X)	**Yes** – positive feedback to re-ordering medication in week 1 and following the revised schedule for the entire cycle
ii.	Hand deliver the FP10 repeat requests to the GP surgery, or scan and email them to the surgery and pharmacy in the same email	**Yes** – the home intends to hand deliver until the GP surgery's pharmacist is ready to accept scanned copies of repeat requests via email (within the next few months)
iii.	The home retains all prescriptions until all request discrepancies and chase-ups are completed by the GP surgery and collected. Once all prescriptions are ready, only then should the pharmacy collect all prescriptions at once from the home.	**Yes** – very positive feedback to this recommendation as the participants believe it will solve the issue of the GP surgery 'blaming' the pharmacy and vice-versa
iv.	Complete the medicines checking in and changeover process simultaneously by purchase of a spare medicines trolley	**No** – although the recommendation received positive feedback from both participants, they concluded the home does not have enough space in their medicines rooms to hold a spare medicines trolley
v.	GP surgery to hold one person responsible for generating the prescriptions at the GP surgery and pharmacist to sign off repeat prescriptions for the care home	**Yes** – the home agrees this would be a positive implementation and has already started to communicate with the GP practice pharmacist about the role
vi.	Medicines Discrepancy Error Log	**Yes** – participants believed it would be useful to keep track of errors and discrepancies going forward and sharing these results with the GP surgery and pharmacy

Finally, the feedback session participants gave their thoughts on the research project and use of Six Sigma on medicines management.

> ***CS1 – CH Manager:*** *I think it's been great having you in and look at things from a very different view point. It's been really helpful and useful and hopefully these recommendations will improve our process, and as you say continue to improve them.*

9. Error Log

Table 17: Medicines Discrepancy Error Log

Medication Discrepancy Error Log											
Discrepancy Type	**Cycle Number** **Date**										
	1 **(d/m/y)**	**2** **(d/m/y)**	**3** **(d/m/y)**	**4** **(d/m/y)**	**5** **(d/m/y)**	**6** **(d/m/y)**	**7** **(d/m/y)**	**8** **(d/m/y)**	**9** **(d/m/y)**	**10** **(d/m/y)**	**Totals**
Omissions											
Incorrect Quantities											
Additional Items											
Mis-prescribed Items											
Total Discrepancies											

The error log highlights the total number of discrepancies encountered each month and the total number of each type of discrepancy (omissions, incorrect quantities, additional items and mis-prescribed items) each cycle. The aim of the log is for the care home to be able to recognise any emerging patterns or trends and determine strategies to tackle those issues (involving the concerned stakeholders where necessary), once multiple cycles are logged.

SIX SIGMA APPLICATION TO CASE STUDY 2

DEFINE – CASE STUDY 2

1. **VOC**

The VOC indicated that many discrepancies between repeat re-order requests from care homes and the items prescribed by the GP surgery were present. The following quote from an interview depicts this challenge.

> ***CS2 – P7 [medicines management lead]:*** *Missing items is the worst flaw to the system*
>
> ---
>
> ***CS2 – P1 [carer]:*** *It can be problematic with the GP surgery, some surgeries, because when they change dosage, or change the medication, they don't always give us authorisation to do that. And we cannot dispense until we've got that written authorisation. That can take time, so you could say that it's not good for the resident because they might be waiting a day or more for that medication.*
>
> *Sometimes the pharmacy is chasing the GPs for the script and then they are delivering maybe late at night because they haven't got the medication. So it can be problematic. The system doesn't work as well as it could do.*
>
> ***CS2 – P1 [carer]:*** *I would think delivery is not often very efficient. I don't think the GPs, maybe they're busy, look at quality of life as much as we do. Sometimes that leads to inefficiency because that leads to delays in getting the prescription and correct medication.*
>
> ---
>
> ***CS2 - medicines management area lead:*** *I mean it's interesting because I asked our home, can you all tell me what your issues are. And they all said that even when they*

say they don't want things, they still come and that's such an inefficient use of medicines

Again, in this case study, request discrepancies and communication with the GP surgery were identified as challenges to the system, as seen from the VOC above.

2. Types of Discrepancies derived from CTQ Tree

Examples from CS2 of each type of discrepancy are given in the table below.

Table 18: Examples of Types of Discrepancies within the 28-day Supply of Medicines Cycle

Examples of Types of Discrepancies within the 28-day Supply of Medicines Cycle [CS2]	
Omitted Items	The care home has requested a salbutamol inhaler (which is on the resident's repeat medication list) for a resident, however the GP surgery has not prescribed the salbutamol inhaler.
Additional Items	The care home did not request the repeat order of 30 Laxido sachets this cycle, as the resident has enough already to last the entire subsequent cycle. The GP surgery has still prescribed 30 Laxido sachets for the resident this month.
Incorrect Quantity	The care home requested 50 Zapain tablets for a resident (because on average the resident uses 50 Zapain tablets per month or less). The repeat item on the resident's profile is for 100 Zapain tablets per repeat cycle and therefore the GP has prescribed 100 Zapain tablets. The pharmacy then dispensed and delivered 100 Zapain tablets.
Mis-prescribed items	None for this case study

3. Request Discrepancies Measurement System – determined by CTQ Tree

Similar to table 13 (page 124), presented in CS1, the table below represents the estimated number of discrepancies encountered during the medicines checking-in task. Of the discrepancies found during medicines checking-in (second column), the third column represents the number of discrepancies still present at the changeover stage (which is the night before day 1 of the new cycle in this CS2). Therefore, the estimated number of discrepancies may be the same number in both the checking-in and changeover columns, meaning the discrepancy caught at the checking-in stage still hasn't been resolved by the time of medicines changeover. The total number of estimated discrepancies at medicines changeover for CS1 is 65. The remainder of the DMAIC tools employed use data produced from the estimated number of discrepancies during medicines changeover, as these are the discrepancies which were not solved in time for the new 28-day supply of medicines cycle.

Table 19: Number of discrepancies encountered during medicines checking-in and changeover task in CS2

Estimated Number of Discrepancies Encountered [CS2]		
Category	**Medicines Checking-in**	**Medicines Changeover**
Omitted Items	9 items + 4 entire residents (all medications → 8 medications each = 32) = 41 items	5 items + 4 entire residents (all medications → 4 residents x 8 medications = 32) = 37 items
Incorrect Quantity	26 items	26 items
Additional Items	2 items	2 items
Mis-prescribed Items	0 items	0
Total Discrepancies	37 items + 4 entire residents (all medications → 8 medications each = 32) = 69 items	33 items + 4 entire residents (all medications → 4 residents x 8 medications each = 32) = 65 items

Four residents from CS2 did not have medications for a full cycle's supply the day before the start of the new cycle, however the care home was able to obtain an emergency supply of medication from the supplying pharmacy in time to administer the medications to all four residents during the Day 1 morning medication round.

4. Pareto Analysis

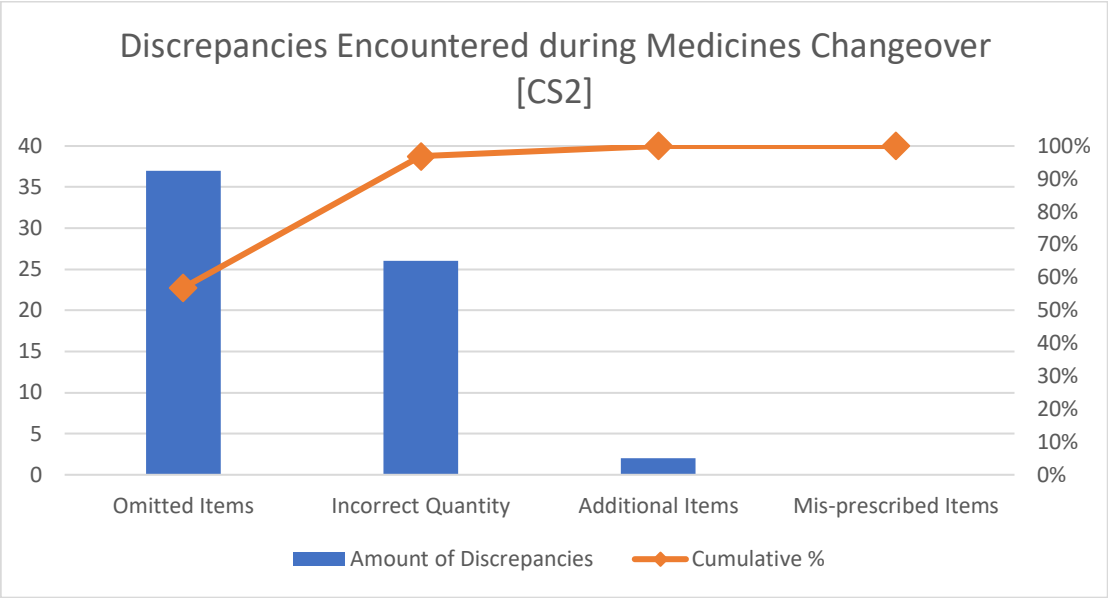


Figure 21 - Pareto Chart of Discrepancies Encountered during one 28-Day Supply of Medicines cycle in CS2

Similar to CS1, the Pareto Chart produced highlights that omitted items and incorrect quantity discrepancies account for over 80% of quality problems in Order Request to Prescription Generation accuracy for each case study. According to the Pareto Principle, these problems (omitted items and incorrect quantity discrepancies) can be traced to 20% of root causes. Potential root causes to these discrepancies will be discussed in the *Analyse* phase.

ANALYSE – CASE STUDY 2

5. Sigma Performance Levels

Barber et al. (2009) state care home residents are on an average on eight medications. The total number of residents (58) in CS2 were therefore multiplied by eight medications to obtain the number of opportunities for defects.

$$\begin{aligned} &Opportunities\ for\ Defects \\ &= Care\ home\ residents\ \times\ average\ no.of\ medications\ per\ resident \\ &= 58\ \times\ 8 \\ &= 464 \end{aligned}$$

$$Therefore, there\ are\ 464\ total\ opportunities\ for\ defects\ for\ CS2$$

Table 20: DPMOs encountered during the medicines changeover task in CS2

DPMOs Encountered during Medicines Changeover [CS2]		
Type of Discrepancy	**Defects in total opportunities (376)**	**DPMO**
Omitted Items	37	79,741.38
Incorrect Quantity	26	56,034.48
Additional Items	2	4,310.34
Mis-prescribed Items	0	0
Total Discrepancies	65	140,086.21
		Sigma Performance Level: 2.58

Therefore, the current DPMO is 140,086.21; giving a sigma performance level of 2.58.

6. Fishbone Diagram

The fishbone diagram of root causes is the same as for CS1 and CS3, please refer to page 127, figure 19.

7. "As is" Cross-functional Process Map [CS2]

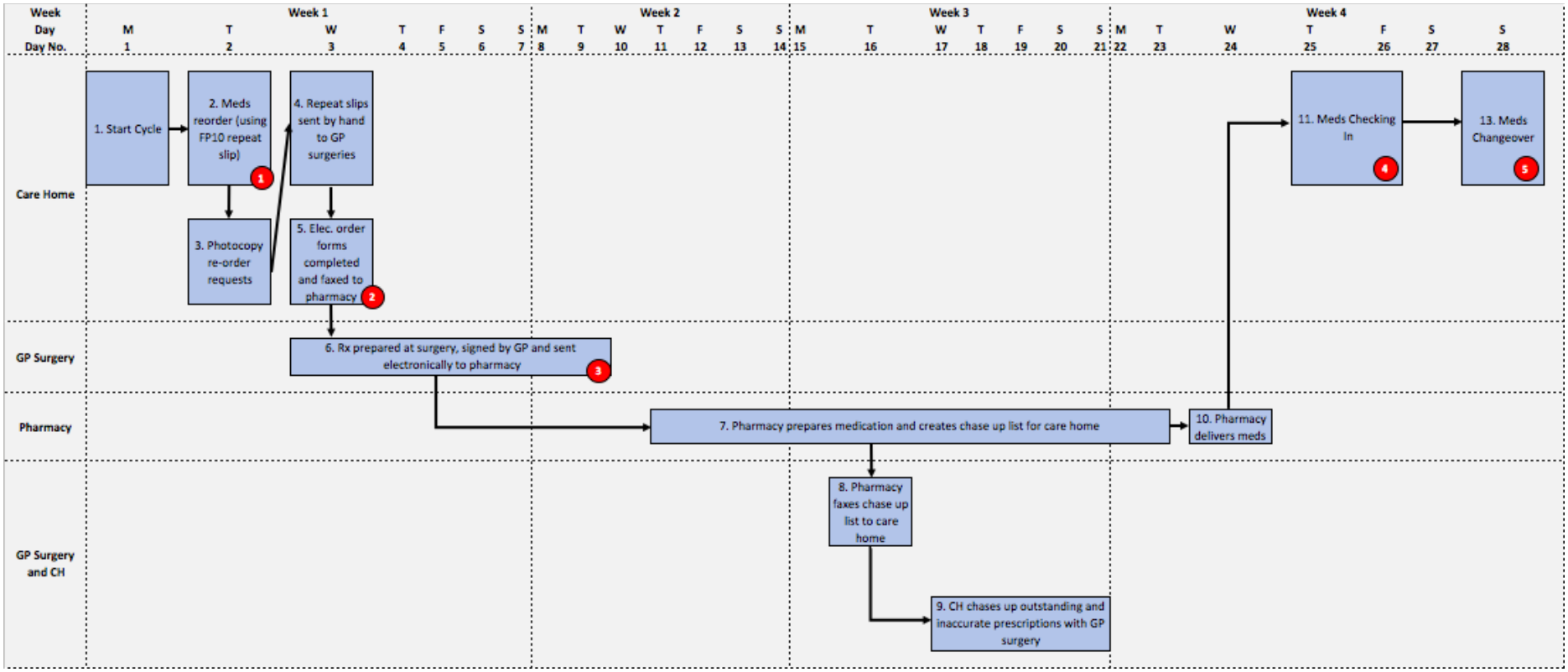


Figure 22: 'As is' cross-functional process map for CS2

**Each number enclosed in a red circle represents an area for improvement which corresponds to the order of recommendations in the Improve phase (next section).*

Abbreviations: meds (medicines); GP (General Practitioner); elec. (electronic); Rx (prescription); CH (care home)

IMPROVE & CONTROL – CASE STUDY 2

8. Recommendations & Stakeholder Feedback Session [CS2]

This section explains each recommendation and provides quotes from stakeholder feedback session participants on their perspective of each recommendation.

The feedback session for CS2 was conducted twice. The first feedback session was one hour and six minutes with the care home manager and medicines management lead. The second feedback session was thirty-eight minutes with the medicines management area lead.

The *first* recommendation provided to this home was the use of the 'Monthly Re-order Form' generated from the electronic system as the re-order request, rather than use of FP10 repeat slips.

The following list summarises the process this care home was using to re-order medications from the GP surgery:

a. The medicines management lead fills out the right-hand side of FP10 prescriptions to re-order medications
b. After completing the right-hand side of FP10 prescriptions, the medicines management lead transfers this information onto the electronic medicines management system by ticking the medications ordered for the next cycle and entering the quantity ordered onto the electronic system
c. After inputting this information electronically, the system generates a report called the 'Monthly Re-order Form'
d. The completed FP10 repeat slips are then hand delivered to each of the three surgeries the care home works with
e. The 'Monthly Re-order Form' is shared with the pharmacy across the electronic systems portal

Although 'Monthly Re-order Forms' are listed as a 'Report' on the care home's electronic system, they can be used as a re-order form because they include resident personal details and repeat medication details including: [1] medication [2] strength [3] dose [4] frequency [5] quantity requested/ordered and [6] any additional notes pertaining to the resident or their medication (i.e. dose adjustments or preference for tablets to be crushed, etc.). Furthermore, it is the same form that the pharmacy uses to check the prescribed items against the care home's re-order request; proving that all relevant re-order information is present on the form.

The researcher recommends using one form for both the GP surgery and the pharmacy. As the 'Monthly Re-order Report' is already being filled out and sent to the pharmacy in current practice, the recommendation does not lead to any extra work for the care home or medicines management lead. Instead, using the 'Monthly Re-order Report' reduces the workload for the medicines management lead, as they will no longer need to fill out the FP10 repeat slip, which is small and therefore making changes on the form can get messy, possibly leading to mistakes.

The *second* recommendation provided in this case study was to email the re-order requests to the GP surgery and to the pharmacy for their records at the same time, in the same email. This ensures both organisations have access to the same information and re-order sheets, in a common email thread, serving as a good communication link.

Using email instead of fax or delivering order requests by hand was suggested for the following reasons: [1] faxing can be unreliable (often the GP surgery complains they have not received the re-orders, printing mishaps – for example low print cartridge levels or no cartridge left, technology failures), [2] although delivering by hand seems to work better than faxing, pieces of paper can still go missing in the process, [3] delivering re-order requests by hand takes up additional time, as one nurse has to walk or drive the prescriptions over to the surgeries, [4] email will provide an audit trail and it is an instantaneous process.

The care home manager medicines management lead and area lead's thoughts on the first two recommendations are depicted in the following quotes:

> ***CS2 – P5 [care home manager]:*** *Evidence, evidence, evidence. Because if you hand them over, someone took them out of your hands but you've got no evidence. That's evidence with that email. You can lock the form if you need to, you can share passwords on it. So if you lock it down for confidentiality, for GDPR's sake. [GDPR is General Data Protection Regulation which has replaced the Data Protection Act 1998].*
>
> ***Researcher:*** *Yes and it saves you printing it. I know it's a minor cost but*
>
> ***CS2 – P5 [care home manager]:*** *Yes, and it's not the cost so much but it's more about the fact that it makes us more environmentally friendly. So one re-order form that fits*

both the GP and the pharmacy and then it takes down, it literally takes down A) the time to go run and deliver them to all the GPs, and then B) the duplication of the work to the pharmacy and the gap for mistake in-between those two or error is cut because it's one. So the pharmacy is definitely being told exactly what the GP's being told in the same thing. And literally just fill it in and then press the button and it's gone.

CS2 – P7 [medicines management lead]: *I do agree with you. I just think that if we could get one form that fits all it would just make everybody's life so much easier. Because I mean I will put my hands up and I have been known to tick on the FP10 and not put it on here or vice-versa because you're doing so many people it's so easy to make that transcription error. I mean I have done it, I am guilty as much as I try not to make these mistakes.*

CS2 - medicines management area lead: *Exactly, exactly. So I would really appreciate if you could send that to me because there is absolutely no point in people doing tasks twice. It's a complete waste of time. And also, like you're saying, if it's a much cleaner way of doing it, less muddly, I'm all for that.*

The *third* recommendation made by the researcher was to ask the GP surgery or pharmacy for a copy of the prescription tokens as soon as the prescriptions have been signed off by the doctor and sent to the pharmacy for dispensing. A prescription token is a print-off of an electronic prescription, therefore showing all the items that were prescribed on the electronic prescription. The purpose of this suggestion is to enable the care home to check for discrepancies on their own, against their re-order requests using the prescription tokens. This is because the pharmacy was sending the list of discrepancies late in the cycle, which was not allowing for enough time for the care home to address the discrepancies with the GP.

However, the medicines management lead from the case study mentions the pharmacy has been sending the list of discrepancies earlier in the cycle now and they therefore do not feel that they need to take the prescription verification against re-order request task into their own hands. Furthermore, they express that by implementing the first and second recommendation, they believe the margin for error will decrease substantially.

> ***CS2 – P5 [care home manager]:*** *I think we should rely with the pharmacy then, we prefer them completing it.*
>
> *If we've done the dual communication where they have the same thing at the same time then because that information is one, which is what I like better about it, then there can't be any discrepancies where they don't know what the GPs been told. So that missing items issue should then become accurate. Which I think at the minute is we've always got a margin for error, every time you duplicate anything I think there's a margin for error. So I think if we take out that margin for error and there's one communication agreed with the GP surgery then we eliminate that margin for error.*
>
> ***CS2 – P7 [medicines management lead]:*** *I also think that if we did have one form, it would stop all those bits of paper as well. Because I think sometimes, we get them to the surgery in an envelope and they take them out and that odd one might just go walk about and for whatever reason it gets lost.*

The *fourth* recommendation was for the medicines management lead to complete the medicines checking in and changeover process together.

> ***CS2 – P5 [care home manager]:*** *…if somebody starts using those next cycle's medications before the others are gone or there's some left in these other packets, then it gets messy.*
>
> ---
>
> ***CS2 – P5 [care home manager]:*** *Yeah, I think just for house keeping's sake, for accuracy's sake and I think that we've tried it that way and many other ways, we even had a lady coming in here to do it at 1 o'clock in the morning on Monday morning and*

that was just stupid, so we brought it back to a sensible level. Because you've got to be functioning right when you're doing these things too. You can't be doing it when you're tired, that's ridiculous. But actually to have it just before then is just right because then you know that any tablets left in there are the last dose to be given and then you can clear everything else out.

The *fifth* recommendation for this case study was for the GP surgery to hold one person responsible for generating and signing off prescriptions at the GP surgery. If one receptionist is able to generate the prescriptions and one practice pharmacist at the GP surgery is able to sign off on the prescription on this role, there is potential for less errors occurring and reduction in waste. This is because they will have the authority to go into the system and change the quantity prescribed on repeat medications according to the care home's request as well as any other changes in the monthly medication requested.

Furthermore, only one receptionist or prescription clerk should manage the care homes monthly repeat medications. By having one receptionist or prescription clerk in charge of managing the care homes monthly repeat medications and one pharmacist in charge of signing off the prescriptions, there is potential to eliminate communication barriers as any queries can be directly passed onto one of those two individuals at the surgery.

CS2 – P7 [medicines management lead]: *Because I know when I've rang [sic] to chase up scripts or I'm chasing up an item or whatever it is, sometimes they say to me 'oh the pharmacist is on that,' so I don't quite know where their lines are, do you know what I mean?*

CS2 – P7 [medicines management lead]: *I honestly can't tell you. Some things go to the doctor, some things go to the pharmacist. Because I get all sorts of responses saying 'oh no, the pharmacists dealing with that.. oh no, the GPs dealing with that.' So I don't actually know who does our monthly scripts.*

The *final* recommendation was part of the *Control* phase and was to implement a 'Medicines Discrepancy Error Log' (as with CS1, see table 17, page 134).

CS2 – P7 [medicines management lead]: *that's a useful tool. We'll start using that this cycle if you can send us some copies.*

A summary of the recommendations provided, and the care homes response to each is presented in the table below.

Table 21: Summary of Feedback on Recommendations for CS2

	Recommendation	**Will it be Implemented [Y/N]?** **Feedback on Recommendation**
i.	Use the Monthly Re-Order Forms instead of using the right-hand side of FP10 prescriptions	**Yes** – very positive feedback to using the Monthly Re-Order Form generated by the electronic system as their re-order request
ii.	Email or hand delivering repeat requests instead of faxing	**Yes** – positive feedback as provides an audit trail and can still comply with GDPR
iii.	Ask the GP surgery or pharmacy for a copy of the prescription tokens as soon as the prescriptions have been signed off by the doctor and sent to the pharmacy for dispensing	**No** - The pharmacy has been sending the discrepancy list to the care home in a timely manner the past few months so they would like to keep it this way
iv.	Complete the medicines checking-in and changeover process together	**No** – due to the convenience of house-keeping of the cupboards at the end of every cycle, the home has chosen to continue with medicines changeover on Day 28 of the cycle
v.	GP surgery to hold one person responsible for generating the prescriptions at the GP surgery and pharmacist to sign off repeat prescriptions for the care home	**Possibly** – the home agrees this would be a positive implementation, however the home will have to speak to the GP surgery to determine whether they are happy to implement this change
vi.	Medicines Discrepancy Error Log	**Yes** – participants believed it would be useful to keep track of errors and discrepancies going forward and sharing these results with the GP surgery and pharmacy

Finally, the feedback session participants gave their thoughts on the research project and use of Six Sigma on medicines management.

CS2 – P5 [care home manager]: *I think it's been helpful because it's somebody outside and looking at it with a different view point as well. I like the swim-lanes, they're always quite helpful. I like the fact that you can see what's moving where, they're always helpful.*

I can see that there's an error of duplication, it's also probably quite task heavy for the medicines management lead and there's a way of moving that down which is helpful.

But also I mean you've picked up on the communication and that's what this is going to be about isn't it. Meeting with them and trying to make them see and agree to doing it a different way. I want to run through it as well with our medicines management manager for all the homes as well.

SIX SIGMA APPLICATION ON CASE STUDY 3

DEFINE – CASE STUDY 3

1. VOC

The VOC indicated that many discrepancies were present between repeat re-order requests from care homes and the items prescribed by the GP surgery. The following quote from an interview depicts this challenge.

> ***CS3 – P1 [CH Manager]:*** *I think sometimes there's been some communication, either between us or the GP surgery or the GP and the pharmacy. You know and the pharmacy will say 'well we haven't received the prescription' and then the receptionists will say 'oh but we've processed it' or 'we've sent it' so sometimes things like that happen and then we don't have the medication we need on time or the GP has prescribed the wrong quantity or something.*

Again, in this case study, request discrepancies and communication with the GP surgery were identified as challenges to the system, as seen from the VOC above.

2. Types of Discrepancies derived from CTQ Tree

Examples from CS3 of each type of discrepancy are given in the table below.

Table 22: Examples of types of discrepancies within the 28-day supply of medicines cycle

Examples of Types of Discrepancies within the 28-day Supply of Medicines Cycle [CS3]	
Omitted Items	The care home has requested paracetamol tablets (which is on the resident's repeat medication list) for a resident, however the GP surgery has not prescribed the paracetamol tablets.
Additional Items	None for this case study
Incorrect Quantity	The care home requested 30-sachets of Laxido for a resident (because on average the resident takes Laxido once daily). The repeat item on the resident's profile is for 60-sachets of Laxido per repeat cycle and therefore the GP has prescribed 60-sachets of Laxido. The pharmacy then dispenses and delivers 60-sachets of Laxido.
Mis-prescribed items	None for this case study

3. Request Discrepancies Measurement System – determined by CTQ Tree

The table below represents the estimated number of discrepancies encountered during the medicines checking-in and changeover task. This table is slightly different to CS1 and CS2 because the medicines checking-in and changeover task are completed simultaneously at this care home. Therefore, any discrepancies present during medicines checking-in are also present during medicines changeover (as they are essentially part of the same process for this care home). Medicines changeover was performed on Friday of week 4 in this case study. The remainder of the DMAIC tools employed use data produced from this table.

Table 23: Number of Discrepancies Encountered during Medicines Checking-in and Changeover [CS3]

Estimated Number of Discrepancies Encountered [CS3]	
Category	**Medicines Checking-in & Medicines Changeover**
Omitted Items	1 item
Incorrect Quantity	8 items
Additional Items	0
Mis-prescribed Items	0
Total Discrepancies	9 items

4. Pareto Analysis

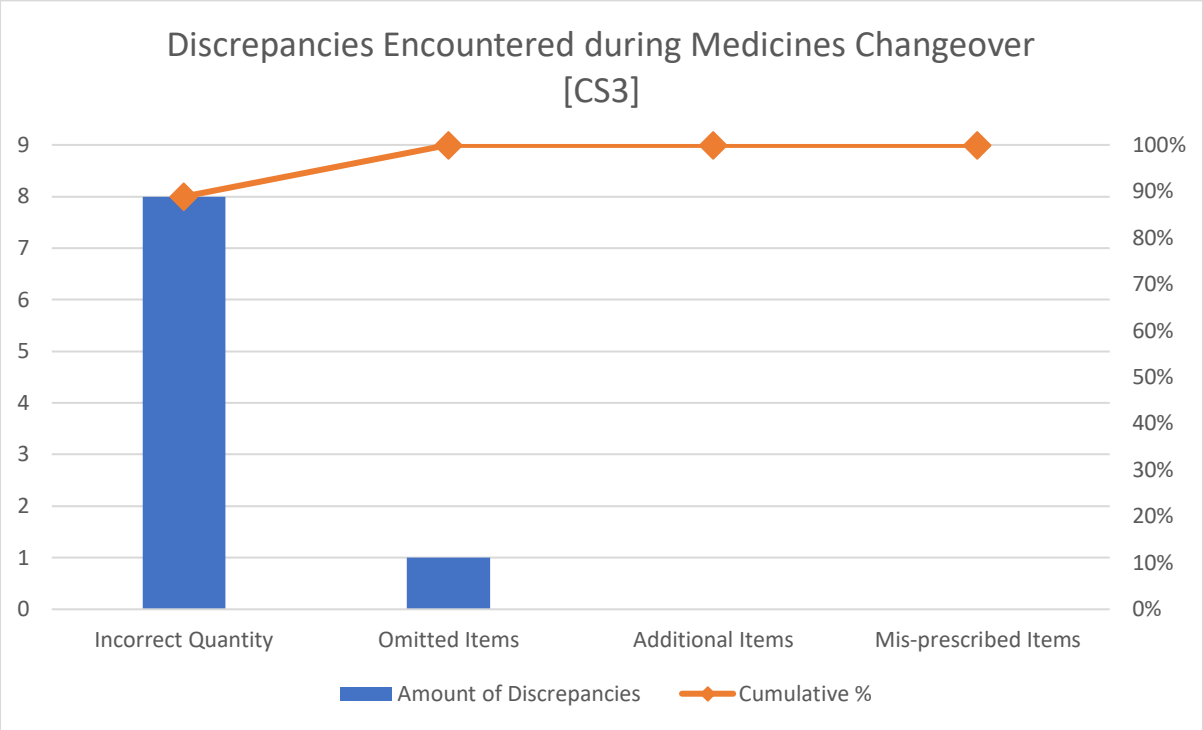


Figure 23: Pareto Chart of Discrepancies Encountered during one 28-day Supply of Medicines Cycle in CS3

The Pareto Chart highlights that incorrect quantity discrepancies alone account for over 80% of quality problems in Order Request to Prescription Generation accuracy for each case study. In CS1 and CS2, majority of quality problems are from omitted items first, then incorrect quantity discrepancies. In CS3, incorrect quantity errors account for over 80% of discrepancies alone. According to the Pareto Principle, these problems (omitted items and incorrect quantity discrepancies) can be traced to 20% of root causes. Potential root causes to these discrepancies will be discussed in the *Analyse* phase.

ANALYSE – CASE STUDY 3

5. Sigma Performance Levels

Barber et al. (2009) state care home residents are on an average on eight medications. The total number of residents (39) in CS3 were therefore multiplied by eight medications to obtain the number of opportunities for defects.

$$Opportunities\ for\ Defects = Care\ home\ residents\ \times\ average\ no.of\ medications\ per\ resident$$

$$= 39\ \times\ 8$$

$$= 312$$

$$Therefore, there\ are\ 312\ total\ opportunities\ for\ defects\ for\ CS3$$

Table 24: DPMOs encountered during medicines changeover task in CS3

DPMOs Encountered during Medicines Changeover [CS3]		
Type of Discrepancy	**Defects in total opportunities (376)**	**DPMO**
Omitted Items	1	3,205.13
Incorrect Quantity	8	25,641.03
Additional Items	0	0
Mis-prescribed Items	0	0
Total Discrepancies	9	28,846.15
		Sigma Performance Level: 3.4

Therefore, the current DPMO is 28,846.15; giving a sigma performance level of 3.4.

CS3 has a much higher sigma performance level than CS1 (2.75) and CS2 (2.58). This signifies CS3 has a lower rate of discrepancies (defects). The most likely explanation is that when prescriptions with discrepancies generated from the GP surgery are sent back for amendment, the care home retains the rest of the prescriptions until all prescriptions sent for amendment have been received again. The pharmacy then collects all prescriptions together, whereas in CS1 and CS2 accurate prescriptions are sent to the pharmacy even when some prescriptions have been returned to the GP surgery for amendments. All medications coming from the pharmacy to the care home (CS3) should therefore be correct, provided that the pharmacy has not make any errors, whereas CS1 and CS2 invite another

source for process variation as they now have to chase-up individual prescriptions from the GP surgery and send them individually to the pharmacy as and when they are received.

6. Fishbone Diagram

The fishbone diagram of root causes is the same as for CS1 and CS3, please refer to page 127, figure 19.

7. "As is" Cross-functional Process Map [CS3]

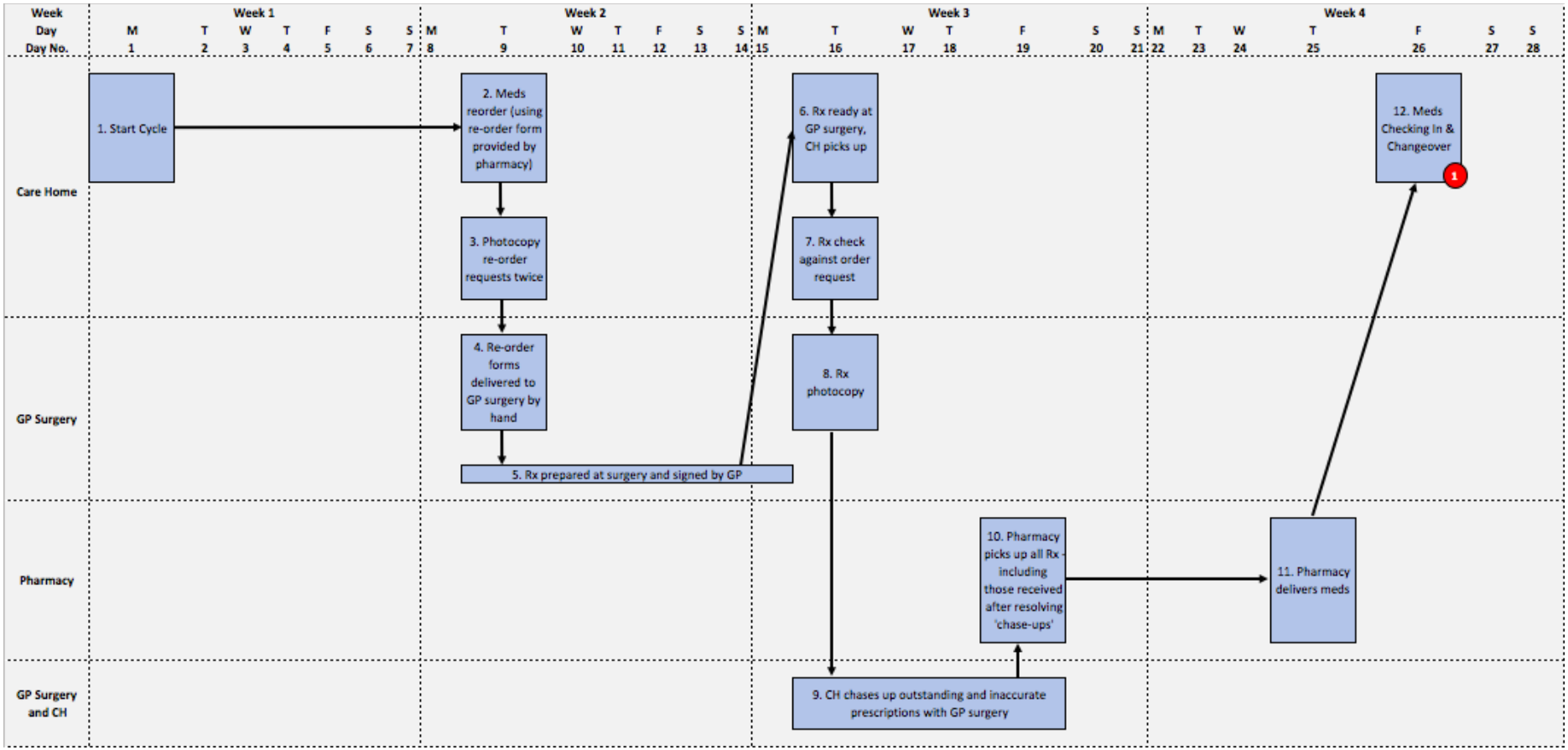


Figure 24: 'As is' Cross-functional Process Map for CS3

**Each number enclosed in a red circle represents an area for improvement which corresponds to the order of recommendations in the Improve phase (next section).*

Abbreviations: meds (medicines); GP (General Practitioner); Rx (prescription); CH (care home)

IMPROVE & CONTROL – CASE STUDY 3

8. Recommendations & Stakeholder Feedback Session [CS3]

This section explains each recommendation and provides quotes from stakeholder feedback session participants on their perspective of each recommendation.

The feedback session for CS3 was 31 minutes with the care home manager, clinical lead and medicines management lead. The care home manager and clinical lead in this case study had both left the organisation between the time the interviews and participant observations were completed to the time when the researcher conducted the feedback session. Therefore, the only member of staff present since the participant interviews until the feedback session was the medicines management lead for the organisation. The new care home manager and clinical lead were also present for the feedback session.

The *first* recommendation provided to this home was to re-order medications using an Excel spreadsheet by email. The use of an Excel spreadsheet was only recommended in this case study because it had the resources to carry out this recommendation and the home had agreed to it with the surgery.

> ***CS3 – medicines management lead:*** *We did try but it was taking a lot of time. Because every month there are medicines stopped or changed dosage, and we had to make all the changes then. So then when I order them, we had to delete some and to add some and we also have to type it in so it was taking a lot of time. The re-order sheet is easier because it's done for us by the pharmacy so all we have to do is just tick it and then we can deliver it.*

The *second* recommendation was to send the re-order requests by scanning the requests and emailing them to the surgery.

> ***CS3 – medicines management lead:*** *yes, I think you're right. Scanning would be a good idea, especially because they are far to deliver to by hand and it seems like a safe option the way you have suggested it.*

The *final* recommendation was part of the *Control* phase and was to implement a 'Medicines Discrepancy Error Log' Log' (as with CS1, see table 17, page 134) as a measure of control which the care home is going to start using on their current medicines ordering cycle.

> ***CS3 – CH Manager:*** *we can do that. It seems like a good idea to keep track of progress and a great auditing tool.*

	Recommendation	**Will it be Implemented [Y/N]?** **Feedback on Recommendation**
i.	Re-order medications using an Excel spreadsheet	**Implemented but reverted back** – the home did implement the recommendation however they found it to be more work as they had to amend the spreadsheet, whereas if they use the re-order sheets provided by the pharmacy, they are produced for them automatically
ii.	Scan and email re-order forms instead of faxing or hand delivering repeat requests	**Yes** – positive feedback as provides an audit trail and can still comply with GDPR and takes less time than delivering and is more reliable than faxing
iii.	Medicines Discrepancy Error Log	**Yes** – participants believed it would be useful to keep track of errors and discrepancies going forward and sharing these results with the GP surgery and pharmacy

Table 25: Summary of feedback on recommendations provided to CS3

GENERAL CONCEPTUAL FRAMEWORK RECOMMENDATIONS

Recommended Cross-functional Process Map

The process map depicted below is a general framework of recommendations across all care homes. As care homes across the UK generally follow a similar process to those outlined in CS1, CS2 and CS3 and this framework does not give detailed steps of how to complete each task but rather the lists the task along a recommended framework, this framework can be used across care homes within the UK.

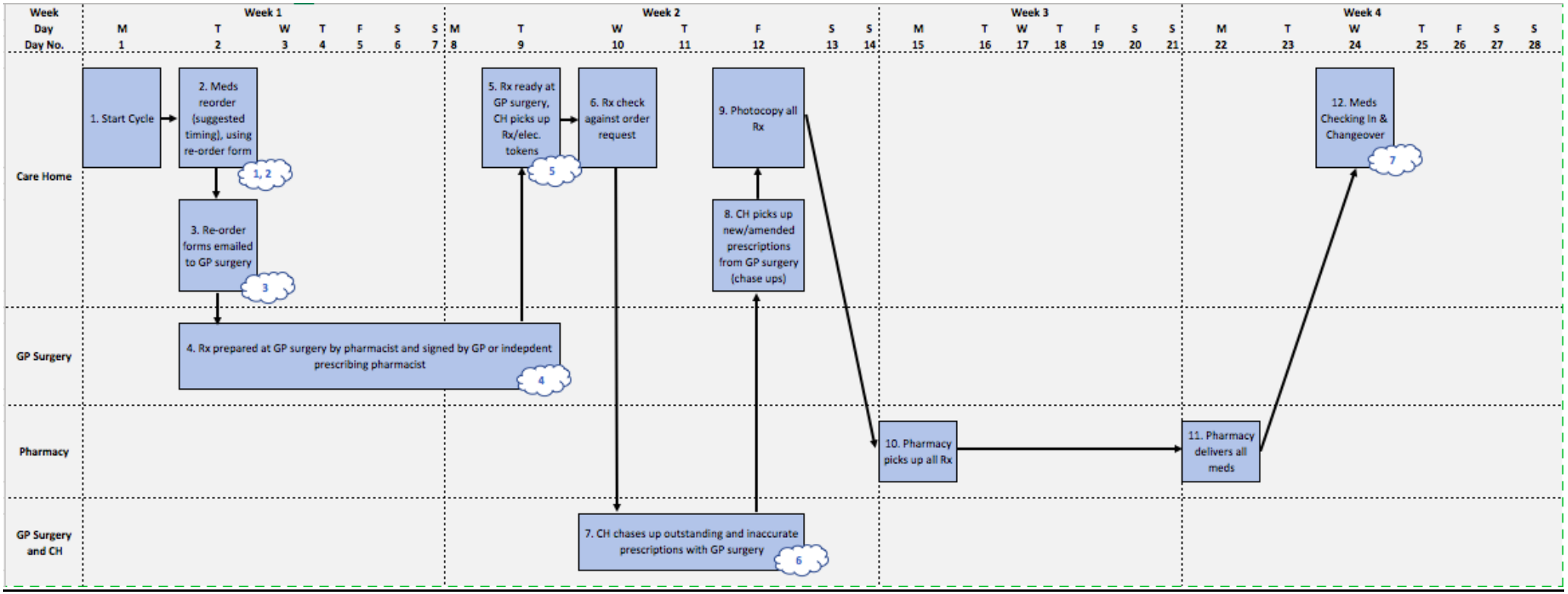


Figure 25: Recommended Cross-functional process map

**Each number enclosed in a white and blue cloud shape corresponds to recommendation number in the next phase (Specific Recommendations for the 28-day Supply of Medicines Cycle within Care Homes).*

Specific Recommendations for the 28-day Supply of Medicines Cycle within Care Homes

1 **Meds Re-order (suggested timing Week 1 – Day 2)** - to complete the medicines re-order task in Week 1, preferably day 2, to allow sufficient time for subsequent tasks in the 28-day cycle; subsequent tasks to be completed according to the process map timeline in figure

In CS1 and CS3, both care homes complete the re-ordering task in Week 2 of the medicines management cycle. The researcher suggests completing the re-ordering task on Week 1 – Day 2 of the cycle to allow for ample time at each subsequent task during the cycle. If the repeat medications are ordered on Week 1 – Day 2, many GP surgeries would be able to have prescriptions ready for the care home by the Week 1 (Day 5). However, if the GP surgery needs a longer turn-around period, they can take up to one full week without causing any concerns in the cycle. Potential benefits of completing the medicines re-order task at the beginning of Week 1 are listed below:

- GP surgery can take up to one full week to prepare prescriptions for surgery without causing any time constraints or concerns in subsequent tasks the cycle.
- Allowing the GP surgery to take up to one full week (if needed) to prepare prescriptions may allow GPs enough time to make any adjustments requested by the care home (i.e. quantity adjustments that receptionists are not authorised to make – see further details in recommendation 4), resulting in fewer request discrepancies.
- Subsequent tasks in the medicines management process have enough time to be completed and less time pressure

2 **Re-order Forms supplied by pharmacy (instead of right hand side of FP10 - repeat slip)** - to complete the medicines re-order task using the re-order forms provided by supplying pharmacies, as they are neater than the right-hand side of FP10 prescriptions and allow for more room for amendments

The researcher recommends using a formal re-order form to request repeat medication from the surgery, rather than FP10 repeat prescription slips. Repeat re-order forms are usually supplied by the pharmacy. An example of a FP10 repeat slip and repeat re-order form are provided on pages 75 and 34 respectively. Table 26 lists potential advantages of using a standardised repeat re-order form provided by the pharmacy in comparison to FP10 repeat slips.

Table 26: Differences between repeat re-order forms and right-hand side of FP10 prescriptions

Repeat Re-order Forms	Right-hand side of FP10 Prescription
- Larger, therefore less messy - Well organised - Space for additional comments (i.e. dose changes from mid-cycle, quantity adjustments, etc.) - Ability to notify surgery of discontinued items	- Smaller, therefore more likely to look messy and get lost - If additional comments are added by the medicines management lead, it can get messy and confusing - Easy to misinterpret tick boxes as ticked or left blank, especially when extra comments are added.

Emailing Re-order Forms to GP surgery (instead of fax) - to email (first preference) or hand-deliver (second preference) repeat request forms to the GP surgery

Email allows for an audit trail and by sending the same email to pharmacy, it ensures both organisations have received the same information about items to be prescribed and dispensed; alternatively hand-delivering repeat request forms if the surgery is in close proximity to the care home eliminates technical difficulties encountered with fax machines, including faulty lines, ink cartridge mishaps, failed transmissions, etc.

Prescription prepared at GP surgery by one pharmacy technician (point of contact) and signed by GP or independent prescribing pharmacist - GP surgery pharmacists to sign off repeat prescriptions for care home residents instead of GP, to ensure prescriptions are altered according to care home requests, where appropriate (e.g. quantity changes)

At most GP surgeries, receptionists prepare prescriptions when repeat prescription requests are received. Receptionists are unable to authorise any changes to the repeat medications (i.e. dose changes or quantity changes). The prescription is printed off or prepared electronically by the receptionist and is then given to the GP to sign for authorisation. If a receptionist has noticed a dose change or quantity adjustment requested by the medicines management lead or a patient, they are likely to leave a sticky-note or electronic note asking the GP to make the necessary changes before signing off the prescription.

Due to hectic schedules and time constraints, GPs often to not feel they have the time to go back into the system and change minor discrepancies, such as quantity adjustments. In this case, the

prescription is often left as the original quantity on the repeat prescription item, as seen from participant observations.

As the role of pharmacy technicians is continuously developing and they are being introduced to work in GP surgeries more often, the researcher suggests a trained pharmacy technician takes responsibility for generating the prescription and one clinical pharmacist authorises (by signing) all prescriptions for care homes. Furthermore, if the surgery does not have a pharmacy technician for this role, one appointed and trained receptionist could take on this responsibility, with the final prescription authorisation taking place by a clinical pharmacist.

Prescription ready at GP surgery, care home picks up prescriptions or electronic tokens (instead of going straight to pharmacy) - when prescriptions are ready at the GP surgery, they should be picked up by the care home and checked against their original re-order request for any discrepancies, also recommended by the RPSGB (RPSGB, 2009)

Care home chases up outstanding and inaccurate prescriptions with GP surgery (right away, and before sending prescriptions to pharmacy) - any discrepancies found during the fifth recommendation should be chased-up with the pharmacy technician acting as the point of contact and then transferred to the independent prescribing pharmacist (if needed) at the GP surgery promptly; once all discrepancies are resolved, the pharmacy should pick up all prescriptions from the care home at once

Medicines Checking in & Changeover (complete both tasks simultaneously) - CS1 and CS2 complete the medicines checking in and medicines changeover process separately. Both care homes require the medicines management lead to come in on Week 4 – Day 28 (Sunday) to complete the medicines changeover process. For CS1, the medicines management lead reports the process as taking at least two hours, up to four hours, after the bedtime medication round has been completed (9pm). The medicines management lead in CS2, reports that the changeover process takes the entire day (up to seven hours), sometimes split over two days (Day 27 and Day 28, Saturday and Sunday).

To eliminate the need for the medicines management lead to come in on Day 28 of the cycle, the researcher suggests the medicines checking-in and changeover process are done simultaneously on

Week 4 – Day 24. CS3 performs both tasks at the same time and has informed the researcher on an efficient process for CS1 and CS2, by use of a spare medicines trolley or separated section in care home resident's medication cupboards.

Medication Discrepancy Error Log

Finally, each care home is recommended to record discrepancies during each 28-day supply of medicines cycle, and perform an audit every annual quarter to determine if processes are improving, worsening, or remaining consistent. The care home and organisations involved should use these results to brainstorm and implement system improvements in subsequent cycles.

SUMMARY

The researcher used the Six Sigma methodology, DMAIC to observe and analyse the 28-day supply of medicines cycle within three care homes. During the *define* stage, the researcher employed the VOC tool by analysing the responses from the semi-structured interviews already undertaken in this study. Interviews revealed the lack of accuracy between prescription request generated by the care home and the prescription subsequently generated at the GP surgery. During the *measure* stage, the researcher conducted a CTQ tree, identifying the following parameters to measure during direct participant observations in each care home: omitted items, incorrect quantities prescribed and additional items prescribed. During the *analysis* stage, the number of discrepancies were calculated per one million defects and converted into a sigma performance level, a Pareto Analysis was conducted and a fishbone diagram to develop potential root-causes to the problem. Recommendations are then provided in the *improve* stage, and finally, an error log is provided in the *control* stage to encourage recording of discrepancies during each cycle and continuous improvement.

The three care homes studied had an average of 48 nursing residents per home. After observing each care home's 28-day supply of medicines cycle, the three care homes gave an average of 21.33 omitted items, 15.67 items in an incorrect quantity, 2.67 additional items and 0.33 mis-prescribed items; giving a total average of 40 discrepancies during the medicines checking-in process.

During the medicines changeover process, the only average that changed was for omitted items, which decreased to an average of 19.33 omitted items. This subsequently gives a total average of 28 discrepancies during the medicines changeover process. Using an average of eight medications per

care home resident, the average number of opportunities was 384 per care home. Therefore, giving an average rate of 38 defects per 384 opportunities per care home. This gives an average DPMO of 98,958.33 and average sigma performance level of 2.79 between all the three homes. Only data for the average number of discrepancies present in medicines changeover is depicted in the table below because these figures are most important as they are the average number of discrepancies present on Day 28 (the day before the start of the new cycle).

Table 27: Average Discrepancies Encountered between all case studies

Average Discrepancies Encountered in Medicines Changeover [CS1, CS2, CS3]		
Type of Discrepancy	**Defects in total opportunities (384)**	**DPMO**
Omitted Items	19.33 items	50,347.22
Incorrect Quantity	15.67 items	40,807.29
Additional Items	2.67 items	6,953.13
Mis-prescribed Items	0.33 items	859.38
Total Discrepancies	38 items	98,958.33
		Average Sigma Performance Level: 2.79

Six residents (4.17%) out of a total of 144 residents in all three care homes did not have medications for a full cycle's supply on Day 1 of the new medicines cycle. Two of these residents were from CS1, leading to ADEs of wrong timing, and four of the residents were from CS2, where the home was able to secure an emergency supply in time for the Day 1 morning medication round.

CHAPTER 7

DISCUSSION

This chapter provides a short summary of findings from the study, followed by an in-depth discussion of each recommendation provided for the 28-day supply of medicines cycle in care homes by linking each recommendation to current literature. A discussion of Six Sigma within this study is then provided, followed by limitations of the study, implications and scope for future work within the area. Finally, the chapter will end the thesis with concluding remarks.

SUMMARY OF FINDINGS

This study provides a visual framework and definition of the 28-day supply of medicines cycle, depicting the tasks within the cycle and definitions of each task. A DMAIC framework employing Six Sigma tools for care homes to use to examine and improve their own 28-day supply of medicines cycle is provided. A taxonomy of discrepancies (near-misses) between the medication re-order request and prescription generated is provided through the Critical-to-Quality tree (Chapter 6, page 115), delivering the key measurements each care home should make to evaluate their own baseline performance. The general conceptual framework recommendations can be found in the previous chapter (page 158-159) with a brief description of each recommendation, as well as the use of an error log to encourage continuous improvement.

Finally, this study found a general lack of proper communication and collaborative working between the stakeholders involved, as well as an opportunity for improved medical waste management and use of Six Sigma DMAIC for medicines management, and more specifically the 28-day supply of medicines cycle in care homes.

DISCUSSION OF FINDINGS

All three case studies have shown the sheer complexity of the 28-day supply of medicines cycle within care homes. The results of this study have shown the various tasks the care home staff complete throughout the cycle and the complexity of communication and collaboration between at least another two organisations (GP surgery and pharmacy).

This study has created and successfully applied a DMAIC framework to three case studies (depicted below). This framework can be applied to all care home settings experiencing discrepancies between their medications requested and medications prescribed, to analyse their own 28-day supply of medicines cycle. The framework provides the tools used within each DMAIC phase as a template for care homes to analyse their own cycle. The tools within the framework have been used successfully in many healthcare-related Six Sigma studies (Benitez et al., 2007; Chan, 2004).

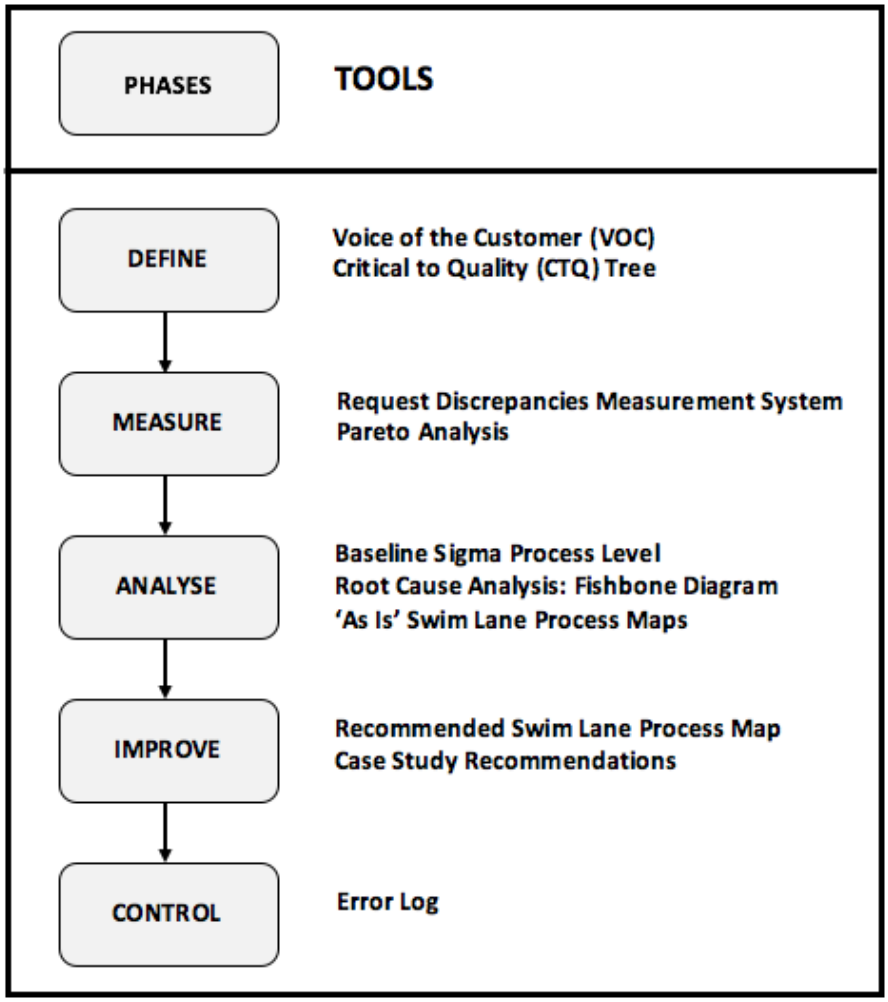


Figure 26: DMAIC Framework incorporating Six Sigma Tools

With some amendments, these tools can also be used to analyse other issues within healthcare organisations. For example, they could be used to analyse the prescription generating process within GP surgeries or the dispensing process within pharmacies. Furthermore, the tools could be used to analyse patient waiting times in a GP practice, where the request discrepancies measurement system can be altered, for example, to a system measuring patient waiting time according to time of day or type of appointment.

The Critical-to-Quality (CTQ) tree used in this study classified the types of discrepancies seen during the 28-day supply of medicines cycle in care homes. It further provided the measurements needed to analyse the cycle and determine the sigma performance level. This taxonomy of discrepancies has generalisability outside of the three case studies in this thesis, as it can be used to classify and measure discrepancies within any care home's 28-day supply of medicines cycle, regardless of how their organisations cycle is carried out.

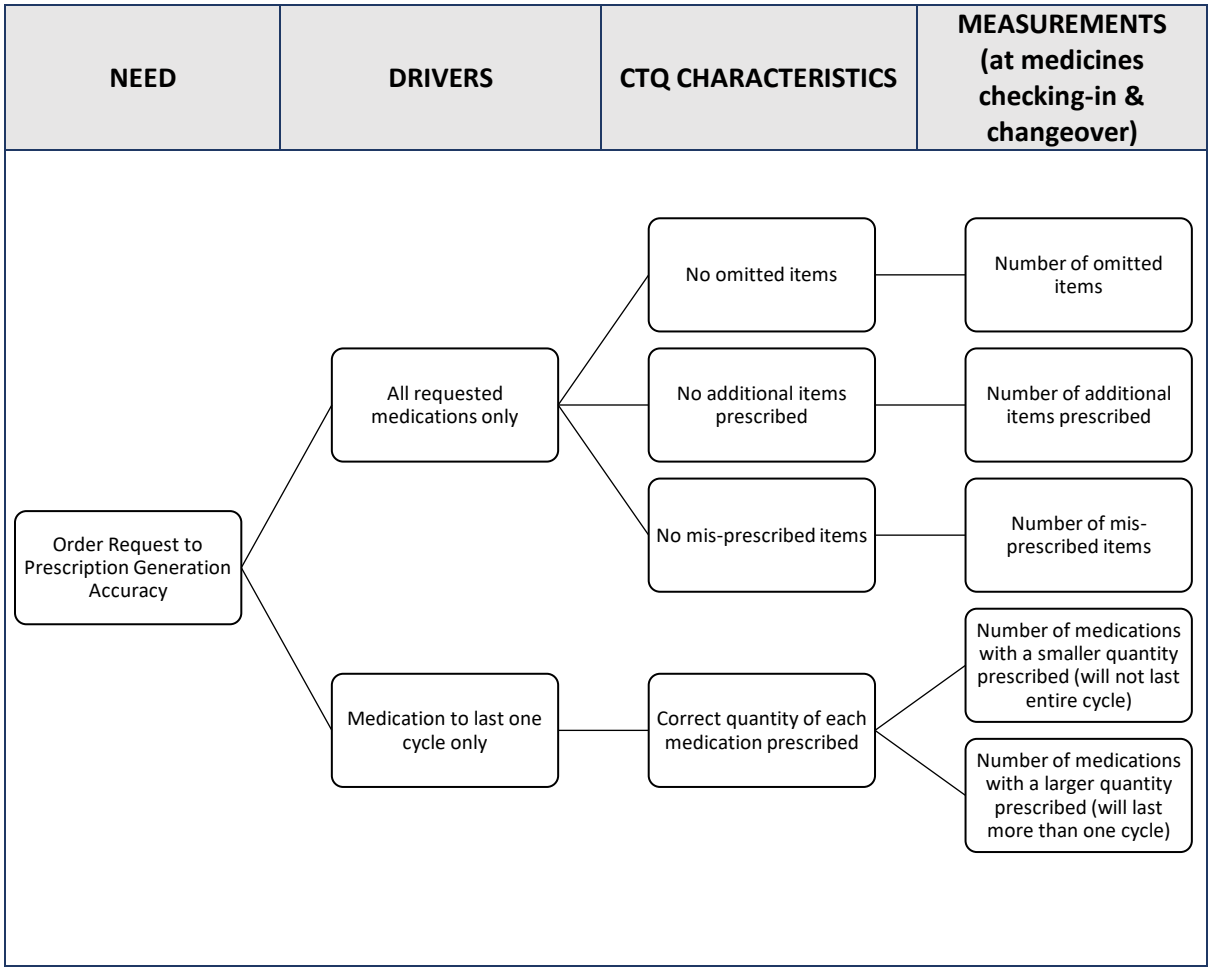


Figure 27: CTQ Tree with Measurements for Care Homes to use

The CTQ tree presents three types of discrepancies which are similar to types of near-misses or errors found in other research: omissions, additional items and mis-prescribed items (Alldred et al., 2009; Oxfordshire CCG, 2015). The final type of discrepancy found in this study is incorrect quantities prescribed compared to the re-order request. This is a significant finding as it would contribute significantly to medication waste within care homes.

As seen from the results, the two most common types of discrepancies (near-misses) were omission and incorrect quantities prescribed. Literature suggests omission is one of the most common type of medication error and cause of ADEs (Alldred et al., 2009; Aspden et al., 2007; Rostami et al., 2019; Sheikhtaheri, 2014). Experts believe the number of near-misses and medication errors are directly correlated, meaning one would expect to see a similar types of near-misses to medication errors and in numbers which are directly proportional (Sheikhtaheri, 2014). This PhD study confirms that omission is one of the most common discrepancies (near-misses) found in the 28-day supply of

medicines cycle, at an average of 50.87% of all discrepancies reaching the medicines changeover phase, but not the patient.

Omission as one of the most frequent discrepancies (near-misses) in this study demonstrates that there may be a causal link between near-misses and medication errors. Omissions were the most frequent near-miss detected and the most frequent medication error detected is wrong timing within care homes (Barach and Small, 2000a; Kaplan, 2003). The two are related through the 28-day supply of medicines cycle because an omitted item is caught during the cycle, so even though the discrepancy is present during medicines changeover, the care home is actively working on fixing the discrepancy. Therefore, the omission error would usually become a medication given at the wrong time rather than a dose completely omitted. Further research examining both near-misses and ADEs within care homes may help in understanding what near-miss trends lead to the various types of ADEs.

The second most prominent type of error found in the 28-day supply of medicines cycle in this study was prescribing the incorrect quantity of medication as per order request from the care home. As this is the first study to examine rates of incorrect quantities prescribed in repeat medication orders, it cannot be compared to current literature. However, it is important to note an average of 39% of all errors observed in this thesis were incorrect quantities, with the vast majority prescribed at larger quantities than requested, potentially leading to significant waste at the end of each 28-day supply of medicines cycle within care homes.

The NHS produces 600,000 tonnes of clinical, pharmaceutical, infectious and domestic waste, costing £42 million annually (Coote, 2002). In 2004, the NHS generated an estimated 384,698 tonnes of waste, with 120,547 tonnes clinical waste (31%) (Barratt et al., 2004). Furthermore, £50 million worth of NHS supplied medicines are disposed of unused by care homes annually (Barratt et al., 2004).

It is a national priority to reduce waste within NHS and private healthcare settings and one way of achieving this goal is reducing waste associated with repeat prescribing (Jesson et al., 2005). Preventable categories of waste production include error of prescription, order or supply (Jesson et al., 2005). Although there is somewhat limited literature on waste management within healthcare, many authors attribute blame to the overall mismanagement of repeat prescriptions (Anon, 2000). The second most prominent discrepancy or type of near-miss observed in this study was incorrect quantity of medications prescribed, leading to a waste of dispensed medication, as ultimately the unused medication will be discarded at the end of the subsequent 28-day supply of medicines cycle.

Further studies examining waste produced by nursing home settings are needed to evaluate the level of waste produced by the 28-day supply of medicines cycle, other causes of waste within this setting and the overall level of waste produced by nursing homes. However, improved communication and management of repeat medications through the 28-day supply of medicines cycle, by following the recommended process map from this study (figure 28 depicted below) and amending prescription discrepancies throughout the cycle, can help reduce medication wastage in care homes.

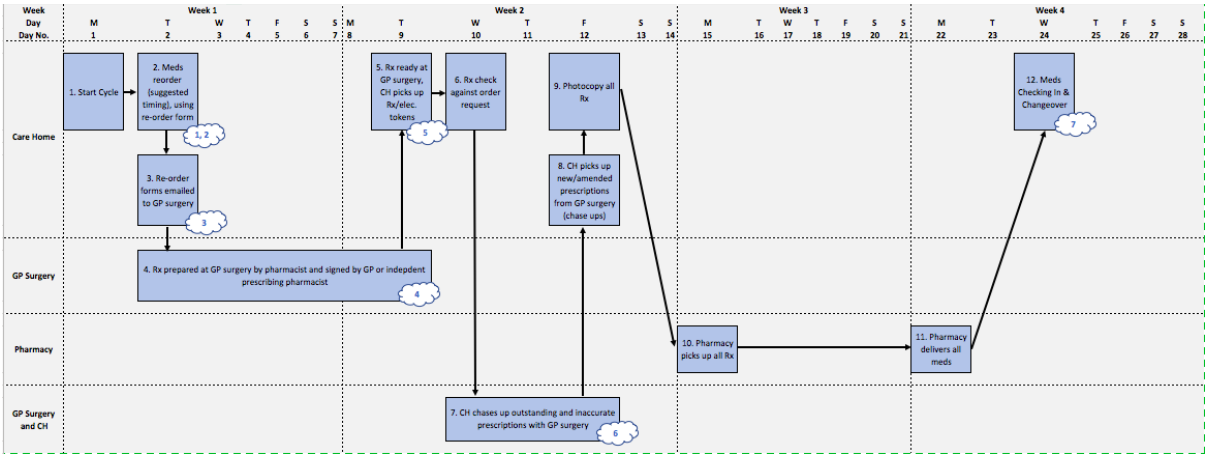


Figure 28: General Conceptual Framework displaying Ideal Timings for Tasks within the 28-day Supply of Medicines Cycle - Please refer to page 157, figure 25 for a larger and clearer image.

This study recommends the same pathway suggested by Alldred et al. (highlighting RPSGB recommendations) is followed. The findings of this study are consistent with the recommendation set by NICE, RPSGB and Alldred et al., that care home providers should retain responsibility for ordering medicines from the GP practice and should not delegate this to the supplying pharmacy. In this study, all three care homes created the prescription requests (medicines re-order), rather than the pharmacy as this can result in overstock of resident medications, ultimately leading to waste (Alldred et al., 2009; NICE, 2014). The request should then be sent to the GP surgery for prescription generation.

Again, the findings of this study are consistent with previous recommendations for ready prescriptions to be sent to the care home for checking (prescription check against re-order), rather than directly to the pharmacy. Two of the three case studies in this research followed this recommendation, whereas one care home had the prescriptions sent directly to the pharmacy and the pharmacy create a 'chase-up' list for the resident. When the prescriptions are at the pharmacy, they are dispensed and medications are delivered to the care homes, also following the pathway set by Alldred et al.

NICE guidelines suggest each task within the 28-day supply of medicines cycle are as follows: prescribing, ordering, dispensing and supplying. In contrast to the tasks labelled by the NICE guideline on medicines management, referring to a 28-day supply of medicines cycle, this research labels the tasks within the cycle as follows: medicines re-ordering and prescription check against re-order (comparable to ordering task defined by NICE), medicines checking-in (occurs after prescribing and dispensing tasks defined by NICE), medicines changeover (occurs after prescribing and dispensing tasks defined by NICE), and medicines administration (comparable to supplying task defined by NICE).

This research has looked at the cycle from the care home perspective, therefore labelling all tasks which occur within the care home only. The figure below was derived in Chapter 4 to depict the cycle.

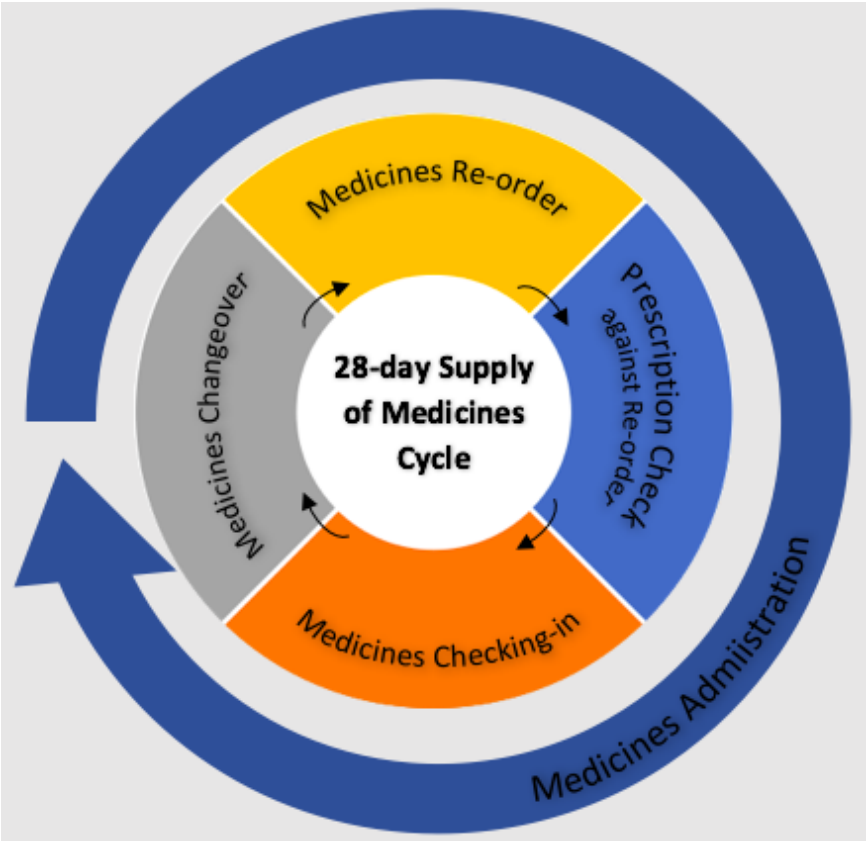


Figure 29: 28-day Supply of Medicines Cycle within Care Homes

The first task defined by this study is medicines re-ordering, which is comparable to the 'ordering' task set in the NICE guideline on medicines management. No literature has stated the most appropriate time to complete the medicines re-ordering task within the 28-day supply of medicines cycle. This study recommends completing the medicines re-order task in Week 1, preferably day 2 as depicted

on the recommended process map (page 158), to allow sufficient time for subsequent tasks in the 28-day cycle (Recommendation 1).

A goal of Six Sigma is to deliver goods and services to the customer in a timely manner. Academic and industrial literature supports the notion that when one process is held up in a cycle, subsequent processes fail to meet their deadlines (Schroeder et al., 2008). Therefore, it is paramount that each task within an end-to-end process has sufficient time scheduled to be able to perform its duty to an excellent standard (Schroeder et al., 2008). Therefore, completing the medicines re-ordering task as soon as the cycle starts, allows sufficient time for subsequent tasks within the 28-day supply of medicines cycle for the GP surgery, pharmacy and care home. As important as the timescale of medicines re-ordering, is the method of re-ordering.

The NICE Guideline on '*Managing Medicines in Care Homes'* state that medicines can be ordered in the following ways (NICE, 2014): [1] the home orders directly from the GP practice using the repeat prescription ordering form (also known as the 'right-hand side' of the prescription form [FP10]), [2] the home orders directly from the GP practice using the medicines administration record, [3] through the supplying pharmacy, with the pharmacy ordering prescriptions after visiting and/or consulting with the care home or [4] through the supplying pharmacy, with the pharmacy ordering prescriptions directly from the GP practice without contacting the care home. This study found some care homes currently use option 1, the right-hand side of the prescription form to re-order medicines. However, this study found the use of the right-hand side of prescription forms to order medications is inefficient due to the small size of the form and therefore recommends completing the medicines re-order task using the re-order forms provided by supplying pharmacies, as they are neater and allow for more room for amendments (Recommendation 2).

A study by Swinglehurst et al. (2011) examined receptionist roles in the process of repeat prescribing at four GP surgeries. In three of the surgeries, 'processing of repeat prescriptions took place in reception, which was busy, unpredictable and characterised by frequent interruptions' (Swinglehurst et al., 2011). Additionally, work completed at reception involved moving between 'cramped physical spaces and making do with materials and space available' (Swinglehurst et al., 2011). As the right-hand side of FP10 prescriptions are much smaller than repeat re-order forms, less than half the size of A4 size versus A4 size respectively, the repeat slips may be easier to misplace and perhaps cause confusion between other patient repeat slips and care home resident repeat slips in busy, cramped physical spaces within GP surgery receptions.

Having a designated administrative office for prescription clerks, which is relatively free of interruptions perhaps eliminates errors caused by interruptions, busy and loud GP receptions (Swinglehurst et al., 2011). Studies have found smartcards are removed from computers in reception when the system is running slow to increase capacity for other users (Swinglehurst et al., 2011), this could have an effect on receptionist's processing of repeat prescriptions and lead to transcription errors.

Furthermore, this study found the primary means of communication between each stakeholder organisation (GP surgery, pharmacy and care home) was using a fax machine. This included faxing the medicines re-order (whether the right-hand side of prescriptions or re-order forms supplied by the pharmacy) to the GP surgery, as well as for other tasks including sending 'chase-up' lists between the stakeholder organisations.

A common complaint between all three organisations (GP surgery, care home and pharmacy) is the GP surgery and pharmacy blaming one another for items not prescribed or dispensed. Findings from this study on this type of 'blame culture' has been similarly well documented in previous literature (Stevenson and Moore, 2019; Waring, 2005). In this study, the care homes often got caught in the middle, attempting to figure out which organisation has made an error and how to rectify the problem in time to get a medication to the resident. This specific communication problem can be solved by emailing re-order requests to the GP surgery and including the supplying pharmacy in the email, ensuring both parties have identical information supplied.

Although fax machines were once the preferred method of communication, plenty of recent research has shown the inefficiencies of fax machines and advantages of newer technologies, including email. Therefore, in line with other research, this study recommends emailing medicines re-orders from the care home to the GP surgery and pharmacy (Recommendation 3).

Although fax machines allow documents to be easily, cheaply and almost instantaneously exchanged, regardless of physical distance, there are also numerous drawbacks to their use (Etemadieh, 2018; O'Hagan, 1996). The first problem is that the resolution of the output text isn't always sufficient to reproduce small or intricate characters accurately (O'Hagan, 1996), definitely posing a concern to the small size of the right-hand side of prescriptions. Perhaps the most significant concerns would be the danger of 'wrong number' errors when using fax machines, which can compromise patient

confidentiality (Etemadieh, 2018; O'Hagan, 1996). To assure patient confidentiality, stakeholders can choose to make files password protected.

Overall email allows for an audit trail and by sending the same email to pharmacy, it ensures both organisations have received the same information about items to be prescribed and dispensed. The table below outlines some differences between each type of communication.

Table 28: Differences between means of communication

Fax	Email
- Faxed items seem to be easily misplaced by receptionists - Can be misinterpreted easily (e.g. ink cartridge mishaps) - More technological issues	- Better reliability than fax machines - Creates audit trail - Easy means of communication - Faster - Most care homes have at least one computer that can be used by the medicines management lead to email requests

Finally, this recommendation is in line with the recent ban on fax machines in the NHS by the UK health secretary is due to phase out all fax machines by April 2020 (Department of Health and Social Care, 2018). Matt Hancock stresses the importance of getting rid of fax machines in healthcare organisations to encourage use of newer technologies, IT platforms and forms of artificial intelligence. NHS organisations will be required to use 'modern communication methods,' such as email (Department of Health and Social Care, 2018).

The medicines management lead was responsible for ordering resident medication, checking prescriptions against the re-order, checking delivered medications and changing over the old cycle medications to the new cycle medications, All three care homes studied, abided by the following NICE guideline recommendations: [1] each medicines management lead had protected time for these tasks [2] each care home had two staff members appropriately trained to order medications [3] each care kept records of medicines ordered to check prescriptions and medicine deliveries against the record to ensure all medicines ordered have been prescribed and supplied correctly and [4] care home residents were only given medications prescribed to them and there were no stock medications in any of the homes (NICE, 2014).

Previous literature has recommended care homes be associated with one GP surgery, rather than multiple surgeries. One case study in this research dealt with multiple GP surgeries. This research

agrees with current literature and policy recommendations for each care home to use one GP surgery (NHS England, 2016). Although concerns have been addressed on diminishing the patient to GP relationship, having one GP surgery associated with an entire care home allows for more efficient communication, building rapport between the care home, GP and supplying pharmacy, as well as the opportunity for the GP to build a new relationship with new residents during weekly medication rounds, as recommended by NHS policy (NHS England, 2016).

The fourth recommendation made in this study relates to the process of prescription generation at the GP surgery. This study recommends a pharmacy technician is held responsible for generating prescriptions off the care home's re-order request and is the point of contact for the care home, while a practice-based clinical independent prescribing pharmacist is responsible for medicines management within care homes (Recommendation 4).

Work by Zermansky, as early as 1996 has suggested more research be put into the role pharmacists could possibly have in managing repeat medications, along with several more recent studies (Avery et al., 2013; Inch et al., 2019; Maidment et al., 2016; Szczepura, 2008; Wright et al., 2016). Included in the medicines management responsibility, the study recommends the practice-based pharmacist signs-off all repeat prescriptions for the care home residents. Pharmacists can provide a safe and effective option for managing repeat medications for care home residents (NHS England, 2019a; RPSGB, 2019a).

Numerous studies have reported concern about the clinical safety and management of repeat prescribing, particularly in older populations (Price et al., 2017). Furthermore, intensifying control of repeat prescriptions is important to medication safety and cost reduction (De Smet and Dautzenberg, 2004). As practice pharmacists become more common within GP surgeries, the task of authorising care home resident repeat medications should come within their job description (RPSGB, 2019b). Pharmacists have the pharmaceutical and clinical skills to review medication and an increasing number of pharmacists have prescribing qualifications, allowing them to make necessary prescribing decisions in their areas of competency (NHS England, 2019a).

In the US, consultant pharmacists have been reviewing care home resident medication every month for quite a few years now, showing benefit (Barlas, 2012). Since the completion of the CHUMS study, Clinical Commissioning Group (CCG) pharmacists in the UK now perform regular medication reviews in care homes (Swift and Trumper, 2017). This study found problems despite these reviews, however

the researcher strongly believes pharmacists responsibility in managing aspects medicines management within care homes will improve process efficiency. Use of a pharmacist independent prescriber in care home medicines management is supported by further studies (Alldred et al., 2009; Maidment et al., 2016; Wright et al., 2016).

Recent initiatives through the NHS have been implementing pharmacists and pharmacy technicians in care home medicines management (NHS England, 2019a; RPSGB, 2019a). Pharmacists involved in care home resident medicine management shows promising results by reducing polypharmacy, implementing cost saving strategies and reduction in resident falls (Inch et al., 2019; Rai, 2018). Pharmacy technicians have been valuable in ensuring effective medication reconciliation and decrease the workload for busy care home environments and GPs for care home resident medicines management (Hemsley, 2018). Therefore, training pharmacy technicians to produce repeat prescriptions to then be signed by an independent prescribing pharmacist has potential to create fewer errors and stream-line efficiency of the process and communication.

Similar to findings from Müller and colleagues, this study also revealed communication barriers, primarily between care home staff and GPs (Müller et al., 2018), during interviews and participant observations. This study found that care home staff have a lack of understanding in concerns to how repeat prescriptions are authorised at GP surgeries and which queries are handled by receptionists, doctors or pharmacists at the surgery. The researcher was unable to find this result stated elsewhere in current literature.

Interview data and direct participant observation data from this study outline the communication challenges between the GP surgery, supplying pharmacy and care home under study. Miscommunications are common between the care home and GP surgery. Receptionists often tell care home staff they have not received re-order requests, when care home staff insist they have already faxed it. Nurses requests for specific patients which need to be addressed by the doctor can also get mistranslated by receptionist staff.

Research has found a lack of communication or poor communication to be a major risk factor in medication errors and sometimes even death amongst all healthcare settings (Illingworth, 2015; O'Hara et al., 2018). Communication errors are considered the most common cause of medical errors, up to one third of errors, complaints and work time inefficiencies in healthcare settings and should be largely preventable by well-designed procedural policies and good execution (Ford, 2015; Murphy and

Dunn, 2010; Vermeir et al., 2015). The CHUMS study found that 29% of communication related medication errors were between the care home and the GP surgery (Alldred et al., 2009). Of this 29%, less than the 50% of communication related medication errors were between the care home and the pharmacy (Alldred et al., 2009). It is therefore important for stakeholders involved in the care of care home residents to work collaboratively and focus on effective communication.

Poor communication costs the US healthcare system $1.7 billion in malpractice costs and nearly 2000 lives (Kern, 2016). In all malpractice claims in the US, a total of 30% accounted back to communication breakdown between 2009 and 2013 and 37% of high-severity harm cases including death, involved communication failure (Kern, 2016). The highest percent of miscommunication was between two or more healthcare providers, at 57% (Kern, 2016).

Furthermore, the importance of improving communication between stakeholders to improve patient and medication-related care services is well documented (Alldred et al., 2009; Buttigieg et al., 2016; Creswick et al., 2009; Swinglehurst et al., 2011). Therefore, designating the task of authorising repeat prescriptions to the practice pharmacist will alleviate some of the frustrations relating to miscommunications and resolving queries, as the care home and linked pharmacy will know who to speak to within the GP surgery for queries. This study has found the lack of effective communication can cause more discrepancies in the 28-day supply of medicines cycle and efforts to stream-line communication between all stakeholders, thereby reducing the margin for error to increase patient safety should be made, as supported by other studies (Alldred et al., 2009; Kern, 2016; Vermeir et al., 2015).

In the January 2018 update of the NICE Guideline, the Guideline Development Group (GDG) concludes that GP practices should have written processes for prescribing and issuing prescriptions for their patients living in care homes that consider prescribing the right amount of medicines to fit into the 28-day supply cycle if appropriate. All care homes investigated ordered repeat medications for a 28-day supply, however prescriptions quantities did not always meet the criteria of fitting into the 28-day supply. A limitation of this study, is the lack of semi-structured interviews with GPs, and participant observations within GP surgeries, therefore the researcher is unable to confirm whether GP surgeries had standard operating procedures (SOPs) for generating prescriptions for care home residents.

As discussed at the beginning of this section, findings from this study are consistent with recommendations by NICE, RPSGB and Alldred et al. that prescriptions should be picked up by the care home and checked against their original re-order request for discrepancies, before being picked up by the pharmacy (Recommendation 5).

The Six Sigma philosophy is grounded in reducing the number of defects or errors within each task of any particular process (Allen, 2019). The recommendations thus far have aimed to reduce the number of discrepancies between the care home's re-order request and the prescription subsequently generated by starting the first task of the cycle sooner to allow more time to complete subsequent tasks, by emailing re-orders and using re-order forms supplied by the pharmacy, by keeping a pharmacy technician and practice-based clinical pharmacist responsible for generating prescriptions and signing-off prescriptions (respectively) to enhance communication between the GP surgery, care home and pharmacy.

Although the aim of the recommendations is to reduce the number of defects coming through to the prescription check against re-order stage, the 28-day supply of medicines cycle must incorporate an efficient system to deal with any discrepancies proactively, to reduce the number of discrepancies coming in later in the cycle when there is insufficient time for amendments. Numerous studies have employed the Six Sigma philosophy of reducing the number of defects and becoming a proactive process to 'errors' rather than reactive (Kapur and Potters, 2012; Liu, 2019; Varkey et al., 2007).

Therefore, Recommendation 6 enables the cycle to be proactive to discrepancies: prescriptions without any discrepancies should be retained at the care home until any prescriptions with discrepancies have been amended and collected by the care home. This should reduce the margin for error and increase patient safety. It is also the likely reason CS3 performed much better than CS1 and CS2 in this study. Any discrepancies found between the care home's original medicines re-order request and the prescriptions generated at the GP surgery should be 'chased-up' with the practice-based clinical pharmacist at the GP surgery within 24-hours of receiving the prescriptions.

The practice-based clinical pharmacist should then aim to resolve all discrepancies within 24-hours of contact from the care home. Once the care home picks up these prescriptions and checks them against their original re-order, the pharmacy should pick up all prescriptions from the care home at once (Recommendation 6). Unlike this study, NICE, RPSGB and Alldred et al. do not discuss any

recommendations regarding dealing with discrepancies found between the care home's re-order requests and the prescriptions generated. No other sources were found either.

Once all prescriptions have been collected by the supplying pharmacy, dispensed and checked, the pharmacy delivers the medications to the care home. This study found that care homes obtain all their repeat medications items from one pharmacy, similar to findings by Burns and McQuillan, and in line with recommendations by RPSGB (Burns and McQuillan, 2011; RPSGB, 2016).

In every case study, the supplying pharmacy supplied resident MAR charts, as recommended by NICE (NICE, 2014), as well as re-order forms to use for the next time the home will be re-ordering repeat medications. Any ad-hoc medicines started between the monthly supplies, were added to the MAR chart by a trained nurse or carer in line with previous findings (Odberg et al., 2019). Similar to other research and NICE recommendations, this study found MAR charts produced by the pharmacy avoided transcription errors, difficult to read handwriting and was a more efficient use of time than the care home manually preparing the MAR charts (Alldred et al., 2009; CPA, 2014; NICE, 2014). Finally, each care home followed NICE recommendations to have a process in place to ensure all details of each MAR chart are correct and signed-off by two care home staff members (NICE, 2014).

NICE recommends care home providers keep records of medicines ordered and that medicines delivered to the care home should be checked against a record of the order to make sure that all medicines ordered have been prescribed and supplied correctly (NICE, 2014). This study found medicines delivered are checked against the care home's re-order by the medicines management lead and one other staff member (trained carer or nurse). The medicines changeover process is then completed by the medicines management lead, and in two case studies, with the help of another nurse or carer.

This study recommends the medicines checking-in and medicines changeover process, should be completed simultaneously (Recommendation 7) to make the task safer. As some homes conduct the medicines changeover process on Sunday night after the bedtime medication round, it poses a risk to patient safety as late-evening or night-time shifts for nurses are often prone to more errors (Gander et al., 2019). Additionally, performing the medicines checking-in and changeover process simultaneously means the task is completed during regular hours for the medicines management lead and saves the care home labour costs of the medicines management lead coming in on Day 28 of the cycle, Sunday evening.

Finally, this study recommends the use of the 'Medicines Discrepancy Error Log' during each 28-day supply of medicines cycle (Recommendation 8). Various studies within healthcare settings using Six Sigma methodologies have recommended the use an error log or chart during the *Control* phase (Benitez et al., 2007; Castle et al., 2005; Chan, 2004). The researcher created the error log to help sustain improvements made via recommendations to each case study in this thesis and encourage continuous improvement. However, the error log can be used throughout care homes in the UK to keep track of the number of discrepancies encountered each 28-day supply of medicines cycle between the re-order request made and prescriptions generated or ultimately, medications delivered. The log is a simple and quick report to fill out to ensure the medicines management lead does not feel the burden of an extra task.

The error log is a tool for organisations involved in the 28-day supply of medications, to report levels of near-misses and discrepancies per cycle. Its purpose is to encourage continuous improvement within the cycle, act as a report of collected near-miss data, and has the potential to be used for auditing purposes by several individuals and organisations, including the care home manager, company medicines management leads and the CCG (Clinical Commissioning Group). However, there is extensive literature sharing concerns around organisations under-reporting near-miss and error events to regulators (Shojania, 2008; Waring, 2005). Therefore, an error log between the stakeholders concerned (care home, GP surgery and supplying pharmacy), could be effective in keeping track of discrepancies and subsequently making changes to address concerns and encourage continuous improvement within the cycle.

Participants from all three case study stakeholder feedback sessions were keen to use the error log, stating it would be a good way to track their progress and re-evaluate after a number of cycles. Medicines management leads were pleased the log was simple to use and quick to complete, therefore not adding extra work to their day. Although this feedback is positive, the researcher has considered the effect of socially desirable responses from participants, discussed under limitations (page 183).

A US-based study by Verrue et al. found that 69.7% of all nursing homes studied, had a medication error reporting system in place (Verrue et al., 2011), however these systems did not specifically include near-miss data (labelled discrepancies in this study) from the 28-day supply of medicines cycle. The study found approximately 40% of the nursing homes performed an evaluation of the medication

management process less than once a year (Verrue et al., 2011). The study suggests a proactive evaluation of the medicines management process, errors and patient safety issues within care homes should be performed frequently (Verrue et al., 2011), involving all stakeholders (Cohen, 2010; Leape et al., 1995).

Both researchers within medicines management and experts within the field of applying business concepts to healthcare industries acknowledge the importance of becoming proactive organisations (Ahmed, 2019; Boersma et al., 2019; Waring, 2005). Six Sigma methodologies stress the importance of proactive approaches to improve process management, whilst researchers in medicines management suggest a proactive evaluation of processes and errors, as well as continuous learning to help maintain a higher standard of care to patients (Ahmed, 2019; Frankel et al., 2017; Waring, 2005). Evidence suggests a systems approach which is proactive in identifying system flaws is responsible for progress within patient safety movements (Odom-Forren, 2019).

An American national report recommends nurses in all care settings work to improve systems addressing the most common near-misses in the work environment, participate in evaluating the efficacy of new systems and processes within the setting, implementing error reporting systems and supporting accurate reporting of medication errors (Aspden et al., 2007). As mentioned in Chapter 2, literature review, although the UK NPSA collects information on medication errors, none of their reports directly quote specifically the number of near-misses in the care home environment.

In line with recommendations from Verrue et al. and Aspden et al., the researcher recommends the use of an error log as a proactive way to evaluate the 28-day supply of medicines cycle within care home medicines management. Furthermore, an error log resonates with the recommendation by Greene et al. (2004), to implement continuous quality improvement (CQI) to improve near-miss reporting. Finally, the second part of the UK Health Foundation's publication, *Continuous Improvement of Patient Safety: The Case for Change in the NHS* discusses the importance of looking forward and anticipating risks in terms of patient safety, rather than only learning from past mistakes (Illingworth, 2015). Use of an error log provides organisations with a tool to track past mistakes, but also plan for the subsequent cycle accordingly by anticipating risks and acting upon them.

Finally, as mentioned in the literature review, the NICE Guideline concludes that a collaborative approach between health and social care practitioners is needed to ensure effective communication when medicines are started, stopped or changed, and keeping records of medicines administration

up-to-date within the care home. This study found that although each stakeholder organisation (GP surgery, pharmacy and care home) has a vital role during the 28-day supply of medicines cycle, the overall collaborative approach was lacking. This finding is in line with general concerns in stakeholder teamwork within the healthcare sector (Schot et al., 2019).

A collaborative approach involves building a strong relationship between all three organisations and communicating regularly and efficiently about resident medications (Morgan et al., 2015). The importance of communication was discussed earlier in this chapter and coincides with working collaboratively (Schot et al., 2019). However, the scale of the problem is much larger than just communication and can ultimately be rectified with an IT system providing transparency between the organisations and supporting collaborative teamwork.

There is need for a technological system which is linked between all three organisations, providing a central point for communication and transparency (Ford et al., 2019). Current systems installed in GP surgeries, care homes and pharmacies sometimes have a linked platform between the care home and pharmacy. However, this link only provides a basis for sending messages from one organisation to the other through the IT system and does not actually provide any 'transparency' between the organisations.

Several platforms or 'apps' have been developed to enhance collaborative working between healthcare providers as well as patients (Slotwiner et al., 2019), for example an app created to provide clinical information to both healthcare providers and patients about patient mental health conditions (Torous et al., 2019).

The transparency of the future IT programmes should allow each stakeholder to view the progress of their repeat medication re-order. This means that when the care home presents each resident's re-order form for processing, they can see the pathway of their request; whether it is with the receptionist being processed, with the GP or clinical pharmacist waiting to be signed, waiting to be collected by the care home for checking or picked up by the pharmacy, dispensed at the pharmacy or waiting to be delivered to the care home by the pharmacy delivery driver. Similarly, this type of transparent system can be used for patients handing in repeat medication re-order requests to their GP surgery or pharmacy.

A similar concept has been filed for patent approval in the US which would link prescriber and pharmacy servers and interact with patients (Brunner, 2019). The application would allow a prescription request to prescribe or de-prescribe a medication for a patient, which would then be accepted or rejected by the prescriber on their software platform. If accepted, the prescription would be generated and patient notes updated automatically. An ID tag for prescriber, pharmacy and patient would be produced and the pharmacy can then accept dispensing of the prescription. The patient is then alerted when the medication is ready to be collected (Brunner, 2019).

Use of healthcare IT has the potential to improve communication between stakeholders individually, and patients, as well as encourage collaborative working between stakeholders (Konttila et al., 2019). Introducing systems which stream-line communication and provide transparency within the 28-day supply of medicines cycle for each stakeholder group to know where their medication request, prescription or medication is along the process, would help in eliminating blame culture within the cycle (Brunner, 2019; Konttila et al., 2019).

DISCUSSION OF SIX SIGMA

The purpose of this study was to provide a detailed description of the 28-day supply of medicines cycle within care homes. The study employed Six Sigma methodology, DMAIC to define the scope of the project according to issues and challenges expressed by case study participants, measure and analyse discrepancy and near-miss rates within the cycle, and suggest improvements (framework and recommendations) as well as control measures to ensure continuous improvement of the cycle.

Organisations meeting Six Sigma standards perform at a level of less than 3.4 defects per one million opportunities (DPMO). The average performance level between the three care homes in this thesis indicates approximately 104,167 DPMO which is an average sigma performance level of 2.8 between the homes. Whilst Six Sigma strategies have been used in various healthcare settings, it is the first time it has been applied to the 28-day supply of medicines cycle within care homes.

As discussed in Chapter 5, Six Sigma has shown promising results in healthcare-related studies (Chandra et al., 2012; DeYong and Sehwail, 2003; Kumar and McKewan, 2011; Lazarus and Stamps, 2002) and medicines management related studies (Benitez et al., 2007; Chan, 2004). Chandra et al. (2012) as well as Kumar and McKewan (2011) used DMAIC specifically for improvement measures.

Majority of studies using Six Sigma techniques within healthcare have focussed on the hospital setting (Ahmed, 2019; Godley and Jenkins, 2019), whereas the care home setting has been ignored thus far.

This study has not only provided recommendations on each case study's 28-day supply of medicines cycle, in attempt to improve its efficiency, but also provided recommendations for the entire care home sector. Tools specific to the Six Sigma toolbox have been used to analyse findings and develop recommendations. All three care homes under study had positive feedback on the use of Six Sigma within care homes and the 28-day supply of medicines cycle, although the researcher must account for socially desirable responses (discussed under limitations). Each stakeholder feedback session understood how the study was conducted and showed approval towards the study design and generalisability to other care homes. Furthermore, stakeholder feedback session participants within each case study were keen to implement the recommendations derived from use of DMAIC tools and were positive the recommendations would improve the overall efficiency of the cycle.

The Six Sigma tools used within this study are relatively easy to apply to the 28-day supply of medicines cycle as shown through the CTQ tree taxonomy of discrepancies, including what measurements to collect and analyse within any care home. Furthermore, the voice of the customer (VOC) and process map tools are interviews and observations, which could be conducted my senior care home management or policy makers, including the CCG or CQC. If policy makers or care home management are interested in applying the framework specific to counting and analysing near-misses and discrepancies within the cycle, they will be able to do so. In addition, with the use of the error log, near-miss and discrepancy rates will be clearly calculated.

LIMITATIONS, IMPLICATIONS AND SCOPE FOR FUTURE WORK

Limitations

Regardless of how carefully a researcher designs and performs research, all research has limitations (Simon and Goes, 2012). The lack of prior research on medicines management specifically within care homes was as a limitation in creating a rigorous literature review and discussion, as there are very few academic and policy documents on the topic to confirm or compare results with. However, the lack of information available on the topic helped form an explorative multi-case study research design, to gain an in-depth understanding of the 28-day supply of medicines cycle within care homes.

The study sample used nonprobability convenience sampling; meaning participating care homes were not randomly chosen, therefore findings need to be confirmed in other care homes. Although NICE guidelines and the CHUMS study suggest the medicines management process and 28-day supply of medicines cycle could be relatively similar across UK care homes (as they all should be following the same set of NICE guidelines), this study included case studies on three care homes in the Midlands only, and therefore may not be applicable to all care homes within the UK. Furthermore, only five homes (2.60%) were approached for participation, out of a total of 192 'research ready' homes in the Midlands. Homes within the ENRICH database deem themselves as 'research ready' and researchers suggest that care homes voluntarily agreeing to participate in research, are usually high performing homes as low-performing homes sometimes feel 'threatened' (Lam et al., 2018).This means error rates could be greater in other care homes and results of this study must be interpreted with caution (Lam et al., 2018).

There was a lack of participation from GPs and pharmacists, as only one of each was interviewed and both were from CS3. Therefore, the large majority of interviewees were from the care home setting. This limits the study in providing description of tasks from the GP surgery or pharmacy perspective, the issues encountered from these stakeholders and their perceptions on the 28-day supply of medicines cycle as well as the recommendations provided.

During semi-structured interviews, direct participant observations and stakeholder feedback sessions, all qualitative research is subject to receiving socially desirable responses, meaning some participants may deliver responses that are not honest, but instead what the participant thinks the researcher would want to hear or a response that is 'socially desirable' in today's world (Bensch et al., 2019). The participant will often believe these responses are viewed as favourable to others and often involves over-reporting 'good behaviour or under-reporting 'bad-behaviour' (Bensch et al., 2019).

Reflexivity is a common limitation within qualitative research. It is a concept and a process, pertaining to the 'analytic attention to the researcher's role in qualitative research' (Dowling, 2006). As a concept, it involves the researchers self-awareness or a certain level of consciousness (Lambert et al., 2010). As a process, it is the researcher's continuous process of reflection on their subjectivities, understanding how their 'social background, location and assumptions affect their research practice' (Hesse-Biber, 2011).

The researcher was a female of Asian-Indian ethnicity and born in Canada. People of Asian-Indian decent were one of the minorities amongst staff and residents within all three nursing homes. The researcher was also a pharmacist, meaning she had a certain level of understanding and preconceptions about how care homes operate, as well as the 28-day supply of medicines from generalised healthcare perspective. The researcher was aware of her prior knowledge on the topic and continuously reflected on her activity within the research to ensure taking an objective view as much as possible. The researcher's presence during direct participant observations is also a limitation, as this always carries the possibility of affecting subject responses or behaviours, as described by the Hawthorne Effect (Anderson, 2010; Sedgwick and Greenwood, 2015).

Finally, the study used the average number of medications taken by care home residents daily as the denominator in calculating the defects per million opportunities during each case's *Analyse* phase of DMAIC. This is a limitation as the number is provided from literature rather than the actual total number of medications residents were on in each case study. Furthermore, the average of eight medications taken from the literature was also used to calculate the number of omitted medications. For example, if one resident was missing all medications, it was estimated that eight medications were omitted however, it could be possible that the resident was only taking two medications and these were missing. Therefore, omitted medication calculations could be inaccurate in comparison to actual figures, however, the researcher was unable to obtain this number from each care home.

Implications

This research has provided a framework and recommendations to guide care homes in their 28-day supply of medicines cycle. Building on the CHUMS study and NICE guideline on medicines management within care homes, this study provides greater depth and understanding into the 28-supply of medicines cycle, which can be further investigated or used to advance development of the current NICE guideline. This study expands on some recommendations and tasks mentioned in NICE guidelines and concurs with findings from the CHUMS study, as well as providing greater detail of the 28-day supply of medicines cycle. Results from this study can inform stakeholder organisations directly involved in the cycle, GP surgeries, supplying pharmacies and care homes, as well as policy makers.

All three participating care homes within this study have already implemented at least one recommendation from the study into their medicines management policy guidelines. Care home managers, medicines management leads, and medicines management area managers can use this

study to inform their own 28-day supply of medicines process. According to issues faced within their organisations they can implement associated recommendations from the study.

Finally, the application of Six Sigma within care homes has not been seen in current literature. Academic researchers and industry experts working within the care home sector have a basic understanding of the underlying theory of Six Sigma from this study. This provides the industry with a successful methodology to explore its' application in new areas pertaining to care homes and healthcare.

Scope for Future Work

Although care homes house 405, 000 people aged 65 and over in the UK alone (AgeUK, 2016), there is a lack of research in this area (Rolland et al., 2009). Large-scale studies in care homes will improve our understanding of the environment and highlight areas needing improvement.

The study presented has provided a 28-day supply of medicines framework and set of recommendations for care homes to instate. Although positive feedback was received on both the framework and recommendations from participating care homes, this data cannot be extrapolated to all care homes within the UK due to study limitations. The researcher therefore suggests applying the framework and recommendations to care homes across a broader geographic region both in the UK and internationally to validate the framework and study recommendations. In doing so, the framework and recommendations can be further developed and amended as necessary.

This research discusses discrepancies (near-misses) within the 28-day supply of medicines cycle. Numerous studies have examined medication error and near-misses within the hospital setting, however there is a dearth of research on the topic within the care home setting. As some of the most vulnerable members of society reside in care homes, it is imperative for future work to be conducted examining rates of medication error and near-misses within this setting.

Although waste generated by the healthcare sector in the UK is an ever-growing concern, the care home setting has been largely neglected in providing figures of annual waste. This study was unable to provide exact figures on waste generated by the three case studies as it was beyond the remit of the study. However, future studies investigating the amount of waste generated by the 28-day supply of medicines cycle can provide useful insight into waste management through repeat management.

In line with other studies (Schot et al., 2019), this research found communication and collaborative working between stakeholder organisations both complex and challenging. Further research on strategies to improve communication, particularly between the GP surgery, care home and pharmacy will be beneficial. This research would ideally concentrate on using IT systems to provide transparency between the stakeholder organisations regarding repeat medications in the 28-day supply of medicines cycle.

CONCLUSIONS

This is the first study that has implemented a widely-used management methodology to solve a long-standing healthcare challenge, namely medication management in the care home environment and more specifically repeat medication management from the 28-day supply of medicines cycle. As repeat medication management directly impacts patient safety and medical waste, improving the 28-day supply of medicines cycle efficiency through Six Sigma DMAIC has potential to reduce medication near-misses and generated waste in the care home setting.

Six Sigma has been used within many healthcare sectors, including the hospital setting, pharmaceutical companies, medication manufacturing, therapy areas, etc. This study expands the scope of using Six Sigma, specifically DMAIC in another area and setting within healthcare, medicines management and care homes. As Six Sigma promotes continuous improvement strategies and process efficiency, this study has shown great potential for the use of Six Sigma within the 28-day supply of medicines cycle around care homes worldwide.

This study has provided several outputs including a definition of each task within the 28-day supply of medicines cycle from the care home perspective, along with a visual framework of the cycle (Chapter 4, page 91). The researcher applied the Six Sigma DMAIC methodology for the first time in published literature on the 28-day supply of medicines cycle within care homes. In doing so, the researcher created a DMAIC framework to potentially be used to improve 28-day supply of medicines cycles in care homes worldwide, as well as a taxonomy of discrepancies during the cycle and associated measurements for discrepancies. Finally, the researcher has presented a recommended cross-functional process map for care homes to follow in order for each stakeholder to have sufficient time for each task within the cycle (Chapter 6, page 158) and provided recommendations for care homes to improve their 28-day supply of medicines cycle Chapter 6, page 159) using Six Sigma tools.

The 28-day supply of medicines cycle ultimately manages care home resident repeat prescriptions and is a process present in every care home. Effective management of this cycle is critical to providing adequate patient safety. Using DMAIC and the recommendations provided in this study should transform current reactive 28-day supply of medicines cycles to be proactive cycles in reducing discrepancy rates. As discrepancies are near-misses, and research has shown a direct correlation between near-misses and preventable medication errors, decreasing near-miss rates is crucial to providing patient safety. Therefore, application of DMAIC and the recommendations from this study should decrease discrepancy (near-miss) rates within the 28-day supply of medicines cycle, which could ultimately lead to decreased preventable medication errors.

This study contributes to research in the care home sector which has been largely ignored to date. This study has largely extended the knowledge of medicines management within care homes and repeat medication management via the 28-day supply of medicines cycle. It is the first study to provide case study examples defining processes within the 28-day supply of medicines cycle via interviews and participant observations. The descriptions provided in this thesis give the reader a better understanding of tasks within the cycle. Six Sigma, DMAIC methodology has been applied to the entire 28-day supply of medicines cycle (excluding medicines administration) for the first time in any setting and has subsequently provided three individual case studies with individualised recommendations. Finally, the frameworks created throughout this study have the potential to be extrapolated and used in other settings, as well as against other processes in in primary or secondary applied healthcare research or academic literature.

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APPENDIX A

Interview Schedule Date: _____

Name

Profession

Organisation

Which care home do you work with regularly?

Is it a residential home, nursing home or both?

Location of Organisation

1. **Please describe the process of medicines management in your organisation.**
    a. Can you talk me through the process of ordering medications for residents to receiving those medications?
    b. What is the timeframe of the process?
2. **What is your role in medicines management (i.e. for care homes: medicines ordering, prescribing, preparing, administering; for GP surgeries: preparing prescriptions, authorising prescriptions; for pharmacies: preparing medications, checking medications, preparing MAR charts, etc.) in your organisation?**
    a. What types of tasks do you complete throughout the processes we just spoke about?
3. **Do you find there are any issues within the process that could be made better or does the process generally run smoothly?**
    a. If there are any issues, what types of issues are you likely to come across during the cycle?
4. **Any additional thoughts/comments/questions or concerns**

APPENDIX B

Participant Observations Protocol

The researcher employed direct participant observations of the 28-day supply of medicines cycle. To arrange observation times, the researcher conversed with each case study's medicines management lead to determine what days and times each medicines management task is undertaken for the duration of one cycle.

The researcher then arranged to come into the care home on those days to observe each task within the 28-day cycle. Tasks observed included: medicines re-ordering, prescription check against re-order, medicines checking-in and medicines changeover. During observations of each task, the researcher took notes of the role of each member of staff involved and the medicines management lead explained each task throughout the process. The researcher observed silently, however asked questions regarding each task whenever necessary.

Step 1
Arrange approximate dates and times with medicines management lead to observe all processes during the 28-day supply of medicines cycle

Step 2
Observe the medicines re-ordering process
Finalise date and time for prescription check against re-order process observations

Step 3
Observe prescription check against re-order process
Finalise date and time for medicines checking-in process observations

Step 4
Observe medicines checking-in process
Finalise date and time for medicines changeover process observations

Step 5
Observe medicines changeover process
Finalise date and time for medicines administration process observations

Step 6
Observe medicines administration process

APPENDIX C

Stakeholder Feedback Session Schedule

1. Do you think the recommendations are possible to carry out?
2. Have some of your issues been addressed?
3. Do you have any other suggestions towards the process?
4. What do you think about Six Sigma/DMAIC as an improvement tool in medicines management within care homes?
5. Comments, feedback, questions

APPENDIX D: Participant Information Sheet - Care Homes

Project Title: Creating a dementia medicines management supply chain model to improve patient satisfaction and cost efficiency in UK care homes

Chief Investigator: Medha Kothari (PhD Researcher, Aston University)

Invitation

Your care home is being invited to take part in a research study conducted by a self-funded PhD researcher at Aston University. The importance of the research and your organisation's role is outlined below. Please take the time to read the following information carefully before deciding whether to take part.

What is the purpose of this study?

The purpose of this research is to use supply chain management strategies (an operations and management business theory) to improve overall cost-effectiveness between stakeholders involved in medicines management to people with dementia within care homes. The aim is to determine current practice and give recommendations on possible ways to increase cost-effectiveness of medicines management within care homes. The research will focus on the medicines management of people with dementia residing in care homes and on the coordination between doctors, pharmacists and care home staff in providing optimal medicines management to residents.

Why has your care home been invited?

Your care home has been invited to participate because it is an ENRICH labelled 'research ready' care home and your organisation has residents with dementia. Additionally, your care home has valued healthcare professionals with experience of caring for people with dementia and managing their medicines.

What will happen to the care home if it takes part?

If you agree for your care home to participate, a minimum of the following professionals will be invited to an interview: the care home manager, one nurse or carer, one doctor and one pharmacist that regularly serves the residents of your care home. Interview questions will address the current medicines management process for dementia residents within care homes. The care home manager will be asked to sign a Consent Form to approve the care home's participation in the study. Additionally, each interview participant will be asked to sign a Consent Form before the interview.

After completion of interviews and sufficient time for data analysis by the researcher, a meeting will be organised to disseminate the research and gain feedback on the supply chain model constructed by the researcher. The researcher aims to give the care home recommendations on making their medicines management process more effective. All participants from your care home will be invited to this meeting and feedback for the researcher will be encouraged.

Interview

The interview will last up to an hour, depending on how much the participant has to say. It will take place at a location and time convenient for the participant and the care home. The interview will be

face-to-face or via Skype, although it can be by phone if that is what is preferred. The interview will be audio recorded.

The interviewer will ask for some basic background information including: the participant's profession and place of work. The interview will then continue to ask a series of questions where the participant will be asked to determine if each factor is determined more by resident quality of life/patient satisfaction or cost-efficiency.

All interviews will be audio-recorded with a Dictaphone and all data will be kept strictly confidential in line with the Data Protection Act 1998. Interview questions will not ask for any specific patient details or interactions, but rather be a conversation about medicines management in general.

Will the care home benefit from taking part?

The study may not directly benefit the care home however, participating will help discover the strengths and weaknesses of current medicines management processes. In doing so, you will help in achieving our research goal, creating a supply chain model to determine potential ways in which medicines management within care homes can be improved in a cost-effective manner.

Additionally, the study aims to be able to provide the care home with recommendations to improve the effectiveness of their medicines management process. Although this outcome cannot be guaranteed, the researcher will put every effort forward to achieve this goal.

Are there any potential risks taking part?

We believe the risks from taking part are minor. There is the possibility of any part of the interview or specific questions raised being sensitive or distressing to you. In this situation, you will not have to answer any questions you are uncomfortable with. You may also take a break from the interview at any time and return to it at a later date and time convenient for yourself and the care home. Additionally, you will always have the option to halt the interview and withdraw from the study without giving a reason. At this point, you will also be able to decide what will happen to the data collected up to that time (see 'Withdraw from the study' below).

Does the care home have to take part?

No. Taking part in the study is completely voluntary, meaning it is ultimately the care home manager's choice.

Will the data be kept confidential?

Yes. Following all interviews, identifying information will be removed from the audio recording by the researcher and replaced with a number and it will be saved to a password protected computer. This anonymised recording will be typed up by the researcher and any extracts from what participants have told us that are included in the reporting of the project will be anonymous. Anonymised data will be kept until one year after the completion of the lead researchers PhD (anticipated to keep data until September 2020). It will then be destroyed by the lead researcher.

What do I do if I want to withdraw the care home from the study?

If you decide you would like to withdraw the care home from the study at any point, you should get in contact with the lead researcher (see 'Contact Information' below). You should also contact the lead researcher if a participant wants to withdraw any information they provided within 2 months of

the date of their interview. They do not have to give a reason for this although it may be useful for us to understand their decision when developing future projects. Once the 2-month period has elapsed, all data will be retained for use within the study.

What happens if a participant tells you something that concerns you about their health or welfare, or about the health or welfare of my care home's patients or residents?

In the unlikely event of this happening, we will discuss how this should be addressed with the concerned participant. If necessary, to protect the participant, we will report their concern to the appropriate person or bodies. Additionally, if the concern is regarding patients or residents of your care home, we will report the concern to the appropriate person or bodies to protect them.

Who do I contact if I have any concerns about the way in which the research is being conducted, or want to make a complaint?

Ethical approval has been obtained from the Aston Business School Research Ethics Committee. For any queries or concerns regarding the ethical approval of this study, please contact the Aston Business School Research Ethics Committee at e.bridges@aston.ac.uk.

Who do I contact if I have any questions about the study?

Medha Kothari, Chief Investigator (see contact information below).

Thank you for taking the time to consider taking part in this study.

If you are happy to participate in the study, please register your interest by emailing the lead researcher, Medha Kothari at kotharim@aston.ac.uk. Additionally, for more information about the study, please contact the lead researcher by the email above or calling 07397391867.

Thank you for your time,

Medha Kothari
kotharim@aston.ac.uk
07397391867
06/03/18

APPENDIX E: CONSENT FORM - Care Home

PROJECT TITLE: Creating a dementia medicines management supply chain model to improve patient satisfaction and cost efficiency in UK care homes

Name of Chief Investigator: Medha Kothari (PhD Researcher, Aston University)

Please initial the boxes (NOT tick) if you agree. One signed copy of the form is for you to keep and the other will be kept by the researcher.

	Please initial box
1. I confirm that I have read and understand the Care Home Participant Information Sheet for this study. I have had the opportunity to ask questions and have had these answered to my satisfaction.	☐
2. I understand that the care homes participation is voluntary and that we are free to withdraw at any time. We can also withdraw any information we have provided within two months of the date of interview. We do not need to give a reason in either situation.	☐
3. We understand that all information collected from us for this study will be held confidentially until one year after the completion of the lead researchers PhD (anticipated to keep data until September 2020). The lead researcher will hold the information and destroy it.	☐
4. We agree to interviews being audio recorded.	☐
5. We agree to have the Chief Investigator observe, audio record and take notes on the medicines management process within the organisation.	☐
6. We understand that the recording of interviews and research observations will be transcribed.	☐
7. Personal details and any information that may identify participants will not appear in any publication and we agree that anonymised extracts from the recordings can be used in any reports, publications or events where results from the study will be disseminated.	☐
8. We understand that if we tell the researcher something that raises concerns about the participant's health or welfare that the researcher may have a duty to report this in accordance with safeguarding policy. This will be discussed with the participant.	☐
9. We understand that if we tell the researcher something that raises serious concerns about the safety of residents or patients within the organisation that the researcher may have a duty to report this in accordance with safeguarding policy. This will be discussed with the participant.	☐
10. The care home agrees to take part in the above study.	

Name of Care Home:	
Name of Care Home Manager (Print):	
Care Home Manager Signature:	Date:

APPENDIX F: Participant Information Sheet - Healthcare Professionals

Project Title: Creating a dementia medicines management supply chain model to improve patient satisfaction and cost efficiency in UK care homes

Chief Investigator: Medha Kothari (PhD Researcher, Aston University)

Invitation

You are being invited to take part in a research study conducted by a self-funded PhD researcher at Aston University. The importance of the research and your role is outlined below. Please take the time to read the following information carefully before deciding whether to take part.

What is the purpose of this study?

The purpose of this research is to use supply chain management strategies (an operations and management business theory) to improve overall cost-effectiveness between stakeholders involved in medicines management to people with dementia within care homes. The aim is to determine current practice and give recommendations on possible ways to increase cost-effectiveness of medicines management within care homes. The research will focus on the medicines management of people with dementia residing in care homes and on the coordination between doctors, pharmacists and care home staff in providing optimal medicines management to residents.

Why have I been invited?

You have been invited to participate because you are a valued healthcare professional within the field.

What will happen to me if I take part?

If you agree to participate, you will be invited to one interview to answer some questions about the current medicines management process for dementia residents within care homes. You will also be asked to sign a Consent Form before taking part.

Interview

The interview will last up to an hour, depending on how much you have to say. It will take place at a location and time convenient for you. The interview will be face-to-face or via Skype, although it can be by phone if that is what you would prefer. The interview will be audio recorded.

The interview will ask for some basic background information including: your profession, place of work, and if you work closely with any care homes. The interview will then continue to ask a series of questions where you will be asked to determine if each factor is determined more by resident quality of life/patient satisfaction or cost-efficiency.

All interviews will be audio-recorded with a Dictaphone and all data will be kept strictly confidential in line with the Data Protection Act 1998. Interview questions will not ask for any specific patient details or interactions, but rather be a conversation about medicines management in general.

Will I benefit from taking part?

The study may not directly benefit you. However, you will be helping to discover the strengths and weaknesses of current medicines management processes. In doing so, you will help in achieving our

research goal, creating a supply chain model to determine potential ways in which medicines management within care homes can be improved in a cost-effective manner.

Are there any potential risks taking part?

We believe the risks from taking part are minor. There is the possibility of any part of the interview or specific questions raised being sensitive or distressing to you. In this situation, you will not have to answer any questions you are uncomfortable with. You may also take a break from the interview at any time and return to it at a later date and time convenient for you. Additionally, you will always have the option to halt the interview and withdraw from the study without giving a reason. At this point, you will also be able to decide what will happen to the data collected up to that time (see 'Withdraw from the study' below).

Do I have to take part?

No. Taking part in the study is completely voluntary, meaning it is your choice.

Will my data be kept confidential?

Yes. Following your interview, identifying information will be removed from the audio recording by the researcher and replaced with a number and it will be saved to a password protected computer. This anonymised recording will be typed up by the researcher and any extracts from what you have told us that are included in the reporting of the project will be anonymous. Anonymised data will be kept until one year after the completion of the lead researchers PhD (anticipated to keep data until September 2020). It will then be destroyed by the lead researcher.

What do I do if I want to withdraw from the study?

If you decide you would like to withdraw from the study at any point, you should get in contact with a member of the research team (see 'Contact Information' below). You should also contact them if you want to withdraw any information you have provided within 2 months of the date of your interview. You do not have to give a reason for this although it may be useful for us to understand your decision when developing future projects. Once the 2-month period has elapsed, your data will be retained for use within the study.

What happens if I tell you something that concerns you about my health or welfare, or about the health or welfare of my patients or residents?

In the unlikely event of this happening, we will discuss how this should be addressed with you. If necessary, to protect you, we will report your concern to the appropriate person or bodies. Additionally, if the concern is regarding your patients or residents, we will report the concern to the appropriate person or bodies to protect them.

Who do I contact if I have any concerns about the way in which the research is being conducted, or want to make a complaint?

Ethical approval has been obtained from the Aston Business School Research Ethics Committee. For any queries or concerns regarding the ethical approval of this study, please contact the Aston Business School Research Ethics Committee at e.bridges@aston.ac.uk.

Who do I contact if I have any questions about the study?

Medha Kothari, Chief Investigator (see contact information below).

Thank you for taking the time to consider taking part in this study.

If you are happy to participate in the study, please register your interest by emailing the lead researcher, Medha Kothari at kotharim@aston.ac.uk. Additionally, for more information about the study, please contact the lead researcher by the email above or calling 07397391867.

Thank you for your time,

Medha Kothari
kotharim@aston.ac.uk
07397391867
06/03/18

PPENDIX G: CONSENT FORM - Healthcare Professionals

PROJECT TITLE: Creating a dementia medicines management supply chain model to improve patient satisfaction and cost efficiency in UK care homes

Name of Chief Investigator: Medha Kothari (PhD Researcher, Aston University)

Please initial the boxes (NOT tick) if you agree. One signed copy of the form is for you to keep and the other will be kept by the researcher.

	Please initial box
11. I confirm that I have read and understand the Participant Information Sheet for this study. I have had the opportunity to ask questions and have had these answered to my satisfaction.	☐
12. I understand that my participation is voluntary and that I am free to withdraw at any time. I can also withdraw any information I have provided within two months of the date of my interview. I do not need to give a reason in either situation.	☐
13. I understand that all information collected from me for this study will be held confidentially until one year after the completion of the lead researchers PhD (anticipated to keep data until September 2020). The lead researcher will hold the information and destroy it.	☐
14. I agree to the interview being audio recorded.	☐
15. I agree to have the Chief Investigator observe, audio record and take notes on the medicines management process within my organisation.	☐
16. I understand that the recording of interviews and research observations will be transcribed.	☐
17. Personal details and any information that may identify me will not appear in any publication and I agree that anonymised extracts from the recording can be used in any reports, publications or events where results from the study will be disseminated.	☐
18. I understand that if I tell the researcher something that raises concerns about my health or welfare that the researcher may have a duty to report this in accordance with safeguarding policy. This will be discussed with me.	☐
19. I understand that if I tell the researcher something that raises serious concerns about the safety of residents or patients within my organisation that the researcher may have a duty to report this in accordance with safeguarding policy. This will be discussed with me.	☐
20. I agree to take part in the above study.	

Name of Participant (Print):
Profession (Circle): Doctor Pharmacist Care Home Nurse Care Home Manager Other (please specify): _____
Signature: Date: